GOLD COAST HEALTH PLAN
TOTAL Care ADVANTAGE℠

# 2026

## Gold Coast Health Plan Total Care Advantage (HMO D-SNP)

# PART B CLINICAL GUIDELINES

# Abecma *(idecabtagene vicleucel)*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses (FDA approved indication)** | Abecma is a B-cell maturation antigen (BCMA)-directed genetically modified autologous T cell immunotherapy indicated for the treatment of adult patients with relapsed or refractory multiple myeloma after two or more prior lines of therapy, including an immunomodulatory agent, a proteasome inhibitor, and an anti-CD38 monoclonal antibody. |
| **Exclusion Criteria** | None. |
| **Required Medical Information** | Medical records supporting the request must be provided. |
| **Other Criteria** | Must follow NCD Chimeric Antigen Receptor (CAR) T-cell Therapy (110.24). https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?ncdid=374 |
| **Age Restriction** | None. |
| **Prescriber Restrictions** | None. |
| **Coverage Duration** | In accordance with the FDA-approved labeling or accepted standards of medical practice. |
| **Other Criteria/Information** | Refer to the Gold Coast Health Plan Medicare Part B Reference and Summary of Evidence document. |

| HCPCS | Description | Billing Units/How Supplied |
|---|---|---|
| Q2055 | Abecma (Idecabtagene vicleucel) | **Billing unit: per therapeutic dose**<br><br>SD infusion bag |

| STATUS | DATE REVISED | REVIEW DATE | APPROVED/REVIEWED BY | EFFECTIVE DATE |
|---|---|---|---|---|
| Created | 3/26/2025 | 3/26/2025 | Dawn Shojai, PharmD, Senior Pharmacy Benefit Consultant (PSG) | N/A |
| Approved | N/A | 5/15/2025 | Pharmacy & Therapeutics (P&T) Committee | 5/15/2025 |
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# ActemraIV *(tocilizumab)*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses (FDA approved indication)** | Actemra is an interleukin-6 inhibitor (IL-6i) indicated for multiple inflammatory conditions including rheumatoid arthritis (RA), giant cell arteritis, and juvenile idiopathic arthritis (JIA). |
| **Exclusion Criteria** | Must not be used in combination with other biological drugs, Otezla, or Janus Kinase Inhibitor (JAKis). SSc-ILD is not approved for intravenous administration. |
| **Required Medical Information** | Medical records supporting the request must be provided, including documentation of prior therapies and responses to treatment. |
| **Age Restriction** | None. |
| **Prescriber Restrictions** | Provider is a specialist or has consulted with a specialist for the condition being treated. |
| **Coverage Duration** | Two years. Dose will be approved according to the FDA-approved labeling or within accepted standards of medical practice. |
| **Other Criteria/Information** | Refer to the Gold Coast Health Plan Medicare Part B Reference and Summary of Evidence document. |

| HCPCS | Description | Billing Units/How Supplied |
|---|---|---|
| J3262 | Actemra IV (tocilizumab) solution vial | **Billing unit: 1 mg**<br><br>80 mg/4 mL, 200 mg/10 mL, 400 mg/20 mL SDV |

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|---|---|---|---|---|
| Created | 3/26/2025 | 3/26/2025 | Dawn Shojai, PharmD, Senior Pharmacy Benefit Consultant (PSG) | N/A |
| Approved | N/A | 5/15/2025 | Pharmacy & Therapeutics (P&T) Committee | 5/15/2025 |
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# Adakveo *(crizanlizumab)*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses (FDA approved indication)** | Adakveo is a selectin blocker indicated to reduce the frequency of vaso-occlusive crises in adults and pediatric patients 16 years of age and older with sickle cell disease (SCD). |
| **Exclusion Criteria** | None. |
| **Required Medical Information** | Medical records supporting the request must be provided. |
| **Other Criteria** | Must first try hydroxyurea for six months or have an intolerance or contraindication. |
| **Age Restriction** | None. |
| **Prescriber Restrictions** | None. |
| **Coverage Duration** | Two years. Dose will be approved according to the FDA-approved labeling or within accepted standards of medical practice. |
| **Other Criteria/Information** | Refer to the Gold Coast Health Plan Medicare Part B Reference and Summary of Evidence document. |

| HCPCS | Description | Billing Units/How Supplied |
|---|---|---|
| J0791 | Adakveo (crizanlizumab) | **Billing unit: 5 mg**<br><br>100 mg/10 mL SDV |

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| Created | 3/26/2025 | 3/26/2025 | Dawn Shojai, PharmD, Senior Pharmacy Benefit Consultant (PSG) | N/A |
| Approved | N/A | 8/21/2025 | Pharmacy & Therapeutics (P&T) Committee | 8/21/2025 |
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# Adzynma *(ADAMTS13, recombinant-krhn)*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses (FDA approved indication)** | Adzynma is a human recombinant form of the A disintegrin and metalloproteinase with thrombospondin motifs 13 enzyme (rADAMTS13). The ADAMTS13 protein is involved with blood clotting. Adzynma replaces the missing or deficient ADAMTS13 enzyme in patients diagnosed with congenital thrombotic thrombocytopenic purpura (cTTP). TTP is a rare blood disorder that results in blood clots forming in small blood vessels throughout the body which can cause ischemic end organ damage. |
| **Exclusion Criteria** | None. |
| **Required Medical Information** | For initial and reauthorization requests: Medical records supporting the request must be provided, including the patient's current weight for dosing purposes.<br><br>For initial requests: Must also have one genetic testing confirming the diagnosis of congenital thrombotic thrombocytopenic purpura (cTTP); and two ADAMTS13 activity less than 10%. |
| **Other Criteria** | For initial requests: The initial dosing frequency for prophylactic use must be every 2 weeks. The frequency may be adjusted to once weekly based on prior prophylactic dosing regimen or clinical response and supporting documentation is required.<br><br>For reauthorization requests: Must demonstrate a beneficial response to therapy (e.g., decrease in acute and subacute TTP events, improvement in platelet count from baseline, decrease in microangiopathic hemolytic anemia episodes). |
| **Age Restriction** | None. |
| **Prescriber Restrictions** | Must be prescribed by, or in consultation with, a specialist for the disease state. |
| **Coverage Duration** | Initial: 12 months. Reauthorization: 12 months. Dose will be approved according to the FDA approved labeling or within accepted standards of medical practice. |
| **Other Criteria/Information** | Refer to the Gold Coast Health Plan Medicare Part B Reference and Summary of Evidence document. |

| HCPCS | Description | Billing Units/How Supplied |
|---|---|---|
| J7171 | Adzynma (ADAMTS13, recombinant-krhn) | **Billing Unit 10 IU**<br><br>500 IU SDV, 1500 IU SDV |

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# Alyglo *(immune globulin intravenous, human-stwk)*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses (FDA approved indication)** | Alyglo is approved for the treatment of primary humoral immunodeficiency (PI) in adults. This includes, but is not limited to, congenital agammaglobulinemia, common variable immunodeficiency (CVID), Wiskott-Aldrich syndrome, and severe combined immunodeficiencies. |
| **Exclusion Criteria** | None. |
| **Required Medical Information** | Medical records supporting the request must be provided, including documentation of prior therapies and responses to treatment. |
| **Other Criteria** | Must follow LCD L34771 for Immune Globulins. https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdid=34771&ver=49&= |
| **Age Restriction** | None. |
| **Prescriber Restrictions** | None. |
| **Coverage Duration** | Two years. Dose will be approved according to the FDA-approved labeling or within accepted standards of medical practice. |
| **Other Criteria/Information** | Refer to the Gold Coast Health Plan Medicare Part B Reference and Summary of Evidence document. |

| HCPCS | Description | Billing Units/How Supplied |
|---|---|---|
| J1552 | Alyglo (immune globulin intravenous, human-stwk) | **Billing unit: 500 mg**<br><br>5 g/50 mL, 10g/ 100 mL, 20 g/200 mL SDV |

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| Approved | N/A | 8/21/2025 | Pharmacy & Therapeutics (P&T) Committee | 8/21/2025 |
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# Alymsys *(bevacizumab-maly)*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses (FDA approved indication)** | Alymsys is a biosimilar to Avastin, bevacizumab is a vascular endothelial growth factor inhibitor indicated for the treatment of multiple cancers including:<br><br>metastatic colorectal cancer, in combination with intravenous fluorouracil-based chemotherapy for first- or second-line treatment;<br><br>metastatic colorectal cancer, in combination with fluoropyrimidine-irinotecan- or fluoropyrimidine oxaliplatin-based chemotherapy for second-line treatment in patients who have progressed on a first-line bevacizumab product-containing regimen;<br><br>unresectable, locally advanced, recurrent or metastatic non-squamous non-small cell lung cancer, in combination with carboplatin and paclitaxel for first-line treatment;<br><br>recurrent glioblastoma in adult;<br><br>metastatic renal cell carcinoma in combination with interferon alfa, and more. |
| **Exclusion Criteria** | None. |
| **Required Medical Information** | Medical records supporting the request must be provided, including documentation of prior therapies and responses to treatment. |
| **Other Criteria** | Criteria will be applied consistent with LCD L37205: Chemotherapy Drugs and their Adjuncts. https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdId=37205&ver=15 |
| **Age Restriction** | None. |
| **Prescriber Restrictions** | None. |
| **Coverage Duration** | Up to one year. Dose will be approved according to the FDA approved labeling or within accepted standards of medical practice. |
| **Other Criteria/Information** | Refer to the Gold Coast Health Plan Medicare Part B Reference and Summary of Evidence document. |

| HCPCS | Description | Billing Units/How Supplied |
|---|---|---|
| Q5126 | Alymsys (bevacizumab-maly) biosimilar | **Billing unit: 10 mg**<br><br>100 mg/4 mL,<br>400 mg/16 mL SDV |

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# Amvuttra *(vutrisiran)*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses (FDA approved indication)** | Amvuttra is a transthyretin-directed small interfering RNA indicated for the treatment of the polyneuropathy of hereditary transthyretin-mediated amyloidosis (hATTR amyloidosis) in adults. |
| **Exclusion Criteria** | Must not be used in combination with TTR stabilizers (e.g., tafamidis) or TTR-lowering agents (e.g., Onpattro) – AND – Patient must not have had a liver transplant. |
| **Required Medical Information** | Medical records supporting the request must be provided – AND –<br>Must have documentation of a transthyretin (TTR) mutation (e.g., V30M)<br>Must have documentation of a baseline polyneuropathy disability (PND) score less than or equal to IIIb and/or baseline FAP Stage 1 or 2<br>Must have documentation of clinical signs and symptoms of the condition (e.g., motor disability, peripheral/autonomic neuropathy, etc.). |
| **Other Criteria** | For reauthorization: Must have a positive clinical response to Amvuttra compared to baseline (e.g., improved neuropathy symptoms, motor function, quality of life; slowing of disease progression). |
| **Age Restriction** | Must be at least 18 years of age. |
| **Prescriber Restrictions** | None. |
| **Coverage Duration** | One year initial and reauthorization. Dose will be approved according to the FDA-approved labeling or within accepted standards of medical practice. |
| **Other Criteria/Information** | Refer to the Gold Coast Health Plan Medicare Part B Reference and Summary of Evidence document. |

| HCPCS | Description | Billing Units/How Supplied |
|---|---|---|
| J0225 | Injection, vutrisiran, 1 mg | **Billing unit: 1 mg**<br><br>25mg/0.5ml SD syringe |

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# Apretude *(cabotegravir)*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses (FDA approved indication)** | Apretude is indicated for pre-exposure prophylaxis (PrEP) to reduce the risk of sexually acquired HIV-1 infection in adults and adolescents weighing at least 35 kg who are at risk for HIV-1 acquisition. |
| **Exclusion Criteria** | None. |
| **Required Medical Information** | Medical records supporting a negative HIV-1 test prior to initiating therapy. |
| **Other Criteria** | Drug coverage is determined under Medicare NCD: Pre-Exposure Prophylaxis (PrEP) for Human Immunodeficiency Virus (HIV) Prevention (210.15), which covers drugs used for HIV PrEP under Part B. Refer to the Medicare Coverage Database for the full NCD and/or LCD/LCA at https://www.cms.gov/medicare-coverage-database/search.aspx. |
| **Age Restriction** | None. |
| **Prescriber Restrictions** | None. |
| **Coverage Duration** | In accordance with the FDA-approved labeling or accepted standards of medical practice. |
| **Other Criteria/Information** | Refer to the Gold Coast Health Plan Medicare Part B Reference and Summary of Evidence document. |

| HCPCS | Description | Billing Units/How Supplied |
|---|---|---|
| J0739 | Apretude (cabotegravir) | **Billing unit: 1 mg**<br><br>600mg/3ml kit |

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# Aucatzyl *(obecabtagene autoleucel)*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses (FDA approved indication)** | Aucatzyl is a CD19-directed genetically modified autologous T cell immunotherapy indicated for the treatment of adult patients with relapsed or refractory B-cell precursor acute lymphoblastic leukemia (ALL). |
| **Exclusion Criteria** | None. |
| **Required Medical Information** | Medical records supporting the request must be provided. |
| **Other Criteria** | Must follow NCD Chimeric Antigen Receptor (CAR) T-cell Therapy (110.24). https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?ncdid=374 |
| **Age Restriction** | None. |
| **Prescriber Restrictions** | None. |
| **Coverage Duration** | In accordance with the FDA-approved labeling or accepted standards of medical practice. |
| **Other Criteria/Information** | Refer to the Gold Coast Health Plan Medicare Part B Reference and Summary of Evidence document. |

| HCPCS | Description | Billing Units/How Supplied |
|---|---|---|
| Q2058 | Obecabtagene autoleucel | **Billing unit: per dose**<br><br>10 to up to 400 x 106 CD19 CAR+ T cells, per infusion |

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| Approved | N/A | 5/15/2025 | Pharmacy & Therapeutics (P&T) Committee | 5/15/2025 |
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# Avastin *(bevacizumab)*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses (FDA approved indication)** | Bevacizumab is a vascular endothelial growth factor inhibitor indicated for the treatment of multiple cancers including:<br>metastatic colorectal cancer, in combination with intravenous fluorouracil-based chemotherapy for first- or second-line treatment;<br>metastatic colorectal cancer, in combination with fluoropyrimidine-irinotecan- or fluoropyrimidine oxaliplatin-based chemotherapy for second-line treatment in patients who have progressed on a first-line bevacizumab product-containing regimen;<br>unresectable, locally advanced, recurrent or metastatic non-squamous non-small cell lung cancer, in combination with carboplatin and paclitaxel for first-line treatment;<br>recurrent glioblastoma in adult;<br>metastatic renal cell carcinoma in combination with interferon alfa, and more. |
| **Exclusion Criteria** | None. |
| **Other Criteria** | Criteria will be applied consistent with LCD L37205: Chemotherapy Drugs and their Adjuncts. https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdId=37205&ver=15 |
| **Required Medical Information** | Medical records supporting the request must be provided, including documentation of prior therapies and responses to treatment. |
| **Age Restriction** | None. |
| **Prescriber Restrictions** | None. |
| **Coverage Duration** | Up to one year. Dose will be approved according to the FDA approved labeling or within accepted standards of medical practice. |
| **Other Criteria/Information** | Refer to the Gold Coast Health Plan Medicare Part B Reference and Summary of Evidence document. |

| HCPCS | Description | Billing Units/How Supplied |
|---|---|---|
| J9035 | Avastin (bevacizumab) | **Billing unit: 10 mg**<br><br>100mg/4 mL, 400 mg/16 mL SDV |

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| Created | 3/26/2025 | 3/26/2025 | Dawn Shojai, PharmD, Senior Pharmacy Benefit Consultant (PSG) | N/A |
| Approved | N/A | 5/15/2025 | Pharmacy & Therapeutics (P&T) Committee | 5/15/2025 |
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# Avsola *((infliximab-axxq)*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses (FDA approved indication)** | Avsola is a tumor necrosis factor inhibitor (TNFi) indicated for several conditions including Crohn's Disease (CD), Ulcerative Colitis (UC), fistulizing CD, Rheumatoid Arthritis (RA), active ankylosing spondylitis (AS), psoriatic arthritis (PsA), and plaque psoriasis (PsO). |
| **Exclusion Criteria** | Must not be used in combination with other biologic drugs, Otezla, or Janus Kinase Inhibitor (JAKis). |
| **Required Medical Information** | Medical records supporting the request must be provided, including documentation of prior therapies and responses to treatment. |
| **Age Restriction** | None. |
| **Prescriber Restrictions** | Prescriber is a specialist or has consulted with a specialist for the condition being treated. |
| **Coverage Duration** | Two years. Dose will be approved according to the FDA approved labeling or within accepted standards of medical practice. |
| **Other Criteria/Information** | Refer to the Gold Coast Health Plan Medicare Part B Reference and Summary of Evidence document. |

| HCPCS | Description | Billing Units/How Supplied |
|---|---|---|
| Q5121 | Avsola (infliximab-axxq) | **Billing unit: 10 mg**<br><br>100 mg SDV |

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| Approved | N/A | 5/15/2025 | Pharmacy & Therapeutics (P&T) Committee | 5/15/2025 |
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# Benlysta IV *(belimumab)*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses (FDA approved indication)** | Benlysta is a B-lymphocyte stimulator (BLyS)-specific inhibitor indicated for the treatment of patients 5 years of age and older with active systemic lupus erythematosus (SLE) who are receiving standard therapy and patients 5 years f age and older with active lupus nephritis (LN) who are receiving standard therapy. |
| **Exclusion Criteria** | Must not be used with another biologic drug or Lupkynis. |
| **Required Medical Information** | For all medically-accepted indications: Medical records supporting the request must be provided, including documentation of prior therapies and responses to treatment.<br><br>For SLE Initial Coverage: Must also have a SELENA-SLEDAI score of 6 or more before starting Benlysta - AND - either an anti-dsDNA antibody greater than 30 IU/ml or ANA greater than 1:80.<br><br>For Lupus Nephritis Initial Coverage: Must also have a confirmed diagnosis of SLE - AND<br><br>- a kidney biopsy confirming class 3, 4, and/or 5 disease. |
| **Age Restriction** | None. |
| **Prescriber Restrictions** | Prescriber must be a specialist in treating the condition or have consulted with a specialist. |
| **Coverage Duration** | One year initial coverage; two years reauthorization. Dose will be approved according to the FDA approved labeling or within accepted standards of medical practice. |
| **Other Criteria/Information** | Refer to the Gold Coast Health Plan Medicare Part B Reference and Summary of Evidence document. |

| HCPCS | Description | Billing Units/How Supplied |
|---|---|---|
| J0490 | Benlysta IV (belimumab) vial | **Billing unit: 10 mg**<br><br>120 mg, 400 mg SDV |

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| Approved | N/A | 8/21/2025 | Pharmacy & Therapeutics (P&T) Committee | 8/21/2025 |
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# Bivigam *(immune globulin)*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses (FDA approved indication)** | Bivigam, an intravenous immunoglobulin (IVIG) that are human derived antibodies used to treat various autoimmune, infectious, and idiopathic diseases including, but not limited to: Chronic Inflammatory Demyelinating Polyneuropathy (CIDP), Chronic Lymphocytic Leukemia (CLL), multiple myeloma, myasthenia gravis, and Immune Thrombocytopenia (ITP). |
| **Exclusion Criteria** | None. |
| **Required Medical Information** | Medical records supporting the request must be provided, including documentation of prior therapies and responses to treatment. |
| **Other Criteria** | Must follow LCD L34771 (Immune Globulin).<br>https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdid=34771&ver=49&= |
| **Age Restriction** | None. |
| **Prescriber Restrictions** | None. |
| **Coverage Duration** | Two years. Dose will be approved according to the FDA-approved labeling or within accepted standards of medical practice. |
| **Other Criteria/Information** | Refer to the Gold Coast Health Plan Medicare Part B Reference and Summary of Evidence document. |

| HCPCS | Description | Billing Units/How Supplied |
|---|---|---|
| J1556 | Bivigam (immune globulin) intravenous | **Billing unit: 500 mg**<br><br>5 gm/50 ml SDV<br>10 gm/100 ml SDV |

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| Approved | N/A | 8/21/2025 | Pharmacy & Therapeutics (P&T) Committee | 8/21/2025 |
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# BIZENGRI® *(zenocutuzumab-zbco)*

<table>
<tr><th>PA Criteria</th><th>Criteria Details</th></tr>
<tr><td>Description</td><td>BIZENGRI® is a bispecific human epidermal growth factor 2 (HER2) and HER3-directed antibody.</td></tr>
<tr><td>Covered Uses<br>(FDA approved indication)</td><td>BIZENGRI® is indicated for the treatment of:<ul><li>adults with advanced, unresectable or metastatic non-small cell lung cancer (NSCLC) harboring a neuregulin 1 (NRG1) gene fusion with disease progression on or after prior systemic therapy*.</li><li>adults with advanced, unresectable or metastatic pancreatic adenocarcinoma harboring a neuregulin 1 (NRG1) gene fusion with disease progression on or after prior systemic therapy*.</li></ul>*This indication is approved under accelerated approval based on objective response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in the confirmatory trial.</td></tr>
<tr><td>Dosing and Administration</td><td>
<table>
<tr><th>Indication</th><th>Dosing Regimen</th></tr>
<tr><td>NSCLC, pancreatic adenocarcinoma</td><td>750 mg IV infusion every two weeks; administer infusion over four hours<br><br>Continue until disease progression or unacceptable toxicity.<br><br>Recommended Premedications prior to EACH infusion:
<table>
<tr><th>Premedication</th><th>Dose</th><th>Route of Administration</th></tr>
<tr><td>Corticosteroid*</td><td>Dexamethasone 10 mg</td><td>PO or IV</td></tr>
<tr><td>Antipyretic</td><td>APAP 1000 mg</td><td>PO or IV</td></tr>
<tr><td>H1 Antihistamine</td><td>Dexchlorpheniramine 5 mg or other anti-H1 equivalent</td><td>PO or IV</td></tr>
</table>
*Optional after initial BIZENGRI infusion</td></tr>
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</td></tr>
<tr><td>Billing and Coding Information</td><td>
<table>
<tr><th>10-digit NDC</th><th>11-digit NDC</th></tr>
<tr><td>71837-1000-2</td><td>71837-1000-02</td></tr>
</table>
<table>
<tr><th>HCPCS Code</th><th>Description</th></tr>
<tr><td>J9382</td><td>Injection, zenocutuzumab-zbco, 1 mg</td></tr>
</table>
<table>
<tr><th>CPT Procedural Codes</th><th>Description</th></tr>
<tr><td>96413</td><td>Chemotherapy IV infusion, up to one hour</td></tr>
<tr><td>96415</td><td>Chemotherapy IV infusion, additional hour*</td></tr>
</table>
*Used as an add-on code for every hour of infusion that is more than 30 min past the initial 1 hour</td></tr>
<tr><td>Product Availability</td><td>Single dose vial: 375 mg/18.75 mL (two vials per carton = 750 mg = 37.5 mL)</td></tr>
<tr><td>Contraindications</td><td>None.</td></tr>
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| **Recommended Medical Monitoring** | Patients received BIZENGRI® are chosen based on the presence of an NRG1 gene fusion in tumor specimens with disease progression.<br><br>**BLACK BOX WARNING: Embryo-Fetal Toxicity** – BIZENGRI can cause fetal harm when administered to pregnant women, including effects on cardiac, vascular and neuronal development, and embryolethality.<br>a. Advise patients of potential risk to fetus; verify pregnancy status of females of reproductive potential prior to initiation of therapy<br>b. Recommend effective contraception during treatment and for two months after last dose.<br><br>Patients should be monitored for any of these reactions. BIZENGRI dose may be delayed, reduced or permanently discontinued based on the severity of adverse reactions.<br><br>BIZENGRI® has been associated with:<br>a. Infusion-related reactions (IRR)/Hypersensitivity/Anaphylactic Reactions<br>b. Interstitial Lung Disease (ILD) and Pneumonitis<br>c. Left Ventricular Dysfunction<br>d. Embryo-fetal Toxicity **(BBW)** |
| **Approval Criteria**<br><br>**NSCLC** | a. Physician administered IV infusion; in-office or HOPD<br>i. Cannot be self-administered<br>b. Non-Small Cell Lung Cancer **(must meet all)**:<br>i. Diagnosis of advanced, unresectable or metastatic NSCLC<br>ii. Prescribed by or in consultation with an oncologist<br>iii. Patient age ≥ 18 years<br>iv. Disease is positive for NRG1 gene fusion<br>v. Failure of at least one prior systemic therapy (see Appendix)<br>vi. Request meets one of the following:<br>1. Dose does not exceed 750 mg every two weeks<br>2. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (prescriber must submit supporting evidence) |
| **Approval Criteria**<br><br>**Pancreatic Adenocarcinoma** | a. Physician administered IV infusion; in-office or HOPD<br>i. Cannot be self-administered<br>b. Pancreatic Adenocarcinoma (must meet all):<br>i. Diagnosis of advanced, unresectable or metastatic pancreatic adenocarcinoma<br>ii. Prescribed by or in consultation with an oncologist<br>iii. Patient age ≥ 18 years<br>iv. Disease is positive for NRG1 gene fusion<br>v. Failure of at least one prior systemic therapy (see Appendix)<br>vi. Request meets one of the following:<br>1. Dose does not exceed 750 mg every two weeks<br>vii. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (prescriber must submit supporting evidence) |

GOLD COAST HEALTH PLAN TOTAL Care ADVANTAGE℠

<table>
<tr><td>Age Restriction</td><td>Adults ≥ 18 years old.</td></tr>
<tr><td>Coverage Duration</td><td>Initial: six months. Reauthorization: 12 months.<br><br>Dose will be approved according to the FDA approved labeling or within accepted standards of medical practice.</td></tr>
<tr><td>Appendix</td><td>Refer to the Gold Coast Health Plan Medicare Part B Reference and Summary of Evidence document.<br><br>
<table>
<tr><th>Examples of systemic therapies for NSCLC</th><th>Examples of systemic therapies for pancreatic adenocarcinoma</th></tr>
<tr><td>a. Platinum therapies (e.g. carboplatin, cisplatin)<br>b. Anti-PD1/PD-L1 therapy (e.g. Keytruda, Libtayo, Opdivo, Imfinzi, Tecentriq)<br>c. Bevacizumab (Avastin, Alymsys, Avzivi, Mvasi, Vegzelma, Zirabev)<br>d. Gemcitaine<br>e. Taxane chemotherapy (e.g. Paclitaxel, Docetaxel)</td><td>a. FOLFIRINOX (fluorouracil + leucovorin + irinotecan + oxaliplatin)<br>b. NALIRIFOX (liposomal irinotecan + fluorouracil + leucovorin + oxaliplatin)<br>c. Gemcitabine-based therapy<br>d. Capecitabine-based therapy<br>e. Taxane-based chemotherapy (e.g. albumin-bound paclitaxel)</td></tr>
</table></td></tr>
</table>

| STATUS | DATE REVISED | REVIEW DATE | APPROVED/REVIEWED BY | EFFECTIVE DATE |
|---|---|---|---|---|
| Created | 9/9/2025 | 9/9/2025 | Tamara Chinarian, PharmD, Clinical Pharmacist | N/A |
| Approved | N/A | 11/13/2025 | Pharmacy & Therapeutics (P&T) Committee | 11/13/2025 |
| | | | | |
| | | | | |

# Boniva IV *(ibandronate sodium)*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses (FDA approved indication)** | Boniva is a bisphosphonate indicated for the treatment of osteoporosis in postmenopausal women. |
| **Exclusion Criteria** | None. |
| **Required Medical Information** | Medical records supporting the request must be provided. |
| **Other Criteria** | Must follow LCD L34648: bisphosphonate Drug Therapy.<br>LCD - Bisphosphonate Drug Therapy (L34648) |
| **Age Restriction** | None. |
| **Prescriber Restrictions** | None. |
| **Coverage Duration** | Up to two years. Dose will be approved according to the FDA approved labeling or within accepted standards of medical practice. |
| **Other Criteria/Information** | Refer to the Gold Coast Health Plan Medicare Part B Reference and Summary of Evidence document. |

| HCPCS | Description | Billing Units/How Supplied |
|---|---|---|
| J1740 | Boniva IV (ibandronate sodium) | **Billing unit: 1 mg**<br><br>3 mg/3 mL SD syringe |

| STATUS | DATE REVISED | REVIEW DATE | APPROVED/REVIEWED BY | EFFECTIVE DATE |
|---|---|---|---|---|
| Created | 3/26/2025 | 3/26/2025 | Dawn Shojai, PharmD, Senior Pharmacy Benefit Consultant (PSG) | N/A |
| Approved | N/A | 8/21/2025 | Pharmacy & Therapeutics (P&T) Committee | 8/21/2025 |
| | | | | |
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# BORUZU® *(bortezomib) injection, for IV or subcutaneous use*
# VELCADE® *(bortezomib) injection, for IV or subcutaneous use*

| PA Criteria | Criteria Details |
|---|---|
| **Description** | Bortezomib is a reversible proteasome inhibitor. |
| **Covered Uses (FDA approved indication)** | Bortezomib is indicated for the treatment of:<br>a. adult patients with multiple myeloma.<br>b. adult patients with mantle cell lymphoma. |
| **Dosing and Administration** | Recommended starting dose: 1.3 mg/m$^2$<br><br>Administered as either IV Bolus or subcutaneous injection – recommended final concentration is based on route of administration.<br><br>• **IV:** final concentration of 1 mg/mL (IV preferred for prev. untreated Mantle Cell Lymphoma)<br>• **SC:** final concentration of 2.5 mg/mL<br><br>**Multiple Myeloma:** administered for nine, six-week treatment cycles (shown below).<br><br>• Retreatment may be considered for patients previously treated with Bortezomib who responded to treatment but may have relapsed at least six months after completion of treatment.<br>• Retreatment will be started at the last tolerated dose<br>• Bortezomib is often used in other therapy combinations for previously untreated and relapsed or refractory disease *(see Appendix)*.<br>• **Discontinue for disease progression or unacceptable toxicity.** |

| Indication | Twice Weely BORTEZOMIB (Cycle one to four) | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | Week | 1 | | | | 2 | | 3 | 4 | | 5 | | 6 |
| Multiple Myeloma (Previously untreated) | Bortezomib (1.3 mg/m2) | Day 1 | -- | -- | D4 | D8 | D11 | Rest Period | D22 | D25 | D29 | D32 | Rest Period |
| | | | | | | | | | | | | | |
| | **Once Weely BORTEZOMIB (Cycle five to nine)** | | | | | | | | | | | | |
| | **Week** | **1** | | | | **2** | | **3** | **4** | | **5** | | **6** |
| | Bortezomib (1.3 mg/m2) | Day 1 | -- | -- | -- | D8 | -- | Rest Period | D22 | -- | D29 | -- | Rest Period |

**Mantle Cell Lymphoma:** administered as IV bolus injection (preferred) for six, three-week treatment cycles (shown below).

- IV administration of Bortezomib is preferred for previously untreated mantle cell lymphoma patients, used in combination with IV rituximab, cyclophosphamide, doxorubicin and PO prednisone.
- Bortezomib is administered first, followed by rituximab.
- Retreatment may be considered for patients previously treated with Bortezomib who responded to treatment but may have relapsed at least six months after completion of treatment.
- Retreatment will be started at the last tolerated dose.
- Bortezomib is often used in other therapy combinations for previously untreated and relapsed or refractory disease *(see Appendix)*.
- **Discontinue for disease progression or unacceptable toxicity.**

GOLD COAST HEALTH PLAN
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| Indication | Twice Weely BORTEZOMIB (six, three-week cycles)* | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | Week | 1 | | | | | 2 | 3 |
| Mantle Cell Lymphoma<br><br>(Previously untreated) | **Bortezomib** (1.3 mg/m2) | Day 1 | -- | -- | Day 4 | --- | D8 | D11 | Rest Period |
| | **Rituximab** (375 mg/m2)<br>**Cyclophosphamide** (750 mg/m2)<br>**Doxorubicin** (50 mg/m2) | Day 1 | -- | -- | -- | -- | -- | -- | Rest Period |
| | **Prednisone** (100 mg/m2) | Day 1 | Day 2 | Day 3 | Day 4 | Day 5 | -- | -- | Rest Period |

**Required Dose Modifications**

**Moderate to Severe Hepatic Impairment*:** start Bortezomib at **0.7 mg/m²** per injection for first cycle.

- Consider subsequent dose escalation to 1 mg/m²
- If lower starting dose is not tolerated, consider further lowering dose to **0.5 mg/m²**

*Moderate = bilirubin > 1.5-3X ULN | Severe = bilirubin > 3X ULN

**Billing and Coding Information**

| | 11-digit NDC | 11-digit NDC |
|---|---|---|
| **BORUZU®** | 70121-2484-1 | 70121-2484-01 |
| **VELCADE** | 63020-049-01 | 63020-0049-01 |

| HCPCS Code | Description |
|---|---|
| J9054 | Injection, bortezomib, 0.1 mg - BORUZU |
| J9041 | Injection, bortezomib, 0.1 mg – VELCADE |

| CPT Procedural Codes | Description |
|---|---|
| 96401 | Chemotherapy administration, subcutaneous or IM; non-hormonal anti-neoplastic |
| 96409 | Chemotherapy administration, IV push, single or initial substance/drug |
| 96411 | Chemotherapy administration, IV push, each additional substance/drug |

*Used as an add-on code for every hour of infusion that is more than 30 min past the initial 1 hour

**Product Availability**

**BORUZU** – *Single-dose vial:* 3.5 mg/1.4 mL (2.5 mg/mL); ready-to-use formulation
**VELCADE** – *Single-dose vial:* 3.5 mg lyophilized powder for reconstitution

**Contraindications**

- Hypersensitivity to bortezomib, boron or mannitol, including anaphylactic reactions.
- Intrathecal administration.

| | |
|---|---|
| **Recommended Medical Monitoring** | **Multiple Myeloma** - prior to initiating treatment:<br>• Platelet count ≥ 70 x 109/L<br>• ANC ≥ 1 x 109/L<br>• Nonhematological toxicities should be resolved to Grade 1 or baseline<br><br>**Mantle Cell Lymphoma** – prior to initiating treatment in combination with rituximab, cyclophosphamide, doxorubicin and prednisone:<br><br>• Platelet count ≥ 100 x 109/L<br>• ANC ≥ 1.5 x 109/L<br>• Hemoglobin ≥ 8 g/dL (≥ 4.96 mmol/L)<br>• Nonhematological toxicities should be resolved to Grade 1 or baseline<br><br>Bortezomib has been associated with:<br><br>• Peripheral neuropathy<br>• Hypotension<br>• Cardiac Toxicity<br>• Pulmonary Toxicity<br>• Posterior Reversible Encephalopathy Syndrome<br>• GI Toxicity (N/V/D, constipation)<br>• Thrombocytopenia and neutropenia<br>• Tumor Lysis Syndrome<br>• Hepatic Toxicity<br>• Thrombotic Microangiopathy<br>• Embryo-Fetal Toxicity<br><br>Patients should be monitored for any of these reactions. Bortezomib dose may be delayed, reduced or permanently discontinued based on the severity of adverse reactions.<br><br>Bortezomib can cause fetal harm when administered to a pregnant woman. Verify pregnancy status in females of reproductive potential prior to initiating Bortezomib treatment. Female patients of reproductive potential should be advised to use effective contraception during treatment with Bortezomib and for seven months after the last dose.<br><br>**Drug-Drug Interactions:** Bortezomib is a major substrate for cytochrome P450 3A4.<br><br>• Patients will have to be monitored for concurrent drug-drug interactions.<br>• Concurrent use with strong 3A4 inducers is NOT recommended and should be avoided as it can decrease patient exposure to Bortezomib. |

GOLD COAST HEALTH PLAN
TOTAL Care ADVANTAGE℠

<table>
<tr><td>Approval Criteria</td><td>
a. Physician administered IV push or subcutaneous injection; in-office or HOPD<br>
i. Cannot be self-administered<br>
b. Multiple Myeloma (must meet all):<br>
i. Diagnosis of multiple myeloma<br>
ii. Prescribed by or in consultation with an oncologist<br>
iii. Patient age ≥ 18 years<br>
iv. Platelet count ≥ 70 x 109/L<br>
v. ANC ≥ 1 x 109/L<br>
vi. Nonhematological toxicities Grade 1 or baseline<br>
vii. Dose does not exceed 1.3 mg/m2<br>
viii. Maximum six doses every 28 days<br>
c. Mantle Cell Lymphoma (must meet all):<br>
i. Diagnosis of mantle cell lymphoma<br>
ii. Prescribed by or in consultation with an oncologist<br>
iii. Patient age ≥ 18 years<br>
iv. Platelet count ≥ 100 x 109/L<br>
v. ANC ≥ 1.5 x 109/L<br>
vi. Nonhematological toxicities Grade 1 or baseline<br>
vii. Dose does not exceed 1.3 mg/m2<br>
viii. Maximum six doses every 28 days
</td></tr>
<tr><td>Age Restriction</td><td>Adults ≥ 18 years old.</td></tr>
<tr><td>Coverage Duration</td><td>Initial: six months. Reauthorization: 12 months.<br><br>Dose will be approved according to the FDA approved labeling or within accepted standards of medical practice.</td></tr>
<tr><td>Appendix</td><td>
<table>
<tr><th>Preferred regimens for standard-risk Multiple Myeloma</th><th>Place of BORTEZOMIB therapy in Mantle Cell Lymphoma treatment</th></tr>
<tr><td>
a. DVRd – daratumumab, Bortezomib, lenalidomide, dexamethasone<br>
b. IsaVRd – isatuximab, Bortezomib, lenalidomide, dexamethasone<br>
c. VRd – Bortezomib, lenalidomide, dexamethasone<br>
d. DRd – daratumumab, lenalidomide, dexamethasone<br>
e. VCd aka CyBorD – Bortezomib, cyclophosphamide, dexamethasone
</td><td>
a. HCT ineligible due to age (≥ 65 yrs), comorbid conditions or limited fitness<br>
i. VR-CAP – Bortezomib, rituximab, cyclophosphamide, doxorubicin, prednisone<br>
ii. Rituximab + lenalidomide<br>
iii. Rituximab + bendamustine
</td></tr>
</table>
</td></tr>
</table>

| Preferred regimens for HIGH-RISK Multiple Myeloma | Examples of strong CYP3A4 inducers |
|---|---|
| a. **Autologous HCT Ineligible:**<br>i. IsaVRd<br>ii. DVRd<br>iii. VRd or DRd (preferred for frail pts)<br>b. **HCT Eligible**<br>i. DVRd<br>ii. IsaVRd | a. Carbamazepine<br>b. Dexamethasone<br>c. Fosphenytoin<br>d. Phenobarbital<br>e. Phenytoin<br>f. Rifampin<br>g. St. John's Wort |

| STATUS | DATE REVISED | REVIEW DATE | APPROVED/REVIEWED BY | EFFECTIVE DATE |
|---|---|---|---|---|
| Created | 9/22/2025 | 9/22/2025 | Tamara Chinarian, PharmD, Clinical Pharmacist | N/A |
| Approved | N/A | 11/13/2025 | Pharmacy & Therapeutics (P&T) Committee | 11/13/2025 |
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GOLD COAST HEALTH PLAN TOTAL Care ADVANTAGE℠

TOTAL CARE ADVANTAGE PART B CLINICAL GUIDELINES

# Botulinum toxins type A and type B Botox *(onabotulinumtoxin A)* Daxxify *(daxibotulinumtoxinA-lanm)* Dysport *(abobotulinumtoxin A)* Myobloc *(rimabotulinumtoxin B)* Xeomin *(incobotulinumtoxin A)*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses (FDA approved indication)** | Coverage is limited to the spastic conditions listed under "Codes that Support Medical Necessity" of the Billing and Coding: Botulinum Toxin Type A & Type B (A57474) article. |
| **Exclusion Criteria** | None. |
| **Required Medical Information** | Medical records supporting the request must be provided, including documentation of a covered diagnosis, dose and frequency of injections, clinical effectiveness of the injections, and specific site(s) injected. |
| **Other Criteria** | Must follow the Centers for Medicare & Medicaid Services. Local Coverage Determination (LCD) L33646 Botulinum Toxins.<br>https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?LCDId=33646<br>Meet the following criteria based on the supported indication for the drug requested. Note that supported indications for individual botulinum toxin type A and toxin type B differ. The indications below do not indicate the requested drug is supported for the indication. It is the responsibility of providers to use each drug in accordance with the supported indications.<br>1. Chronic anal fissures: Must try and fail (defined as an inadequate response) conservative treatment such as topical nitrogen.<br>2. Chronic migraines: (1) Must have chronic migraines defined as a headache occurring on 15 or more days a month for more than three months, which, on at least eight days/month have the features of migraine headache - AND - (2) Must try and fail (defined as an inadequate response or intolerance) any two of the following drugs:<br>• Antidepressants (e.g., amitriptyline, nortriptyline)<br>• Beta blockers (e.g., propranolol, metoprolol, timolol)<br>• Anti-epileptics (e.g., valproate, topiramate)<br>3. Detrusor over activity associated with a neurologic condition: (1) Must have documentation of the underlying neurological condition that is the cause of detrusor activity (e.g., spinal cord injury or multiple sclerosis) - AND - (2) Must try and fail (defined as an inadequate response or intolerance) one urinary anticholinergic (e.g., oxybutynin, trospium).<br>4. Hyperhidrosis: (1) Must have hyperhidrosis that significantly affect patient's quality of life – AND – (2) Your condition cannot be controlled adequately on topical agents such as aluminum chloride (Drysol).<br>5. For sialorrhea (excessive salivation): Must try and fail (defined as an inadequate response or intolerance) one anticholinergic drug (e.g., glycopyrrolate, scopolamine patch, benztropine).<br>6. Urge incontinence/overactive bladder: Must try and fail (defined as an inadequate response or intolerance) one urinary anticholinergic (e.g., oxybutynin, trospium) – AND - Myrbetriq. |
| **Age Restriction** | None. |
| **Prescriber Restrictions** | None. |

GOLD COAST HEALTH PLAN TOTAL Care ADVANTAGE℠

| PA Criteria | Criteria Details |
|---|---|
| **Coverage Duration** | Up to two years. Dose will be approved according to the FDA-approved labeling or within accepted standards of medical practice. It is usually considered not medically necessary to give injections for spastic conditions more frequently than every 12 weeks. |
| **Other Criteria/Information** | Refer to the Gold Coast Health Plan Medicare Part B Reference and Summary of Evidence document. |

| HCPCS | Description | Billing Units/How Supplied |
|---|---|---|
| J0585 | Botox (onabotulinumtoxinA) | **Billing unit: 1 unit**<br><br>100-unit, 200-unit SDV |
| J0589 | Daxxify (daxibotulinumtoxinA) | **Billing unit: 1 unit**<br><br>100-unit SDV |
| J0586 | Dysport (abobotulinumtoxin A) | **Billing unit: 5 units**<br><br>300-unit, 500-unit SDV |
| J0587 | Myobloc (rimabotulinumtoxinB) | **Billing unit: 100 units**<br><br>2500 unit/0.5 mL, 5000 unit/mL, 10,000 unit/2 mL SDV |
| J0588 | Xeomin (incobotulinumtoxin A) | **Billing unit: 1 unit**<br><br>50-unit, 100-unit, 200-unit SDV |

| STATUS | DATE REVISED | REVIEW DATE | APPROVED/REVIEWED BY | EFFECTIVE DATE |
|---|---|---|---|---|
| Created | 3/26/2025 | 3/26/2025 | Dawn Shojai, PharmD, Senior Pharmacy Benefit Consultant (PSG) | N/A |
| Approved | N/A | 5/15/2025 | Pharmacy & Therapeutics (P&T) Committee | 5/15/2025 |
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# Breyanzi *(lisocabtagene maraleucel)*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses (FDA approved indication)** | Breyanzi is a CD19-directed genetically modified autologous T cell immunotherapy indicated for the treatment of:<br><br>Adult patients with large B-cell lymphoma (LBCL), including diffuse large B-cell lymphoma (DLBCL) not otherwise specified (including DLBCL arising from indolent lymphoma), high-grade B cell lymphoma, primary mediastinal large B-cell lymphoma, and follicular lymphoma grade 3B, who have:<br><br>Refractory disease to first-line chemoimmunotherapy or relapse within 12 months of first-line chemoimmunotherapy; or<br><br>Refractory disease to first-line chemoimmunotherapy or relapse after first-line chemoimmunotherapy and are not eligible for hematopoietic stem cell transplantation (HSCT) due to comorbidities or age; or<br><br>Relapsed or refractory disease after two or more lines of systemic therapy. |
| **Exclusion Criteria** | None. |
| **Required Medical Information** | Medical records supporting the request must be provided. |
| **Other Criteria** | Must follow NCD 110.24 for Chimeric Antigen Receptor (CAR) T-Cell Therapy.<br>https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?ncdid=374 |
| **Age Restriction** | None. |
| **Prescriber Restrictions** | None. |
| **Coverage Duration** | In accordance with the FDA-approved labeling or accepted standards of medical practice. |
| **Other Criteria/Information** | Refer to the Gold Coast Health Plan Medicare Part B Reference and Summary of Evidence document. |

| HCPCS | Description | Billing Units/How Supplied |
|---|---|---|
| Q2054 | Breyanzi (lisocabtagene maraleucel) | **Billing unit: per dose**<br><br>SD infusion bag |

| STATUS | DATE REVISED | REVIEW DATE | APPROVED/REVIEWED BY | EFFECTIVE DATE |
|---|---|---|---|---|
| Created | 3/26/2025 | 3/26/2025 | Dawn Shojai, PharmD, Senior Pharmacy Benefit Consultant (PSG) | N/A |
| Approved | N/A | 5/15/2025 | Pharmacy & Therapeutics (P&T) Committee | 5/15/2025 |
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# Carvykti *(ciltacabtagene autoleucel)*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses (FDA approved indication)** | Carvykti is a B-cell maturation antigen (BCMA)- directed genetically modified autologous T cell immunotherapy is indicated for the treatment of adult patients with relapsed or refractory multiple myeloma, who have received at least one prior line of therapy, including a proteasome inhibitor and an immunomodulatory agent, and are refractory to lenalidomide. |
| **Exclusion Criteria** | None. |
| **Required Medical Information** | Medical records supporting the request must be provided. |
| **Other Criteria** | Must follow NCD Chimeric Antigen Receptor (CAR) T-cell Therapy (110.24). https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?ncdid=374 |
| **Age Restriction** | None. |
| **Prescriber Restrictions** | None. |
| **Coverage Duration** | In accordance with the FDA approved labeling or accepted standards of medical practice. |
| **Other Criteria/Information** | Refer to the Gold Coast Health Plan Medicare Part B Reference and Summary of Evidence document. |

| HCPCS | Description | Billing Units/How Supplied |
|---|---|---|
| Q2056 | Carvykti (ciltacabtagene autoleucel) | **Billing unit: per dose**<br><br>SD infusion bag |

| STATUS | DATE REVISED | REVIEW DATE | APPROVED/REVIEWED BY | EFFECTIVE DATE |
|---|---|---|---|---|
| Created | 3/26/2025 | 3/26/2025 | Dawn Shojai, PharmD, Senior Pharmacy Benefit Consultant (PSG) | N/A |
| Approved | N/A | 5/15/2025 | Pharmacy & Therapeutics (P&T) Committee | 5/15/2025 |
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# Casgevy *(exagamglogene autotemcel)*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses (FDA approved indication)** | Casgevy is indicated for the treatment of patients 12 years of age and older with:<br>Sickle cell disease (SCD) with recurrent vaso-occlusive crises (VOCs)<br>transfusion-dependent ß-thalassemia (TDT). |
| **Exclusion Criteria** | Casgevy is not covered in patients with prior HSCT or prior gene therapy. |
| **Required Medical Information** | FOR SICKLE CELL REQUESTS:<br>Before the drug is covered, the patient must meet the following requirements:<br>Medical records supporting the request must be provided; AND<br>Patient has a diagnosis of Sickle Cell Disease (SCD) with ßS/ßS, ßS/ß0, or ßS/ß+ genotype confirmed by genetic testing; AND<br>Patient has a history of at least two severe vaso-occlusive events per year in the previous two years; AND<br>Patient's current weight has been provided; AND<br>Patient has adequate organ function and is eligible for HSCT (stem cell transplant);<br>AND<br>Patient does not have a contraindication to any product or procedure required for successful gene therapy treatment; AND<br>Patient has tried and failed hydroxyurea, or if not tolerated, at least one other SCD treatment such as Endari (L-Glutamine).<br><br>FOR BETA THALESSEMIA REQUESTS:<br>Before the drug is covered, the patient must meet the following requirements:<br>Medical records supporting the request must be provided; AND<br>Must have a diagnosis of transfusion dependent beta thalassemia (defined as a history of at least 100 mL/kg/year or 10 units/year of packed red blood cells (pRBC) in the previous two years); AND<br>Must not have a known and available HLA matched donor as determined by the hematologist and/or transplant specialist; AND<br>Provider attests that, in the absence of a known or available HLA-matched family donor, the patient would be otherwise clinically stable and eligible to undergo HSCT. |
| **Age Restriction** | Patient is at least 12 years of age. |
| **Prescriber Restrictions** | Must be prescribed by or in consultation with a hematologist or other clinically appropriate provider. |
| **Coverage Duration** | Six months authorization duration with a limit of one dose (treatment) per lifetime. |

| PA Criteria | Criteria Details |
|---|---|
| **Other Criteria/Information** | Refer to the Gold Coast Health Plan Medicare Part B Reference and Summary of Evidence document. |

| HCPCS | Description | Billing Units/How Supplied |
|---|---|---|
| J3392 | Casgevy (exagamglogene autotemcel) | **Billing unit: per treatment**<br><br>3 × 106 CD34+ cells per kg of body weight, which may be composed of multiple vials. |

| STATUS | DATE REVISED | REVIEW DATE | APPROVED/REVIEWED BY | EFFECTIVE DATE |
|---|---|---|---|---|
| Created | 3/26/2025 | 3/26/2025 | Dawn Shojai, PharmD, Senior Pharmacy Benefit Consultant (PSG) | N/A |
| Approved | N/A | 5/15/2025 | Pharmacy & Therapeutics (P&T) Committee | 5/15/2025 |
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# Cimzia *(certolizumab pegol)*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses (FDA approved indication)** | Cimzia is a tumor necrosis factor inhibitor (TNFi) indicated for certain inflammatory conditions including Crohn's Disease (CD), Rheumatoid Arthritis (RA), active ankylosing spondylitis (AS), psoriatic arthritis (PsA), and plaque psoriasis (PsO). |
| **Exclusion Criteria** | Must not be used in combination with other biologic drugs, Otezla, or Janus Kinase Inhibitor (JAKis). |
| **Required Medical Information** | Medical records supporting the request must be provided, including documentation of prior therapies and responses to treatment. |
| **Age Restriction** | None. |
| **Prescriber Restrictions** | Prescriber is a specialist or has consulted with a specialist for the condition being treated. |
| **Coverage Duration** | Two years. Dose will be approved according to the FDA approved labeling or within accepted standards of medical practice. |
| **Other Criteria/Information** | Refer to the Gold Coast Health Plan Medicare Part B Reference and Summary of Evidence document. |

| HCPCS | Description | Billing Units/How Supplied |
|---|---|---|
| J0717 | Cimzia (certolizumab pegol) lyophilized powder kit | **Billing unit: 1 mg**<br><br>200 mg SDV |

| STATUS | DATE REVISED | REVIEW DATE | APPROVED/REVIEWED BY | EFFECTIVE DATE |
|---|---|---|---|---|
| Created | 3/26/2025 | 3/26/2025 | Dawn Shojai, PharmD, Senior Pharmacy Benefit Consultant (PSG) | N/A |
| Approved | N/A | 5/15/2025 | Pharmacy & Therapeutics (P&T) Committee | 5/15/2025 |
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# Cinqair *(reslizumab)*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses (FDA approved indication)** | Cinqair is an interleukin-5 (IL-5) antagonist indicated for severe eosinophilic asthma add-on therapy. IL-5 is responsible for the growth and survival of eosinophils which contribute to inflammation in the lungs. |
| **Exclusion Criteria** | Must not be used in combination with other biologic drugs. |
| **Required Medical Information** | 1. Medical records supporting the request, including documentation of prior therapies and responses to treatment must be provided -<br>2. Patient's current weight must be provided -<br>3. For initial coverage of severe eosinophilic asthma, must have an elevated eosinophil level greater than or equal to 150 cells/mcL at therapy start - **OR** - greater than or equal to 300 cells/mcL in the previous 12 months. |
| **Age Restriction** | None. |
| **Prescriber Restrictions** | Prescriber is a specialist or has consulted with a specialist for the condition being treated. |
| **Coverage Duration** | Initial: two years; reauthorization: two years. Dose will be approved according to the FDA approved labeling or within accepted standards of medical practice. |
| **Other Criteria/Information** | Refer to the Gold Coast Health Plan Medicare Part B Reference and Summary of Evidence document. |

| HCPCS | Description | Billing Units/How Supplied |
|---|---|---|
| J2786 | Cinqair (reslizumab) | **Billing unit: 1 mg**<br><br>100 mg/10 mL SDV |

| STATUS | DATE REVISED | REVIEW DATE | APPROVED/REVIEWED BY | EFFECTIVE DATE |
|---|---|---|---|---|
| Created | 3/26/2025 | 3/26/2025 | Dawn Shojai, PharmD, Senior Pharmacy Benefit Consultant (PSG) | N/A |
| Approved | N/A | 8/21/2025 | Pharmacy & Therapeutics (P&T) Committee | 8/21/2025 |
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# Cinryze *(C1 esterase inhibitor [human])*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses (FDA approved indication)** | Cinryze is a C1 esterase inhibitor indicated for routine prophylaxis against angioedema attacks in adults, adolescents, and pediatric patients (6 years of age and older) with Hereditary Angioedema (HAE). |
| **Exclusion Criteria** | None. |
| **Required Medical Information** | Medical records supporting the request must be provided, including documentation of prior therapies and responses to treatment. |
| **Age Restriction** | None. |
| **Prescriber Restrictions** | None. |
| **Coverage Duration** | Two years. Dose will be approved according to the FDA approved labeling or within accepted standards of medical practice. |
| **Other Criteria/Information** | Refer to the Gold Coast Health Plan Medicare Part B Reference and Summary of Evidence document. |

| HCPCS | Description | Billing Units/How Supplied |
|---|---|---|
| J0598 | Cinryze (C-1 esterase inhibitor [human]) | **Billing unit: 10 units**<br><br>500-unit SDV |

| STATUS | DATE REVISED | REVIEW DATE | APPROVED/REVIEWED BY | EFFECTIVE DATE |
|---|---|---|---|---|
| Created | 3/26/2025 | 3/26/2025 | Dawn Shojai, PharmD, Senior Pharmacy Benefit Consultant (PSG) | N/A |
| Approved | N/A | 8/21/2025 | Pharmacy & Therapeutics (P&T) Committee | 8/21/2025 |
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# Cosentyx IV *(secukinumab)*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses (FDA approved indication)** | Cosentyx is an interleukin-17 (IL-17) receptor A antagonist indicated for Plaque Psoriasis (PsO), Psoriatic Arthritis (PsA), Rheumatoid Arthritis (RA), and Ankylosing Spondylitis (AS). |
| **Exclusion Criteria** | Must not be used in combination with other biologic drugs, Otezla, or Janus Kinase Inhibitor (JAKis). |
| **Required Medical Information** | Medical records supporting the request must be provided, including documentation of prior therapies and responses to treatment. |
| **Age Restriction** | None. |
| **Prescriber Restrictions** | Prescriber is a specialist or has consulted with a specialist for the condition being treated. |
| **Coverage Duration** | Two years. Dose will be approved according to the FDA approved labeling or within accepted standards of medical practice. |
| **Other Criteria/Information** | Refer to the Gold Coast Health Plan Medicare Part B Reference and Summary of Evidence document. |

| HCPCS | Description | Billing Units/How Supplied |
|---|---|---|
| J3247 | Cosentyx IV (secukinumab) 125mg/5 mL vial | **Billing unit: 1 mg**<br><br>125mg/ 5mL SDV |

| STATUS | DATE REVISED | REVIEW DATE | APPROVED/REVIEWED BY | EFFECTIVE DATE |
|---|---|---|---|---|
| Created | 3/26/2025 | 3/26/2025 | Dawn Shojai, PharmD, Senior Pharmacy Benefit Consultant (PSG) | N/A |
| Approved | N/A | 5/15/2025 | Pharmacy & Therapeutics (P&T) Committee | 5/15/2025 |
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GOLD COAST HEALTH PLAN TOTAL Care ADVANTAGE℠

TOTAL CARE ADVANTAGE PART B CLINICAL GUIDELINES

# DATROWAY® *(datopotamab deruxtecan-dlnk)* for injection, for IV use

| PA Criteria | Criteria Details |
|---|---|
| **Description** | DATROWAY® is a Trop-2-directed antibody and topoisomerase inhibitor conjugate |
| **Covered Uses (FDA approved indication)** | DATROWAY® is indicated for the treatment of:<br>a. adult patients with locally advanced or metastatic EGFR-mutated non-small cell lung cancer (NSCLC) who have received prior EGFR-directed therapy and platinum-based chemotherapy*.<br>b. adult patients with unresectable or metastatic hormone receptor (HR) positive, human epidermal growth factor 2 (HER2) negative (IHC 0, IHC 1+ or IHC 2+/ISH-) breast cancer who have received prior endocrine-based therapy and chemotherapy for unresectable or metastatic disease.<br>**This indication is approved under accelerated approval based on objective response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in the confirmatory trial.* |
| **Dosing and Administration** | **Indication:** Breast Cancer, NSCLC<br>**Dosing Regimen:** 6 mg/kg IV infusion Q3 weeks (21-day cycle)<br>Continue until disease progression or unacceptable toxicity.<br>**Maximum Dose:** 540 mg*<br>*for patients ≥ 90 kg |

| | Infusion Time | Post-Infusion Observation |
|---|---|---|
| **1st infusion** | 90 min | 1 hour |
| **2nd infusion** | 30 min | 1 hour |
| **Subsequent infusions** | 30 min | 30 min |

**Billing and Coding Information**

| 10-digit NDC | 11-digit NDC |
|---|---|
| 65597-801-01 | 65597-0801-01 |

| HCPCS Code | Description |
|---|---|
| J9011 | Injection, datopotamab deruxtecan-dlnk, 1mg |

| CPT Procedural Codes | Description |
|---|---|
| 96413 | Chemotherapy IV infusion, up to one hour |
| 96415 | Chemotherapy IV infusion, additional hour* |

*Used as an add-on code for every hour of infusion that is more than 30 min past the initial 1 hour

| | |
|---|---|
| **Product Availability** | *Single dose vial:* 100 mg lyophilized powder for reconstitution. |
| **Contraindications** | None. |

GOLD COAST HEALTH PLAN
TOTAL Care ADVANTAGE℠

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|---|---|
| **Recommended Medical Monitoring** | Datroway® has been associated with:<br><br>a. Interstitial Lung Disease (ILD) and Pneumonitis<br>b. Ocular adverse reactions (including dry eye, keratitis, blepharitis, meibomian gland dysfunction, increased lacrimation, conjunctivitis, and blurred vision)<br>c. Stomatitis/Oral Mucositis<br>d. Embryo-fetal Toxicity<br><br>Patients should be monitored for any of these reactions. Datroway® dose may be delayed, reduced or permanently discontinued based on the severity of adverse reactions.<br><br>Datroway can cause fetal harm when administered to a pregnant woman. Verify pregnancy status in females of reproductive potential prior to initiating Datroway treatment. Female patients of reproductive potential should be advised to use effective contraception during treatment with Datroway and for **seven months** after the last dose. |
| **Approval Criteria**<br><br>**Breast Cancer** | a. Physician administered IV infusion; in-office or HOPD<br>i. Cannot be self-administered<br>b. Breast Cancer **(must meet all)**:<br>i. Diagnosis of unresectable or metastatic breast cancer<br>ii. Prescribed by or in consultation with an oncologist<br>iii. Patient age ≥ 18 years<br>iv. Documentation of HR+ disease<br>v. Documentation of HER2- disease (IHC 0, IHC 1+ or IHC 2+/ISH-)<br>vi. Patient received prior endocrine-based therapy *(see Appendix)*<br>vii. Patient received prior chemotherapy for unresectable or metastatic disease (see Appendix)<br>viii. Prescribed as single agent<br>ix. Request meets one of the following:<br>1. Dose does not exceed 6 mg/kg or 540 mg total once every three weeks (21-day cycle)<br>2. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (prescriber must submit supporting evidence) |
| **Approval Criteria**<br><br>**NSCLC** | a. Physician administered IV infusion; in-office or HOPD<br>i. Cannot be self-administered<br>b. Non-Small Cell Lung Cancer **(must meet all)**:<br>i. Diagnosis of locally advanced or metastatic NSCLC<br>vii. Prescribed by or in consultation with an oncologist<br>vii. Patient age ≥ 18 years<br>vii. Documentation of EGFR+ disease<br>vii. Patient received prior EGFR-directed therapy and platinum-based chemotherapy *(see Appendix)*<br>vii. Prescribed as a single agent<br>vii. Request meets one of the following<br>1. Dose does not exceed 6 mg/kg or 540 mg total once every three weeks (21-day cycle)<br>2. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (prescriber must submit supporting evidence) |

GOLD COAST HEALTH PLAN
TOTAL Care ADVANTAGE℠

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|---|---|
| **Age Restriction** | Adults ≥ 18 years old. |
| **Coverage Duration** | Initial: six months. Reauthorization: 12 months.<br><br>Dose will be approved according to the FDA approved labeling or within accepted standards of medical practice. |
| **Appendix** | **Examples of systemic therapies for recurrent unresectable or metastatic breast cancer:**<br>a. Albumin-bound Paclitaxel (Abraxane)<br>b. Capecitabine (Xeloda)<br>c. Carboplatin (Paraplatin)<br>d. Cisplatin (Kemoplat)<br>e. Cyclophosphamide (Frindovyx)<br>f. Docetaxel (Taxotere)<br>g. Doxorubicin (Adriamycin)<br>h. Epirubicin (Ellence)<br>i. Eribulin (Halaven)<br>j. Gemcitabine (Gemzar)<br>k. Ixabepilone (Ixempra)<br>l. Liposomal doxorubicin (Doxil)<br>m. Paclitaxel<br>n. Vinorelbine (Navelbine)<br><br>**Examples of endocrine based therapy for breast cancer:**<br>a. Anastrozole (Arimidex)<br>b. Exemestane (Aromasin)<br>c. Letrozole (Femara)<br>d. Tamoxifen<br><br>**Examples of targeted EGFR therapies for NSCLC:**<br>a. Afatinib (Gilotrif)<br>b. Amivantamab (Rybrevant)<br>c. Erlotinib (Tarceva)<br>d. Osimertinib (Tagrisso)<br>e. Sunvozertinib (Zegfrovy)<br><br>**Examples of targeted EGFR therapies for NSCLC:**<br>a. Carboplatin<br>b. Cisplatin |

| STATUS | DATE REVISED | REVIEW DATE | APPROVED/REVIEWED BY | EFFECTIVE DATE |
|---|---|---|---|---|
| Created | 9/8/2025 | 9/8/2025 | Tamara Chinarian, PharmD, Clinical Pharmacist | N/A |
| Approved | N/A | 11/13/2025 | Pharmacy & Therapeutics (P&T) Committee | 11/13/2025 |
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# Docivyx *(docetaxel)*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses (FDA approved indication)** | Docivyx is a microtubule inhibitor indicated for treatment of breast cancer, non- small cell lung cancer (NSCLC), castration-resistant prostate cancer (CRPC), gastric adenocarcinoma (GC), and squamous cell carcinoma of the head and neck (SCCHN). |
| **Exclusion Criteria** | None. |
| **Required Medical Information** | Medical records supporting the request must be provided. |
| **Other Criteria** | Must follow Centers for Medicare & Medicaid Services Local Coverage Determination (LCD) L37205: Chemotherapy Drugs and their Adjuncts.<br>LCD - Chemotherapy Drugs and their Adjuncts (L37205) |
| **Age Restriction** | None. |
| **Prescriber Restrictions** | None. |
| **Coverage Duration** | One year. Dose will be approved according to the FDA approved labeling or within accepted standards of medical practice. |
| **Other Criteria/Information** | Refer to the Gold Coast Health Plan Medicare Part B Reference and Summary of Evidence document. |

| HCPCS | Description | Billing Units/How Supplied |
|---|---|---|
| J9172 | Docivyx (docetaxel) | **Billing unit: 1 mg**<br><br>20 mg/2 mL, 80 mg/8 mL and 160 mg/16 mL SDV |

| STATUS | DATE REVISED | REVIEW DATE | APPROVED/REVIEWED BY | EFFECTIVE DATE |
|---|---|---|---|---|
| Created | 3/26/2025 | 3/26/2025 | Dawn Shojai, PharmD, Senior Pharmacy Benefit Consultant (PSG) | N/A |
| Approved | N/A | 5/15/2025 | Pharmacy & Therapeutics (P&T) Committee | 5/15/2025 |
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# Durysta *(bimatoprost intraocular implant)*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses (FDA approved indication)** | Durysta is a prostaglandin analog indicated for the reduction of intraocular pressure (IOP) in patients with open angle glaucoma (OAG) or ocular hypertension (OHT). |
| **Exclusion Criteria** | None. |
| **Required Medical Information** | Medical records supporting the request must be provided, including documentation or prior therapies and response to treatment. |
| **Age Restriction** | None. |
| **Prescriber Restrictions** | None. |
| **Coverage Duration** | Dose will be approved according to the FDA approved labeling or within accepted standards of medical practice. |
| **Other Criteria/Information** | Refer to the Gold Coast Health Plan Medicare Part B Reference and Summary of Evidence document. |

| HCPCS | Description | Billing Units/How Supplied |
|---|---|---|
| J7351 | Durysta (bimatoprost implant) | **Billing unit: 1 mcg**<br><br>10 mcg implant |

| STATUS | DATE REVISED | REVIEW DATE | APPROVED/REVIEWED BY | EFFECTIVE DATE |
|---|---|---|---|---|
| Created | 3/26/2025 | 3/26/2025 | Dawn Shojai, PharmD, Senior Pharmacy Benefit Consultant (PSG) | N/A |
| Approved | N/A | 8/21/2025 | Pharmacy & Therapeutics (P&T) Committee | 8/21/2025 |
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# Elevidys *(delandistrogene moxeparvovec-rokl)*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses (FDA approved indication)** | Elevidys is a gene therapy for the treatment of Duchenne muscular dystrophy (DMD). DMD is a rare, progressive X-linked disease resulting from mutation(s) of the DMD gene, also known as the Dystrophin gene. Due to the mutation(s), the dystrophin protein, which is key for maintaining the structural integrity of muscle cells, is not produced or very minimally produced. Elevidys encodes for a micro-dystrophin protein to replace the missing dystrophin protein. |
| **Exclusion Criteria** | None. |
| **Required Medical Information** | Before the drug is covered, the patient must meet all of the following requirements:<br><br>Documentation of Duchenne muscular dystrophy (DMD) confirmed by genetic mutation in the DMD gene that is not a deletion in exon 8 or exon 9.<br><br>An anti-AAVrh74 titer <1:400. |
| **Age Restriction** | None. |
| **Prescriber Restrictions** | Must be prescribed by or in consultation with a neurologist or other specialist with experience treating DMD. |
| **Coverage Duration** | Initial and Reauthorization: One year. Dose will be approved according to the FDA-approved labeling or within accepted standards of medical practice. |
| **Other Criteria/Information** | Refer to the Gold Coast Health Plan Medicare Part B Reference and Summary of Evidence document. |

| HCPCS | Description | Billing Units/How Supplied |
|---|---|---|
| J1413 | Elevidys (delandistrogene moxeparvovec-rokl) | **Billing unit: per dose**<br><br>1.33 x 1014 vector genomes per kilogram (vg/kg) of body weight as a single dose |

| STATUS | DATE REVISED | REVIEW DATE | APPROVED/REVIEWED BY | EFFECTIVE DATE |
|---|---|---|---|---|
| Created | 3/26/2025 | 3/26/2025 | Dawn Shojai, PharmD, Senior Pharmacy Benefit Consultant (PSG) | N/A |
| Approved | N/A | 5/15/2025 | Pharmacy & Therapeutics (P&T) Committee | 5/15/2025 |
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GOLD COAST HEALTH PLAN TOTAL Care ADVANTAGE℠

TOTAL CARE ADVANTAGE PART B CLINICAL GUIDELINES

# EMRELIS™ *(telisotuzumab vedotin-tllv)* injection, for IV use

| PA Criteria | Criteria Details |
|---|---|
| **Description** | EMRELIS is a c-Met-directed antibody and microtubule inhibitor conjugate. |
| **Covered Uses (FDA approved indication)** | EMRELIS is indicated for the treatment of:<br>• adult patients with locally advanced or metastatic non-squamous non-small cell lung cancer **(NSCLC)** with high c-Met protein overexpression (defined as present in ≥ 50% of tumor cells with strong (3+) staining), as determined by an FDA-approved test, who have received a prior systemic therapy*.<br>**This indication is approved under accelerated approval based on overall response rate (ORR) and duration of response (DOR). Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s).* |
| **Dosing and Administration** | **Indication:** Non-squamous NSCLC<br>**Dosing Regimen:** 1.9 mg/kg IV infusion every two weeks. Continue until disease progression or unacceptable toxicity. Infuse over **30 minutes**.<br>**Maximum Dose:** 190 mg* (*for patients ≥ 100 kg) |
| **Billing and Coding Information** | **10-digit NDC:** **20 mg:** 0074-1044-01; **100 mg:** 0074-1055-01<br>**11-digit NDC:** **20 mg:** 00074-1044-01; **100 mg:** 00074-1055-01<br>**HCPCS Code / Description:** J3490 Unclassified Drug; J3590 Unclassified Biologics; J9999 Antineoplastic drugs that are not otherwise classified; C9399 Unclassified drugs or biologics<br>**CPT Procedural Codes / Description:** Unclassified Drug — Chemotherapy IV infusion, up to one hour |
| **Product Availability** | *Single dose vial:* 20 mg and 100 mg as a lyophilized powder. |
| **Contraindications** | None. |

| | |
|---|---|
| **Recommended Medical Monitoring** | EMRELIS™ has been associated with:<br><br>a. Peripheral Neuropathy<br>b. Interstitial Lung Disease (ILD) and Pneumonitis<br>c. Ocular Surface Disorders<br>d. Infusion-Related Reactions (IRR)<br>e. Embryo-Fetal Toxicity<br><br>Patients should be monitored for any of these reactions. EMRELIS dose may be delayed, reduced or permanently discontinued based on the severity of adverse reactions.<br><br>EMRELIS can cause fetal harm when administered to a pregnant woman. Verify pregnancy status in females of reproductive potential prior to initiating EMRELIS treatment. Female patients of reproductive potential should be advised to use effective contraception during treatment with EMRELIS and for two months after the last dose.<br><br>**Drug-Drug Interactions:** MMAE is a small molecular component of EMRELIS; it is a strong substrate for cytochrome P450 3A.<br><br>• Concomitant use with strong CYP3A inhibitors may increase unconjugated MMAE AUC, possibly increasing EMRELIS adverse reactions.<br>• Monitor patients closely if coadministered with strong 3A inhibitors *(see Appendix)*.<br><br>**Moderate-to-Severe Hepatic Impairment:** AVOID USE of EMRELIS in patients with moderate to severe hepatic impairment (total bilirubin > 1.5X ULN and any AST).<br><br>• Patients with moderate to severe hepatic impairment are likely to have increased exposure to MMAE, which may increase EMRELIS adverse reactions. |
| **Approval Criteria**<br><br>**Breast Cancer** | a. Physician administered IV infusion; in-office or HOPD<br>i. Cannot be self-administered<br>b. Non-squamous Non-small Cell Lung Cancer **(must meet all)**:<br>i. Diagnosis of non-squamous NSCLC<br>ii. Disease is recurrent, locally advanced or metastatic<br>iii. Disease has all of the following characteristics:<br>1. Non-squamous<br>2. High c-Met protein overexpression, defined as presence in ≥ 50% of tumor cells<br>3. Strong (3+) immunohistochemistry staining (IHC 3+)<br>4. EGFR Wild-type<br>iv. Prescribed by or in consultation with an oncologist<br>v. Age ≥ 18 years<br>vi. Patient received prior systemic therapy for NSCLC (see Appendix)<br>vii. Request is for single agent therapy<br>viii. Request meets one of the following:<br>1. Dose does not exceed 1.9 mg/kg (MAX 190 mg) every two weeks<br>2. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (prescriber must submit supporting evidence) |

GOLD COAST HEALTH PLAN TOTAL Care ADVANTAGE℠

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|---|---|
| **Age Restriction** | Adults ≥ 18 years old. |
| **Coverage Duration** | Initial: six months. Reauthorization: 12 months.<br><br>Dose will be approved according to the FDA approved labeling or within accepted standards of medical practice. |
| **Misc Info, Appendix Etc.** | **Examples of Systemic Therapies for Advanced or Metastatic NSCLC**<br>a. Bevacizumab + Carboplatin + Paclitaxel<br>b. Bevacizumab + Carboplatin + Pemetrexed<br>c. Imjudo + Imfinfzi + Carboplatin + albumin-bound Paclitaxel<br>d. Imjudo + Imfinfzi + Carboplatin + Pemetrexed<br>e. Imjudo + Imfinfzi + Cisplatin + Pemetrexed<br>f. Keytruda + Carboplatin + Pemetrexed<br>g. Keytruda + Cisplatin + Pemetrexed<br>h. Libtayo + Carboplatin + Pemetrexed<br>i. Libtayo + Cisplatin + Pemetrexed<br>j. Opdivo + Yervoy<br>k. Opdivo + Yervoy + Pemetrexed + Carboplatin<br>l. Opdivo + Yervoy + Pemetrexed + Cisplatin<br>m. Tecentriq + Carboplatin + albumin-bound Paclitaxel<br>n. Tecentriq + Carboplatin + Paclitaxel + Bevacizumab<br><br>**Examples of Strong CYP3A Inhibitors**<br>a. Adagrasib<br>b. Atazanavir<br>c. Ceritinib<br>d. Clarithromycin<br>e. Cobicistat and cobicistat-containing coformulations<br>f. Darunavir<br>g. Diltiazem<br>h. Erythromycin<br>i. Grapefruit juice<br>j. Idelalisib<br>k. Indinavir<br>l. Itraconazole<br>m. Ketoconazole<br>n. Lonafarnib<br>o. Lopinavir<br>p. Mifepristone (chronically used)<br>q. Nefazodone<br>r. Nelfinavir<br>s. Nirmatrelvir-ritonavir<br>t. Ombitasvir-paritaprevir-ritonavir<br>u. Ombitasvir-paritaprevir-ritonavir plus dasabuvir<br>v. Posaconazole<br>w. Ritonavir and ritonavir-containing coformulations<br>x. Saquinavir<br>y. Tucatinib<br>z. Verapamil<br>aa. Voriconazole |

| STATUS | DATE REVISED | REVIEW DATE | APPROVED/REVIEWED BY | EFFECTIVE DATE |
|---|---|---|---|---|
| Created | 9/16/2025 | 9/16/2025 | Tamara Chinarian, PharmD, Clinical Pharmacist | N/A |
| Approved | N/A | 11/13/2025 | Pharmacy & Therapeutics (P&T) Committee | 11/13/2025 |
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GOLD COAST HEALTH PLAN TOTAL Care ADVANTAGE℠

TOTAL CARE ADVANTAGE PART B CLINICAL GUIDELINES

# ENCELTO™ *(revakinagene taroretcel-lwey)* implant, for intravitreal use

<table>
<tr><th>PA Criteria</th><th>Criteria Details</th></tr>
<tr><td>Description</td><td>ENCELTO™ is an allogeneic encapsulated cell-based gene therapy; it is an intravitreal implant that releases recombinant human ciliary neutrotrophic factor (rhCNTF).</td></tr>
<tr><td>Covered Uses<br>(FDA approved indication)</td><td>ENCELTO is indicated for the treatment of adults with idiopathic macular telangiectasia type 2 (MacTel).</td></tr>
<tr><td>Dosing and Administration</td><td>
<table>
<tr><th>Indication</th><th>Dosing Regimen</th><th>Maximum Dose</th></tr>
<tr><td>MacTel Type 2</td><td>One single-dose implant per affected eye containing 200,000 to 440,000 allogeneic retinal pigment epithelial cells expressing rhCNTF (NTC-201-6A cell line)<br><br>Administration: ENCELTO implant insertion is a surgical procedure performed in an operating room under aseptic conditions by a qualified ophthalmologist.</td><td>Single dose per affected eye per lifetime</td></tr>
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</td></tr>
<tr><td>Billing and Coding Information</td><td>
<table>
<tr><th>10-digit NDC</th><th>11-digit NDC</th></tr>
<tr><td>82958-501-01</td><td>82958-0501-01</td></tr>
</table>
<table>
<tr><th>HCPCS Code</th><th>Description</th></tr>
<tr><td>C9399</td><td>Unclassified drugs or biologicals</td></tr>
<tr><td>J3490</td><td>Unclassified drugs</td></tr>
<tr><td>J3590</td><td>Unclassified biologics</td></tr>
</table>
<table>
<tr><th>CPT Procedural Codes</th><th>Description</th></tr>
<tr><td>67027</td><td>Implantation of intravitreal drug delivery system, includes concomitant removal of vitreous</td></tr>
</table>
</td></tr>
<tr><td>Product Availability</td><td>Single-dose Intravitreal Implant, Sterile: 200,000 – 440,000 cells per implant</td></tr>
<tr><td>Contraindications</td><td>• Ocular or periocular infections<br>• Known hypersensitivity to Endothelial Serum Free Media (Endo-SFM)</td></tr>
</table>

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|---|---|
| **Recommended Medical Monitoring** | ENCELTO implantation has been associated with:<br>• Severe Vision Loss (defined as ≥ three lines of visual acuity loss)<br>• Infectious Endophthalmitis<br>• Retinal Tear and Detachment<br>• Vitreous Hemorrhage<br>» Increased risk in patients receiving antithrombotic medications (e.g. oral anticoagulants, aspirin, NSAIDs); must stop use prior to implantation<br>• Implant Extrusion<br>• Cataract Formation<br>• Suture Related Complications<br>• Delayed Dark Adaptation<br><br>Patients should be instructed to report any signs/symptoms that could be associated with these events. Additional surgical and/or medical management may be required. |
| **Approval Criteria** | a. Physician administered Intravitreal implant; administered surgically (ambulatory surgery center)<br>i. Cannot be self-administered<br>b. b. MacTel Type 2 **(must meet all)**:<br>i. Diagnosis of MacTel Type 2 in at least one eye<br>ii. Age ≥ 18 years<br>iii. Prescribed by and under care of qualified ophthalmologist<br>iv. Maximum one treatment per eye per lifetime<br>v. Patient will be monitored for signs/symptoms of retinal tears and/or retinal detachment (e.g., acute onset off flashing lights, floaters, and/or loss of visual acuity) |
| **Age Restriction** | Adults ≥ 18 years old. |
| **Coverage Duration** | Approval Duration: two months (one implant per eye per lifetime) |

| STATUS | DATE REVISED | REVIEW DATE | APPROVED/REVIEWED BY | EFFECTIVE DATE |
|---|---|---|---|---|
| Created | 9/17/2025 | 9/17/2025 | Tamara Chinarian, PharmD, Clinical Pharmacist | N/A |
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# Enjaymo *(sutimlimab-jome)*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses (FDA approved indication)** | Enjaymo injection is a classical complement inhibitor indicated for the treatment of hemolysis in adults with cold agglutinin disease (CAD) to be given as 6,500 mg (in patients weighing 39 kg to less than 75 kg) or 7,500 mg by intravenous infusion (in patients weighing 75 kg or more) weekly for two weeks then every two weeks thereafter. |
| **Exclusion Criteria** | Must not be used in combination with biologic drugs. |
| **Required Medical Information** | Medical records supporting the request must be provided, including documentation of prior therapies and responses to treatment must be provided - Must provide patient's current weight, and baseline hemoglobin level. |
| **Age Restriction** | Must be at least 18 years of age. |
| **Prescriber Restrictions** | Must be prescribed by or in consultation with a hematologist. |
| **Coverage Duration** | Initial six months; Reauthorization 12 months. |
| **Other Criteria/Information** | Refer to the Gold Coast Health Plan Medicare Part B Reference and Summary of Evidence document. |

| HCPCS | Description | Billing Units/How Supplied |
|---|---|---|
| J1302 | Enjaymo (sutimlimab-jome) | **Billing unit: 10 mg**<br><br>1,100 mg/22ml (50mg/ml) SDV |

| STATUS | DATE REVISED | REVIEW DATE | APPROVED/REVIEWED BY | EFFECTIVE DATE |
|---|---|---|---|---|
| Created | 3/26/2025 | 3/26/2025 | Dawn Shojai, PharmD, Senior Pharmacy Benefit Consultant (PSG) | N/A |
| Approved | N/A | 8/21/2025 | Pharmacy & Therapeutics (P&T) Committee | 8/21/2025 |
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# Entyvio *(vedolizumab)*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses (FDA approved indication)** | Entyvio is an integrin receptor antagonist indicated for Ulcerative Colitis (UC) and Crohn's Disease (CD). |
| **Exclusion Criteria** | Must not be used in combination with other biologic drugs, Otezla, or Janus Kinase Inhibitor (JAKis). |
| **Required Medical Information** | Medical records supporting the request must be provided, including documentation of prior therapies and responses to treatment. |
| **Age Restriction** | None. |
| **Prescriber Restrictions** | Prescriber is a specialist or has consulted with a specialist for the condition being treated. |
| **Coverage Duration** | Initial coverage: One year. Reauthorization: Two years. Dose will be approved according to the FDA approved labeling or within accepted standards of medical practice. |
| **Other Criteria/Information** | Refer to the Gold Coast Health Plan Medicare Part B Reference and Summary of Evidence document. |

| HCPCS | Description | Billing Units/How Supplied |
|---|---|---|
| J3380 | Entyvio IV (vedolizumab) 300mg vial | **Billing unit: 1 mg**<br><br>300 mg SDV |

| STATUS | DATE REVISED | REVIEW DATE | APPROVED/REVIEWED BY | EFFECTIVE DATE |
|---|---|---|---|---|
| Created | 3/26/2025 | 3/26/2025 | Dawn Shojai, PharmD, Senior Pharmacy Benefit Consultant (PSG) | N/A |
| Approved | N/A | 5/15/2025 | Pharmacy & Therapeutics (P&T) Committee | 5/15/2025 |
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# Erzofri *(paliperidone palmitate)*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses (FDA approved indication)** | Erzofri is an atypical antipsychotic prescribed for the treatment of schizophrenia and schizoaffective disorder in adults. It can be used alone or in combination with mood stabilizers or antidepressants. |
| **Exclusion Criteria** | None. |
| **Required Medical Information** | Medical records supporting the request must be provided, including documentation of prior therapies and responses to treatment. |
| **Age Restriction** | None. |
| **Prescriber Restrictions** | None. |
| **Coverage Duration** | Initial coverage: One year. Reauthorization: Two years. Dose will be approved according to the FDA approved labeling or within accepted standards of medical practice. |
| **Other Criteria/Information** | Refer to the Gold Coast Health Plan Medicare Part B Reference and Summary of Evidence document. |

| HCPCS | Description | Billing Units/How Supplied |
|---|---|---|
| J2428 | Injection, paliperidone palmitate extended release, 1 mg | **Billing unit: per 1 mg**<br><br>39 mg/0.25 mL, 78 mg/0.5 mL, 117 mg/0.75 mL, 156 mg/1 mL, 234 mg/1.5 mL, 351 mg/2.25 mL SD syringe |

| STATUS | DATE REVISED | REVIEW DATE | APPROVED/REVIEWED BY | EFFECTIVE DATE |
|---|---|---|---|---|
| Created | 3/26/2025 | 3/26/2025 | Dawn Shojai, PharmD, Senior Pharmacy Benefit Consultant (PSG) | N/A |
| Approved | N/A | 5/15/2025 | Pharmacy & Therapeutics (P&T) Committee | 5/15/2025 |
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# Evenity *(romosozumab-aqqg)*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses (FDA approved indication)** | Evenity is a humanized IgG2 monoclonal antibody and sclerostin inhibitor indicated for the treatment of osteoporosis in postmenopausal women at high risk for fracture, defined as a history of osteoporotic fracture, or multiple risk factors for fracture; or patients who have failed or are intolerant to other available osteoporosis therapy. |
| **Exclusion Criteria** | Cumulative use of Evenity of more than 12 months is not covered. |
| **Required Medical Information** | Medical records supporting the request must be provided, including documentation of prior therapies and responses to treatment - AND - documentation confirming diagnosis (such as the results from bone scan). |
| **Age Restriction** | None. |
| **Prescriber Restrictions** | Must be prescribed by endocrinologist. |
| **Coverage Duration** | 12 months per lifetime. |
| **Other Criteria/Information** | Refer to the Gold Coast Health Plan Medicare Part B Reference and Summary of Evidence document. |

| HCPCS | Description | Billing Units/How Supplied |
|---|---|---|
| J3111 | Evenity (romosozumab-aqqg) | **Billing unit: 1 mg**<br><br>105 mg/1.17 mL SD syringe |

| STATUS | DATE REVISED | REVIEW DATE | APPROVED/REVIEWED BY | EFFECTIVE DATE |
|---|---|---|---|---|
| Created | 3/26/2025 | 3/26/2025 | Dawn Shojai, PharmD, Senior Pharmacy Benefit Consultant (PSG) | N/A |
| Approved | N/A | 8/21/2025 | Pharmacy & Therapeutics (P&T) Committee | 8/21/2025 |
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# Evkeeza *(evinacumab-dgnb)*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses (FDA approved indication)** | Evkeeza is an angiopoietin-like 3 (ANGPTL3) inhibitor indicated as an adjunct to other low- density lipoprotein-cholesterol (LDL-C) lowering therapies for the treatment of adult and pediatric patients, 5 years of age and older, with homozygous familial hypercholesterolemia (HoFH). It is a recombinant human monoclonal antibody that binds to and inhibits ANGPTL3, a member of the angiopoietin-like protein family that is expressed primarily in the liver and plays a role in the regulation of lipid metabolism. Evinacumab-dgnb reduces LDL-C independent of the presence of LDL receptor (LDLR) by promoting very low-density lipoprotein (VLDL) processing and clearance upstream of LDL formation. Patients with HoFH often have mutations in the LDLR gene, encoding for the LDL receptor (LDLR). |
| **Exclusion Criteria** | None. |
| **Required Medical Information** | Medical records supporting the request, including documentation of prior therapies and responses to treatment must be provided. |
| **Age Restriction** | None. |
| **Prescriber Restrictions** | None. |
| **Coverage Duration** | Two years. Dose will be approved according to the FDA-approved labeling or within accepted standards of medical practice. |
| **Other Criteria/Information** | Refer to the Gold Coast Health Plan Medicare Part B Reference and Summary of Evidence document. |

| HCPCS | Description | Billing Units/How Supplied |
|---|---|---|
| J1305 | Evkeeza (evinacumab-dgnb) | **Billing unit: 5 mg**<br><br>345 mg/2.3 mL, 1200 mg/8 mL SDV |

| STATUS | DATE REVISED | REVIEW DATE | APPROVED/REVIEWED BY | EFFECTIVE DATE |
|---|---|---|---|---|
| Created | 3/26/2025 | 3/26/2025 | Dawn Shojai, PharmD, Senior Pharmacy Benefit Consultant (PSG) | N/A |
| Approved | N/A | 8/21/2025 | Pharmacy & Therapeutics (P&T) Committee | 8/21/2025 |
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# Fasenra *(benralizumab)*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses (FDA approved indication)** | Fasenra is an interleukin-5 (IL-5) antagonist indicated for severe eosinophilic asthma add-on therapy and for the treatment of adult patients with eosinophilic granulomatosis with polyangiitis (EGPA). |
| **Exclusion Criteria** | Must not be used in combination with other biologic drugs. |
| **Required Medical Information** | For initial coverage of severe eosinophilic asthma:<br><br>Medical records supporting the request, including documentation of prior therapies and responses to treatment must be provided.<br><br>Must have an elevated eosinophil level greater than or equal to 150 cells/mcL within six weeks (prior to the immediate start of treatment with Fasenra) - OR - greater than or equal to 300 cells/mcL in the previous 12 months.<br><br>Must try and fail one ICS/LABA inhaler drug in the past six months (fail is defined as an intolerance or inability to improve the condition on required therapy for at least four weeks).<br><br>For initial coverage of eosinophilic granulomatosis with polyangiitis (EGPA): Medical records supporting the request must be provided and include documentation that the patient has non-severe EGPA (defined as absence of life or organ-threatening manifestations).<br><br>For reauthorization requests for severe eosinophilic asthma: (1) Medical records supporting the request must be provided - (2) Must have documentation of clinical benefit (e.g., decrease in exacerbations, improvement in symptoms, decrease in oral steroid use).<br><br>For reauthorization requests for EGPA: (1) Medical records supporting the request must be provided - (2) Must have documentation of clinical benefit (e.g., decrease in exacerbations, improvement in symptoms, decrease in oral steroid use). |
| **Age Restriction** | None. |
| **Prescriber Restrictions** | Prescriber is a specialist or has consulted with a specialist for the condition being treated. |
| **Coverage Duration** | Initial: One year; reauthorization: two years. Dose will be approved according to the FDA approved labeling or within accepted standards of medical practice. |
| **Other Criteria/Information** | Refer to the Gold Coast Health Plan Medicare Part B Reference and Summary of Evidence document. |

| HCPCS | Description | Billing Units/How Supplied |
|---|---|---|
| J0517 | Fasenra (benralizumab) prefilled syringe | **Billing unit: 1 mg**<br><br>30 mg/mL SD syringe |

| STATUS | DATE REVISED | REVIEW DATE | APPROVED/REVIEWED BY | EFFECTIVE DATE |
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| Approved | N/A | 8/21/2025 | Pharmacy & Therapeutics (P&T) Committee | 8/21/2025 |
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# Fylnetra *(pegfilgrastim-pbbk)*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses (FDA approved indication)** | Fylnetra is a leukocyte growth factor indicated to decrease the incidence of infection, as manifested by febrile neutropenia, in patients with nonmyeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a clinically significant incidence of febrile neutropenia. |
| **Exclusion Criteria** | None. |
| **Required Medical Information** | Medical records supporting the request, including documentation of prior therapies and responses to treatment, must be provided. |
| **Age Restriction** | None. |
| **Prescriber Restrictions** | None. |
| **Coverage Duration** | One year. Dose will be approved according to the FDA approved labeling or within accepted standards of medical practice. |
| **Other Criteria/Information** | Refer to the Gold Coast Health Plan Medicare Part B Reference and Summary of Evidence document. |

| HCPCS | Description | Billing Units/How Supplied |
|---|---|---|
| Q5130 | Injection, pegfilgrastim-pbbk (fylnetra), biosimilar, 0.5 mg | **Billing unit: 0.5 mg**<br><br>6 mg/0.6 mL prefilled syringe |

| STATUS | DATE REVISED | REVIEW DATE | APPROVED/REVIEWED BY | EFFECTIVE DATE |
|---|---|---|---|---|
| Created | 3/26/2025 | 3/26/2025 | Dawn Shojai, PharmD, Senior Pharmacy Benefit Consultant (PSG) | N/A |
| Approved | N/A | 5/15/2025 | Pharmacy & Therapeutics (P&T) Committee | 5/15/2025 |
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# Gel-One *(hyaluronan/hyaluronic acid)*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses (FDA approved indication)** | Gel-One Hyaluronate is indicated for the treatment of pain in osteoarthritis (OA) of the knee in patients who have failed to respond adequately to non-pharmacologic therapy, non-steroidal anti-inflammatory drugs (NSAIDs) or simple analgesics, e.g., acetaminophen. |
| **Exclusion Criteria** | None. |
| **Required Medical Information** | Medical records supporting the request must be provided, including documentation of prior therapies and responses to treatment. |
| **Other Criteria** | Must follow LCD L39529 (Intraarticular Knee Injections of Hyaluronan). https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdid=39529 |
| **Age Restriction** | None. |
| **Prescriber Restrictions** | None. |
| **Coverage Duration** | One treatment series every six months. Dose will be approved according to the FDA approved labeling or within accepted standards of medical practice. |
| **Other Criteria/Information** | Refer to the Gold Coast Health Plan Medicare Part B Reference and Summary of Evidence document. |

| HCPCS | Description | Billing Units/How Supplied |
|---|---|---|
| J7326 | Gel-One (hyaluronan/ hyaluronic acid) for intra-articular injection | **Billing unit: per dose**<br><br>30 mg/3 mL SD syringe |

| STATUS | DATE REVISED | REVIEW DATE | APPROVED/REVIEWED BY | EFFECTIVE DATE |
|---|---|---|---|---|
| Created | 3/26/2025 | 3/26/2025 | Dawn Shojai, PharmD, Senior Pharmacy Benefit Consultant (PSG) | N/A |
| Approved | N/A | 5/15/2025 | Pharmacy & Therapeutics (P&T) Committee | 5/15/2025 |
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# GenVisc 850 *(hyaluronan/hyaluronic acid)*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses (FDA approved indication)** | Hyaluronic acid injections are indicated to treat osteoarthritis pain of the knee when conservative nonpharmacologic therapy and non-steroidal anti-inflammatory drugs (NSAIDs) or simple analgesics, such as acetaminophen, have failed. |
| **Exclusion Criteria** | None. |
| **Required Medical Information** | Medical records supporting the request must be provided, including documentation of prior therapies and responses to treatment. |
| **Other Criteria** | Must follow LCD L39529 (Intraarticular Knee Injections of Hyaluronan). https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdid=39529 |
| **Age Restriction** | None. |
| **Prescriber Restrictions** | None. |
| **Coverage Duration** | One treatment series every six months. Dose will be approved according to the FDA approved labeling or within accepted standards of medical practice. |
| **Other Criteria/Information** | Refer to the Gold Coast Health Plan Medicare Part B Reference and Summary of Evidence document. |

| HCPCS | Description | Billing Units/How Supplied |
|---|---|---|
| J7320 | GenVisc 850 (hyaluronan/ hyaluronic acid) for intra-articular injection | **Billing unit: 1 mg**<br><br>25 mg/2.5 mL SD syringe |

| STATUS | DATE REVISED | REVIEW DATE | APPROVED/REVIEWED BY | EFFECTIVE DATE |
|---|---|---|---|---|
| Created | 3/26/2025 | 3/26/2025 | Dawn Shojai, PharmD, Senior Pharmacy Benefit Consultant (PSG) | N/A |
| Approved | N/A | 5/15/2025 | Pharmacy & Therapeutics (P&T) Committee | 5/15/2025 |
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# Granix *(tbo-filgrastim)*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses (FDA approved indication)** | Granix is indicated to reduce the duration of severe neutropenia in adults and pediatric patients one month and older with non-myeloid malignancies receiving myelosuppressive anticancer drugs associated with a clinically significant incidence of febrile neutropenia.<br><br>Colony-stimulating factors (CSFs) are hematopoietic growth factors that regulate the growth and differentiation of cells towards the myeloid and erythroid lineages. Myeloid growth factors (MGFs), such as granulocyte colony-stimulating factors (G-CSF), are primarily used to reduce the incidence of febrile neutropenia (FN) in patients with non-myeloid malignancies receiving myelosuppressive chemotherapy. |
| **Exclusion Criteria** | None. |
| **Required Medical Information** | Medical records supporting the request must be provided. |
| **Age Restriction** | None. |
| **Prescriber Restrictions** | None. |
| **Coverage Duration** | Up to one year. Dose will be approved according to the FDA approved labeling or within accepted standards of medical practice. |
| **Other Criteria/Information** | Refer to the Gold Coast Health Plan Medicare Part B Reference and Summary of Evidence document. |

| HCPCS | Description | Billing Units/How Supplied |
|---|---|---|
| J1447 | Granix (tbo-filgrastim) | **Billing unit: 1 mcg**<br><br>300 mcg/0.5 mL, 480 mcg/0.8 mL SD syringe, 300 mcg/mL, 480 mcg/1.6 mL SDV |

| STATUS | DATE REVISED | REVIEW DATE | APPROVED/REVIEWED BY | EFFECTIVE DATE |
|---|---|---|---|---|
| Created | 3/26/2025 | 3/26/2025 | Dawn Shojai, PharmD, Senior Pharmacy Benefit Consultant (PSG) | N/A |
| Approved | N/A | 5/15/2025 | Pharmacy & Therapeutics (P&T) Committee | 5/15/2025 |
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GOLD COAST HEALTH PLAN TOTAL Care ADVANTAGE℠

TOTAL CARE ADVANTAGE PART B CLINICAL GUIDELINES

# Hemgenix *(etranacogene dezaparvovec-drlb)*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses (FDA approved indication)** | Hemgenix is an adeno-associated virus (AAV) vector-based gene therapy indicated as a one-time treatment for adults with hemophilia B (congenital Factor IX deficiency) who use Factor IX prophylaxis therapy, have a current or historical life-threatening hemorrhage, or who have repeated, serious spontaneous bleeding episodes. |
| **Exclusion Criteria** | Hemgenix is not covered in patients who have received a previous treatment course of Hemgenix or another adeno-associated virus vector-based gene therapy. The safety and effectiveness of repeat administration have not been evaluated. |
| **Required Medical Information** | The following is required for approval:<br><br>Patient has a diagnosis of moderate to severe hemophilia B (a factor IX activity level less than or equal to 2 IU/dL or less than or equal to 2% of normal); AND<br><br>Patient has one of the following:<br><br>Current use of factor IX prophylaxis therapy; OR<br><br>Patient has current or historical life-threatening hemorrhage; OR<br><br>Patient has had repeated, serious spontaneous bleeding episodes.<br><br>Medical records supporting the request must be provided. |
| **Age Restriction** | Must be at least 18 years of age. |
| **Prescriber Restrictions** | Must be prescribed by or in consultation with a hematologist. |
| **Coverage Duration** | One lifetime dose. |
| **Other Criteria/Information** | Refer to the Gold Coast Health Plan Medicare Part B Reference and Summary of Evidence document. |

| HCPCS | Description | Billing Units/How Supplied |
|---|---|---|
| J1411 | Injection, etranacogene dezaparvovec-drlb, per therapeutic dose | **Billing unit: per dose**<br><br>SD infusion bag |

| STATUS | DATE REVISED | REVIEW DATE | APPROVED/REVIEWED BY | EFFECTIVE DATE |
|---|---|---|---|---|
| Created | 3/26/2025 | 3/26/2025 | Dawn Shojai, PharmD, Senior Pharmacy Benefit Consultant (PSG) | N/A |
| Approved | N/A | 5/15/2025 | Pharmacy & Therapeutics (P&T) Committee | 5/15/2025 |
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# Herceptin *(trastuzumab)*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses (FDA approved indication)** | Herceptin (trastuzumab) is the reference product for multiple trastuzumab biosimilars. Trastuzumab biosimilars include, but may not be limited to Ontruzant (trastuzumab-dttb), Ogivri (trastuzumab-dkst), Herzuma (trastuzumab-pkrb), and Trazimera (trastuzumab-qyyp).<br><br>Herceptin is a HER2/neu receptor antagonist indicated in adults for:<br><br>The treatment of HER2-overexpressing breast cancer.<br><br>The treatment of HER2-overexpressing metastatic gastric or gastroesophageal junction adenocarcinoma. |
| **Exclusion Criteria** | None. |
| **Required Medical Information** | Medical records supporting the request must be provided, including documentation of prior therapies and responses to treatment. |
| **Other Criteria** | Must follow Local Coverage Determination (LCD) L37205: Chemotherapy Drugs and their Adjuncts. https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdId=37205&ver=15 |
| **Age Restriction** | None. |
| **Prescriber Restrictions** | None. |
| **Coverage Duration** | One year. Dose will be approved according to the FDA-approved labeling or within accepted standards of medical practice. |
| **Other Criteria/Information** | Refer to the Gold Coast Health Plan Medicare Part B Reference and Summary of Evidence document. |

| HCPCS | Description | Billing Units/How Supplied |
|---|---|---|
| J9355 | Herceptin (trastuzumab) | **Billing unit: 10 mg**<br><br>150 mg SDV |

| STATUS | DATE REVISED | REVIEW DATE | APPROVED/REVIEWED BY | EFFECTIVE DATE |
|---|---|---|---|---|
| Created | 3/26/2025 | 3/26/2025 | Dawn Shojai, PharmD, Senior Pharmacy Benefit Consultant (PSG) | N/A |
| Approved | N/A | 5/15/2025 | Pharmacy & Therapeutics (P&T) Committee | 5/15/2025 |
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TOTAL CARE ADVANTAGE PART B CLINICAL GUIDELINES

# Herceptin Hylecta *(trastuzumab & hyaluronidase)*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses (FDA approved indication)** | Herceptin Hylecta is a combination of trastuzumab, a HER2/neu receptor antagonist, and hyaluronidase, an endoglycosidase, indicated in adults for the treatment of HER2-overexpressing breast cancer. |
| **Exclusion Criteria** | None. |
| **Required Medical Information** | Medical records supporting the request must be provided, including documentation of prior therapies and responses to treatment. |
| **Other Criteria** | Must follow Local Coverage Determination (LCD) L37205: Chemotherapy Drugs and their Adjuncts. https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdId=37205&ver=15 |
| **Age Restriction** | None. |
| **Prescriber Restrictions** | None. |
| **Coverage Duration** | One year. Dose will be approved according to the FDA-approved labeling or within accepted standards of medical practice. |
| **Other Criteria/Information** | Refer to the Gold Coast Health Plan Medicare Part B Reference and Summary of Evidence document. |

| HCPCS | Description | Billing Units/How Supplied |
|---|---|---|
| J9356 | Herceptin Hylecta (trastuzumab and hyaluronidase) | **Billing unit: 10 mg**<br><br>600 mg-10000 unit/5 mL SDV |

| STATUS | DATE REVISED | REVIEW DATE | APPROVED/REVIEWED BY | EFFECTIVE DATE |
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| Approved | N/A | 5/15/2025 | Pharmacy & Therapeutics (P&T) Committee | 5/15/2025 |
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# Hercessi *(trastuzumab-strf)*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses (FDA approved indication)** | Hercessi is a biosimilar to Herceptin.<br><br>Hercessi is a monoclonal antibody that targets HER2 receptors on tumor cells that overexpress the protein, preventing further cell growth, ultimately leading to programmed cell death. |
| **Exclusion Criteria** | None. |
| **Required Medical Information** | Medical records supporting the request must be provided, including documentation of prior therapies and responses to treatment. |
| **Other Criteria** | Must follow LCD L37205: Chemotherapy Drugs and their Adjuncts.<br>https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdId=37205&ver=15 |
| **Age Restriction** | None. |
| **Prescriber Restrictions** | None. |
| **Coverage Duration** | One year. Dose will be approved according to the FDA-approved labeling or within accepted standards of medical practice. |
| **Other Criteria/Information** | Refer to the Gold Coast Health Plan Medicare Part B Reference and Summary of Evidence document. |

| HCPCS | Description | Billing Units/How Supplied |
|---|---|---|
| Q5146 | Hercessi (trastuzumab-strf) biosimilar | **Billing unit: 10 mg**<br><br>150 mg, 420 mg SDV |

| STATUS | DATE REVISED | REVIEW DATE | APPROVED/REVIEWED BY | EFFECTIVE DATE |
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| Created | 3/26/2025 | 3/26/2025 | Dawn Shojai, PharmD, Senior Pharmacy Benefit Consultant (PSG) | N/A |
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# Herzuma *(trastuzumab-pkrb)*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses (FDA approved indication)** | Herzuma is a biosimilar to Herceptin (trastuzumab).<br><br>Herzuma is a monoclonal antibody that targets HER2 receptors on tumor cells that overexpress the protein, preventing further cell growth, ultimately leading to programmed cell death. |
| **Exclusion Criteria** | None. |
| **Required Medical Information** | Medical records supporting the request must be provided, including documentation of prior therapies and responses to treatment. |
| **Other Criteria** | Must follow LCD L37205: Chemotherapy Drugs and their Adjuncts.<br>https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdId=37205&ver=15 |
| **Age Restriction** | None. |
| **Prescriber Restrictions** | None. |
| **Coverage Duration** | One year. Dose will be approved according to the FDA-approved labeling or within accepted standards of medical practice. |
| **Other Criteria/Information** | Refer to the Gold Coast Health Plan Medicare Part B Reference and Summary of Evidence document. |

| HCPCS | Description | Billing Units/How Supplied |
|---|---|---|
| Q5113 | Herzuma (trastuzumab-pkrb) biosimilar | **Billing unit: 10 mg**<br><br>150 mg, 420 mg SDV |

| STATUS | DATE REVISED | REVIEW DATE | APPROVED/REVIEWED BY | EFFECTIVE DATE |
|---|---|---|---|---|
| Created | 3/26/2025 | 3/26/2025 | Dawn Shojai, PharmD, Senior Pharmacy Benefit Consultant (PSG) | N/A |
| Approved | N/A | 5/15/2025 | Pharmacy & Therapeutics (P&T) Committee | 5/15/2025 |
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# Hyalgan *(hyaluronan/ hyaluronic acid)*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses (FDA approved indication)** | Hyaluronic acid injections are indicated to treat osteoarthritis pain of the knee when conservative nonpharmacologic therapy and non-steroidal anti-inflammatory drugs (NSAIDs) or simple analgesics, such as acetaminophen, have failed. |
| **Exclusion Criteria** | None. |
| **Required Medical Information** | Medical records supporting the request must be provided, including documentation of prior therapies and responses to treatment. |
| **Other Criteria** | Must follow LCD L39529 (Intraarticular Knee Injections of Hyaluronan). https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdid=39529 |
| **Age Restriction** | None. |
| **Prescriber Restrictions** | None. |
| **Coverage Duration** | One treatment series every six months. Dose will be approved according to the FDA approved labeling or within accepted standards of medical practice. |
| **Other Criteria/Information** | Refer to the Gold Coast Health Plan Medicare Part B Reference and Summary of Evidence document. |

| HCPCS | Description | Billing Units/How Supplied |
|---|---|---|
| J7321 | Hyalgan (hyaluronan/ hyaluronic acid) for intra-articular injection | **Billing unit: per dose**<br><br>20mg/2 ml SD syringe |

| STATUS | DATE REVISED | REVIEW DATE | APPROVED/REVIEWED BY | EFFECTIVE DATE |
|---|---|---|---|---|
| Created | 3/26/2025 | 3/26/2025 | Dawn Shojai, PharmD, Senior Pharmacy Benefit Consultant (PSG) | N/A |
| Approved | N/A | 5/15/2025 | Pharmacy & Therapeutics (P&T) Committee | 5/15/2025 |
| | | | | |
| | | | | |

# Hymovis *(hyaluronan/ hyaluronic acid)*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses (FDA approved indication)** | Hyaluronic acid injections are indicated to treat osteoarthritis pain of the knee when conservative nonpharmacologic therapy and non-steroidal anti-inflammatory drugs (NSAIDs) or simple analgesics, such as acetaminophen, have failed. |
| **Exclusion Criteria** | None. |
| **Required Medical Information** | Medical records supporting the request must be provided, including documentation of prior therapies and responses to treatment. |
| **Other Criteria** | Must follow LCD L39529 (Intraarticular Knee Injections of Hyaluronan). https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdid=39529 |
| **Age Restriction** | None. |
| **Prescriber Restrictions** | None. |
| **Coverage Duration** | One treatment series every six months. Dose will be approved according to the FDA approved labeling or within accepted standards of medical practice. |
| **Other Criteria/Information** | Refer to the Gold Coast Health Plan Medicare Part B Reference and Summary of Evidence document. |

| HCPCS | Description | Billing Units/How Supplied |
|---|---|---|
| J7322 | Hymovis (hyaluronan/ hyaluronic acid) for intra-articular injection | **Billing unit: 1 mg**<br><br>24 mg/3 mL SD syringe |

| STATUS | DATE REVISED | REVIEW DATE | APPROVED/REVIEWED BY | EFFECTIVE DATE |
|---|---|---|---|---|
| Created | 3/26/2025 | 3/26/2025 | Dawn Shojai, PharmD, Senior Pharmacy Benefit Consultant (PSG) | N/A |
| Approved | N/A | 5/15/2025 | Pharmacy & Therapeutics (P&T) Committee | 5/15/2025 |
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# Hympavzi *(marstacimab-hncq)*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses (FDA approved indication)** | Hympavzi is an anti-tissue factor pathway inhibitor (anti-TFPI) product indicated for the routine prophylaxis to prevent or reduce frequency of bleeding episodes in adults and pediatric patients ≥ 12 years of age with hemophilia A (congenital Factor VIII deficiency) without Factor VIII inhibitors or hemophilia B (congenital Factor IX deficiency) without Factor IX inhibitors. |
| **Exclusion Criteria** | None. |
| **Required Medical Information** | **For initial requests for Hemophilia A:**<br><br>Medical records supporting the request must be provided and include documentation of the following:<br><br>Hympavzi is being used for routine prophylaxis to prevent or reduce the frequency of bleeding episodes;<br><br>Patient has moderate or severe hemophilia A (a clotting factor level <1% or between 1%- 5%) without factors;<br><br>Patient has tried with failure (defined as continuing to have spontaneous bleeds) or intolerance, or has a contraindication to factor VIII prophylaxis therapy or Hemlibra.<br><br>**For initial requests for Hemophilia B:**<br><br>Medical records supporting the request must be provided and include documentation of the following:<br><br>Hympavzi is being used for routine prophylaxis to prevent or reduce the frequency of bleeding episodes;<br><br>Patient has moderate or severe hemophilia B (a clotting factor level <1% or between 1%- 5%) without factors;<br><br>Patient has tried with failure (defined as continuing to have spontaneous bleeds) or intolerance, or has a contraindication to factor IX prophylaxis therapy.<br><br>For reauthorization of hemophilia A and B: (1) Patient continues to use Hympavzi for routine prophylaxis to prevent or reduce the frequency of bleeding episodes; AND (2) Documentation of clinical benefit (e.g., less bleeding episodes; less use of factor VIII replacement therapy or bypassing agents) has been provided. |
| **Age Restriction** | Patient is at least 12 years of age. |
| **Prescriber Restrictions** | Must be prescribed by or in consultation with a hematologist or other specialist. |
| **Coverage Duration** | Initial and reauthorization: 12 months. Dose will be approved according to the FDA-approved labeling or within accepted standards of medical practice. |

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| Other Criteria/Information | Refer to the Gold Coast Health Plan Medicare Part B Reference and Summary of Evidence document. |
|---|---|

| HCPCS | Description | Billing Units/How Supplied |
|---|---|---|
| J7172 | Hympavzi (marstacimab-hncq), 0.5 mg injection | **Billing unit: 0.5 mg**<br><br>150 mg/ml SVD |

| STATUS | DATE REVISED | REVIEW DATE | APPROVED/REVIEWED BY | EFFECTIVE DATE |
|---|---|---|---|---|
| Created | 3/26/2025 | 3/26/2025 | Dawn Shojai, PharmD, Senior Pharmacy Benefit Consultant (PSG) | N/A |
| Approved | N/A | 5/15/2025 | Pharmacy & Therapeutics (P&T) Committee | 5/15/2025 |
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# iDose TR *(travoprost intracameral implant)*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses (FDA approved indication)** | iDose TR is a prostaglandin analog indicated for the reduction of intraocular pressure (IOP) in patients with open-angle glaucoma (OAG) or ocular hypertension (OHT). |
| **Exclusion Criteria** | The requested eye for treatment must not have received prior treatment with IDOSE TR. |
| **Required Medical Information** | Medical records supporting the request must be provided; AND<br>Patient has open angle glaucoma or ocular hypertension. |
| **Age Restriction** | None. |
| **Prescriber Restrictions** | None. |
| **Coverage Duration** | One-time administration as indicated per the FDA-approved labeling or within accepted standards of medical practice. |
| **Other Criteria/Information** | Refer to the Gold Coast Health Plan Medicare Part B Reference and Summary of Evidence document. |

| HCPCS | Description | Billing Units/How Supplied |
|---|---|---|
| J7355 | iDose TR (travoprost intracameral implant) | **Billing unit: 1 mcg**<br><br>75 mcg per each |

| STATUS | DATE REVISED | REVIEW DATE | APPROVED/REVIEWED BY | EFFECTIVE DATE |
|---|---|---|---|---|
| Created | 3/26/2025 | 3/26/2025 | Dawn Shojai, PharmD, Senior Pharmacy Benefit Consultant (PSG) | N/A |
| Approved | N/A | 8/21/2025 | Pharmacy & Therapeutics (P&T) Committee | 8/21/2025 |
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# Ilaris *(canakinumab)*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses (FDA approved indication)** | Ilaris is an interleukin-1 beta (IL-1B) monoclonal antibody. It blocks IL-1 receptor interaction and neutralizes overactive IL-1B activity which is present in disorders such as Cryopyrin-Associated Periodic Syndromes (CAPS), systemic juvenile idiopathic arthritis (SJIA), Still's disease, and gout. |
| **Exclusion Criteria** | Must not be used in combination with other biologic drugs. |
| **Required Medical Information** | Medical records supporting the request must be provided. |
| **Age Restriction** | None. |
| **Prescriber Restrictions** | Prescriber must be a specialist or consulted with a specialist for the condition being treated. |
| **Coverage Duration** | **Gout:** Initial coverage limited to one dose with authorization given for 12 weeks; and reauthorization is one year. Dose will be approved according to the FDA approved labeling or within accepted standards of medical practice.<br><br>**For all others (excludes gout):** Initial and Reauthorization two years. Dose will be approved according to the FDA approved labeling or within accepted standards of medical practice. |
| **Other Criteria/Information** | Refer to the Gold Coast Health Plan Medicare Part B Reference and Summary of Evidence document. |

| HCPCS | Description | Billing Units/How Supplied |
|---|---|---|
| J0638 | Ilaris (canakinumab) | **Billing unit: 1 mg**<br><br>150 mg SDV |

| STATUS | DATE REVISED | REVIEW DATE | APPROVED/REVIEWED BY | EFFECTIVE DATE |
|---|---|---|---|---|
| Created | 3/26/2025 | 3/26/2025 | Dawn Shojai, PharmD, Senior Pharmacy Benefit Consultant (PSG) | N/A |
| Approved | N/A | 5/15/2025 | Pharmacy & Therapeutics (P&T) Committee | 5/15/2025 |
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# Ilumya *(tildrakizumab)*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses (FDA approved indication)** | Ilumya is an interleukin-23 antagonist indicated for the treatment of adults with moderate-to-severe plaque psoriasis who are candidates for systemic therapy or phototherapy. |
| **Exclusion Criteria** | Must not be used in combination with other biologic drugs, Otezla, or Janus Kinase Inhibitor (JAKis). |
| **Required Medical Information** | Medical records supporting the request must be provided, including documentation of prior therapies and responses to treatment. |
| **Age Restriction** | None. |
| **Prescriber Restrictions** | Prescriber is a specialist or has consulted with a specialist for the condition being treated. |
| **Coverage Duration** | Two years. Dose will be approved according to the FDA approved labeling or within accepted standards of medical practice. |
| **Other Criteria/Information** | Refer to the Gold Coast Health Plan Medicare Part B Reference and Summary of Evidence document. |

| HCPCS | Description | Billing Units/How Supplied |
|---|---|---|
| J3245 | Ilumya (tildrakizumab) | **Billing unit: 1 mg**<br><br>100 mg SD syringe |

| STATUS | DATE REVISED | REVIEW DATE | APPROVED/REVIEWED BY | EFFECTIVE DATE |
|---|---|---|---|---|
| Created | 3/26/2025 | 3/26/2025 | Dawn Shojai, PharmD, Senior Pharmacy Benefit Consultant (PSG) | N/A |
| Approved | N/A | 5/15/2025 | Pharmacy & Therapeutics (P&T) Committee | 5/15/2025 |
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# IMAAVY™ *(nipocalimab-aahu)* injection, for IV use

<table>
<tr><th>PA Criteria</th><th>Criteria Details</th></tr>
<tr><td>Description</td><td>IMAAVY™ is a neonatal Fc receptor (FcRn) blocker; it is a human IgG1 monoclonal antibody that binds to FcRn resulting in the reduction of circulating IgG levels.</td></tr>
<tr><td>Covered Uses<br>(FDA approved indication)</td><td>IMAAVY is indicated for the treatment of generalized myasthenia gravis (gMG) in adults and pediatric patients ≥ 12 years of age who are anti-acetylcholine receptor (AChR) or anti-muscle-specific tyrosine kinase (MuSK) antibody positive.</td></tr>
<tr><td>Dosing and Administration</td><td>
<table>
<tr><th>Indication</th><th>Dosing Regimen</th><th>Maximum Dose</th></tr>
<tr><td>Generalized Myasthenia Gravis (gMG)</td><td>Initial Dose: 30 mg/kg IV infusion over 30 min<br><br>Maintenance Dose: 15 mg/kg IV infusion over minimum 15 min; administered two weeks after initial dose; continue every two weeks thereafter.</td><td>Initial Dose: 30 mg/kg<br><br>Maintenance: 15 mg/kg</td></tr>
</table>
</td></tr>
<tr><td>Billing and Coding Information</td><td>
<table>
<tr><th>10-digit NDC</th><th>11-digit NDC</th></tr>
<tr><td>57894-801-01</td><td>57894-0801-01</td></tr>
</table>
<table>
<tr><th>HCPCS Code</th><th>Description</th></tr>
<tr><td>C9399</td><td>Unclassified drugs or biologicals</td></tr>
<tr><td>J3490</td><td>Unclassified drugs</td></tr>
<tr><td>J3590</td><td>Unclassified biologics</td></tr>
</table>
<table>
<tr><th>CPT Procedural Codes</th><th>Description</th></tr>
<tr><td>96365</td><td>IV infusion, for therapy, prophylaxis, or diagnosis; initial, up to one hour</td></tr>
<tr><td>96413</td><td>Chemotherapy administration, IV infusion; up to one hour</td></tr>
</table>
NOTE: an infusion of 15 minutes or less is considered an IV push.
</td></tr>
<tr><td>Product Availability</td><td>Single-dose vial: 1200 mg/6.5 mL (185 mg/mL)<br><br>**300 mg/1.62 mL vial anticipated to be commercially available in 2026**</td></tr>
<tr><td>Contraindications</td><td>Patients with a history of serious hypersensitivity reactions (including anaphylaxis and angioedema) to nipocalimab or any of the excipients in IMAAVY™.</td></tr>
</table>

| | |
|---|---|
| **Recommended Medical Monitoring** | IMAAVY has been associated with:<br>• Infections<br>• Hypersensitivity reactions (angioedema, anaphylaxis, rash, urticaria, and eczema)<br>• Infusion-related reactions<br><br>Patients should be monitored for any of these reactions. IMAAVY dose may be delayed, reduced or permanently discontinued based on the severity of adverse reactions.<br><br>**Immunizations:**<br>• The safety of immunization with LIVE vaccines and the immune response to vaccination during treatment with IMAAVY are unknown.<br>• Because IMAAVY causes a reduction in IgG levels, vaccination with LIVE vaccines is not recommended during treatment with IMAAVY *(see Appendix)*.<br><br>**Drug-Drug Interactions:**<br>• Concomitant use with medications that bind to the human neonatal Fc receptor (FcRn) may lower systemic exposures and reduce effectiveness of said medications *(see Appendix)*.<br>• Closely monitor patients for reduced effectiveness of medications that bind to FcRn |
| **Approval Criteria** | a. Physician administered IV infusion; in-office or HOPD<br>i. Cannot be self-administered<br>b. Generalized Myasthenia Gravis **(must meet all)**:<br>i. Diagnosis of Generalized Myasthenia Gravis<br>1. Myasthenia Gravis Foundation of America classification of II – IV; **AND**<br>2. Myasthenia Gravis Activities of Daily Living (MG-ADL) score ≥ 6<br>ii. Prescribed by or in consultation with a neurologist<br>iii. Patient age ≥ 12 years of age<br>iv. Patient meets ONE of the following:<br>1. Confirmed anti-acetylcholine receptor antibody positive; **OR**<br>2. Confirmed anti-muscle-specific tyrosine kinase antibody positive<br>v. Patient on stable dose of standard of care gMG therapy (see Appendix)<br>vi. Patient has evidence of unresolved symptoms of gMG (see Appendix)<br>vii. Initial dose does not exceed 30 mg/kg as a single dose<br>viii. Maintenance dose does not exceed 15 mg/kg every two weeks |
| **Age Restriction** | Age ≥ 12 years. |
| **Coverage Duration** | Initial: six months. Reauthorization: 12 months.<br><br>Dose will be approved according to the FDA approved labeling or within accepted standards of medical practice. |

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TOTAL Care ADVANTAGE℠

**Appendix**

### Examples of drugs that bind to FcRn Receptors

a. Monoclonal Antibodies
b. Immunoglobulin products
c. Antibody derivatives containing the human Fc domain

- Abrocitinib
- Antithymocyte Globulin
- Baricitinib
- Brincidofovir
- Brivudine
- Certolizumab
- Delgocitinib
- Denosumab
- Deucravacitinib
- Etanercept
- Etrasimod
- Filgotinib
- Inebilizumab
- Infliximab
- Leflunomide
- Natalizumab
- Ocrelizumab
- Ofatumumab
- Omalizumab
- Pimecrolimus
- Ritlecitinib
- Tofacitinib
- Trastuzumab
- Ublituximab
- Upadacitinib

### Examples of standard of care treatments for gMG

a. Any combination of the following:
   i. Anticholinesterase
      - Pyridostigmine
      - Neostigmine
   ii. Corticosteroid
      - Prednisone
   iii. Immunosuppressant
      - Azathioprine
      - Cyclophosphamide
      - Cyclosporine
      - Eculizumab
      - Efgartigimod alfa
      - Methotrexate
      - Mycophenolate mofetil
      - Ravulizumab
      - Rituximab
      - Rozanolixizumab
      - Tacrolimus
      - Zulicoplan

### Examples of unresolved symptoms of gMG

a. Any functional disability resulting in discontinuation of physical activity
b. Changes in facial expressions
c. Decrease in respiratory function
d. Diplopia
e. Fatigue
f. Problems chewing
g. Problems swallowing
h. Problems talking
i. Ptosis
j. Trouble walking
k. Weakness in hands, fingers, feet, legs or neck

### List of Live Vaccinations

- Adenovirus vaccine
- Bacille Calmette-Guérin (BCG)
- Dengue tetravalent live vaccine
- Live attenuated influenza vaccine (intranasal)
- Live attenuated oral poliovirus vaccine
- Measles, mumps, and rubella vaccine
- Measles, mumps, rubella, and varicella vaccine
- Measles vaccine
- Mumps vaccine
- Oral typhoid vaccine
- Rotavirus vaccine (oral)
- Rubella vaccine
- Smallpox vaccine
- Varicella vaccine
- Yellow fever vaccine
- Zoster vaccine live

| STATUS | DATE REVISED | REVIEW DATE | APPROVED/REVIEWED BY | EFFECTIVE DATE |
|---|---|---|---|---|
| Created | 9/18/2025 | 9/18/2025 | Tamara Chinarian, PharmD, Clinical Pharmacist | N/A |
| Approved | N/A | 11/13/2025 | Pharmacy & Therapeutics (P&T) Committee | 11/13/2025 |
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# Infugem *(gemcitabine hcl)*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses (FDA approved indication)** | Infugem is a nucleoside metabolic inhibitor indicated for multiple cancers including:<br>a. in combination with carboplatin, for the treatment of advanced ovarian cancer that has relapsed at least 6 months after completion of platinum- based therapy,<br>b. in combination with paclitaxel, for first-line treatment of metastatic breast cancer after failure of prior anthracycline-containing adjuvant chemotherapy, unless anthracyclines were clinically contraindicated,<br>c. in combination with cisplatin for the treatment of non-small cell lung cancer, and<br>d. as a single agent for the treatment of pancreatic cancer. |
| **Exclusion Criteria** | None. |
| **Required Medical Information** | Medical records supporting the request must be provided, including documentation of prior therapies and responses to treatment. |
| **Other Criteria** | Must follow LCD (L37205) for Chemotherapy Drugs and their Adjuncts.<br>https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdId=37205&ver=15 |
| **Age Restriction** | None. |
| **Prescriber Restrictions** | None. |
| **Coverage Duration** | Up to one year. Dose will be approved according to the FDA approved labeling or within accepted standards of medical practice. |
| **Other Criteria/Information** | Refer to the Gold Coast Health Plan Medicare Part B Reference and Summary of Evidence document. |

| HCPCS | Description | Billing Units/How Supplied |
|---|---|---|
| J9198 | Infugem (gemcitabine HCl) | **Billing unit: 100 mg**<br><br>1200 mg/120 mL, 1300 mg/130 mL, 1400 mg/140 mL, 1500 mg/150 mL, 1600 mg/160 mL, 1700 mg/170 mL, 1800 mg/180 mL, 1900 mg/190 mL, 2000 mg/200 mL, 2200 mg/220 mL single dose infusion bag |

| STATUS | DATE REVISED | REVIEW DATE | APPROVED/REVIEWED BY | EFFECTIVE DATE |
|---|---|---|---|---|
| Created | 3/26/2025 | 3/26/2025 | Dawn Shojai, PharmD, Senior Pharmacy Benefit Consultant (PSG) | N/A |
| Approved | N/A | 5/15/2025 | Pharmacy & Therapeutics (P&T) Committee | 5/15/2025 |
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# Izervay *(avacincaptad pegol sodium/PF)*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses (FDA approved indication)** | Izervay is a complement inhibitor indicated for the treatment of geographic atrophy (GA) secondary to age-related macular degeneration (AMD). Currently, there are no compendia supported uses for this therapy outside the FDA-indication(s). |
| **Exclusion Criteria** | GA secondary to a condition other than AMD is not covered. Izervay must not be used in combination with Syfovre or any other medication for GA (Izervay has not been studied and there is no data to support use in combination with other medications used to treat GA). |
| **Required Medical Information** | Medical records supporting the request must be provided. For initial requests, must also have documentation confirming the diagnosis. |
| **Age Restriction** | None. |
| **Prescriber Restrictions** | Must be prescribed by or in consultation with an ophthalmologist. |
| **Coverage Duration** | Initial: one year. Reauthorization: two years. Dose will be approved according to the FDA- approved labeling or within accepted standards of medical practice.<br><br>For reauthorization: Documentation showing the patient had a measurable improvement or stabilization in the condition compared to pre-treatment baseline (such as GA lesion size reduction, improved visual acuity, or improved/stable disease as seen on fundus autofluorescence or OCT) must be provided. |
| **Other Criteria/Information** | Refer to the Gold Coast Health Plan Medicare Part B Reference and Summary of Evidence document. |

| HCPCS | Description | Billing Units/How Supplied |
|---|---|---|
| J2782 | Izervay (avacincaptad pegol) | **Billing unit: 0.1 mg**<br><br>2 mg/0.1 mL SDV |

| STATUS | DATE REVISED | REVIEW DATE | APPROVED/REVIEWED BY | EFFECTIVE DATE |
|---|---|---|---|---|
| Created | 3/26/2025 | 3/26/2025 | Dawn Shojai, PharmD, Senior Pharmacy Benefit Consultant (PSG) | N/A |
| Approved | N/A | 8/21/2025 | Pharmacy & Therapeutics (P&T) Committee | 8/21/2025 |
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# Kanjinti *(trastuzumab-anns)*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses (FDA approved indication)** | Kanjinti is a biosimilar to the reference product, Herceptin, indicated for the treatment of HER2-overexpressing adjuvant and metastatic breast cancer and HER2-overexpressing metastatic gastric or gastroesophageal junction adenocarcinoma. |
| **Exclusion Criteria** | None. |
| **Required Medical Information** | Medical records supporting the request must be provided, including documentation of prior therapies and responses to treatment. |
| **Other Criteria** | Must follow LCD L37205: Chemotherapy Drugs and their Adjuncts. https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdId=37205&ver=15 |
| **Age Restriction** | None. |
| **Prescriber Restrictions** | None. |
| **Coverage Duration** | One year. Dose will be approved according to the FDA-approved labeling or within accepted standards of medical practice. |
| **Other Criteria/Information** | Refer to the Gold Coast Health Plan Medicare Part B Reference and Summary of Evidence document. |

| HCPCS | Description | Billing Units/How Supplied |
|---|---|---|
| Q5117 | Kanjinti (trastuzumab-anns) biosimilar | **Billing unit: 10 mg**<br><br>150 mg, 420 mg SDV |

| STATUS | DATE REVISED | REVIEW DATE | APPROVED/REVIEWED BY | EFFECTIVE DATE |
|---|---|---|---|---|
| Created | 3/26/2025 | 3/26/2025 | Dawn Shojai, PharmD, Senior Pharmacy Benefit Consultant (PSG) | N/A |
| Approved | N/A | 5/15/2025 | Pharmacy & Therapeutics (P&T) Committee | 5/15/2025 |
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GOLD COAST HEALTH PLAN TOTAL Care ADVANTAGE℠

TOTAL CARE ADVANTAGE PART B CLINICAL GUIDELINES

# KEBILIDI™ *(eladocagene exuparvovec-tneq)* susp, for intraputaminal infusion

| PA Criteria | Criteria Details |
|---|---|
| **Description** | KEBILIDI™ is an adeno-associated virus (AAV) vector-based gene therapy that expresses the human aromatic L-amino acid decarboxylase enzyme (AADC). |
| **Covered Uses (FDA approved indication)** | KEBILIDI is indicated for the treatment of adult and pediatric patients with aromatic L-amino acid decarboxylase (AADC) deficiency*.<br><br>**This indication is approved under accelerated approval based on change from baseline in gross motor milestone achievement at 48 weeks post-treatment. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial.* |
| **Dosing and Administration** | See table below |

| Indication | Dosing Regimen | Maximum Dose |
|---|---|---|
| AADC deficiency | Recommended dose: 1.8 x $10^{11}$ vector genomes (0.32 mL)<br><br>Medication is administered as a single-dose **intraputaminal** infusion.<br>• 1 dose = Four 0.08 mL infusions (0.45 x $10^{11}$ vg each)<br>» 2 infusions per putamen (anterior and posterior)<br>» Administer at rate of **0.003 mL/min** each<br>» Total 27 minutes per site<br>• Administered in a single stereotactic surgery using FDA approved cannula for intraparenchymal infusion<br><br>KEBILIDI is administered at designated treatment centers that specialize in pediatric neurosurgery.<br>• Texas Children's Hospital (Houston, TX)<br>• Boston Children's Hospital (Boston, MA) | 1.8 x $10^{11}$ vector genomes |

**Billing and Coding Information**

| 10-digit NDC | 11-digit NDC |
|---|---|
| Package (carton): 52856-601-01<br>Container (vial): 52855-601-11 | Package (carton): 52856-0601-01<br>Container (vial): 52855-0601-11 |

| HCPCS Code | Description |
|---|---|
| C9399 | Unclassified drugs or biologicals |
| J3590 | Unclassified biologics |

| CPT Procedural Codes | Description |
|---|---|
| 64999 | Unlisted procedure, nervous system |

| | |
|---|---|
| **Product Availability** | *Single-dose vial:* 2.8 x $10^{11}$ vg/0.5 mL vial - intraputaminal administration ONLY. |
| **Contraindications** | Patients who have NOT achieved skull maturity assessed by neuroimaging. |
| **Recommended Medical Monitoring** | KEBILIDI has been associated with:<br>• Dyskinesia<br>• Procedural complications<br>» Respiratory arrest<br>» Cardiac arrest<br>» CSF leak<br>» Intracranial bleeding<br>» Neuroinflammation<br>» Acute infarction<br>» Infection<br><br>There is currently NO clinical data from the use of KEBILIDI in pregnant women or during lactation. However, it is recommended to verify negative pregnancy status in females with reproductive potential prior to administering KEBILIDI. |
| **Approval Criteria** | a. Physician administered intraputaminal infusion via stereotactic surgery<br>b. AADC Deficiency **(must meet all)**:<br>i. Diagnosis of AADC deficiency by documentation of positive testing from **two of the following** core diagnostic tests:<br>1. CSF neurotransmitter metabolite panel<br>2. Single gene or genetic panel testing<br>3. Plasma enzyme assay<br>ii. Patient is experiencing persistent neurological defects secondary to AADC deficiency despite standard medical therapy (see Appendix)<br>iii. Prescribed by or in consultation with a neurologist and/or geneticist<br>iv. Age ≥ 16 months old<br>v. Documentation that patient has achieved skull maturity via neuroimaging<br>vi. Documentation of baseline laboratory tests demonstrating anti-AAV2 neutralizing antibody titer < 1200 fold or ELISA optical density (OD) > 1<br>vii. Dose does not exceed 1.8 x 1011 vector genomes (0.32 mL total volume) |
| **Age Restriction** | Age ≥ 16 months old – must confirm skull maturity (assessed via neuroimaging).<br><br>KEBILIDI has NOT been studied in patients < 16 months old or ≥ 65 years old. |
| **Coverage Duration** | Total approval duration: one-time approval ONLY **(maximum one dose per lifetime)**<br><br>Dose will be approved according to the FDA approved labeling or within accepted standards of medical practice. |

GOLD COAST HEALTH PLAN
TOTAL Care ADVANTAGE℠

**Appendix**

| Classic Clinical Symptoms of AADC Deficiency (per 2017 iNTD Guidelines) | Core Diagnostic Tools for Identifying AADC Deficiency (per 2017 iNTD Guidelines) |
|---|---|
| a. Movement disorders<br>• Hypotonia<br>• Dystonia<br>• Dyskinesia<br>• Tremor<br>• Myoclonus<br>• Oculogyric crisis<br>• Hypokinesia<br>b. Developmental Delay<br>• Delayed motor development<br>• Delayed speech development<br>• Delayed cognitive development<br>c. Tone Regulation<br>• Floppy infant syndrome<br>• Hypotonia<br>• Hypertonia<br>• Poor head control | There are three core diagnostic tools for identifying AADCD:<br>1. Low CSF level of 5-HIAA, HVA and MHPG with normal CSF pterins and increased levels of LDopa, 3-OMD and 5-HTP<br>2. Genetic diagnosis showing compound heterozygous or homozygous disease-causing variants in the DDC gene<br>3. Decreased AADC enzyme activity in plasma<br><br>To confirm diagnosis of AADC deficiency, genetic testing should be completed and two of the three core diagnostic tests should be POSITIVE.<br><br>If local resources allow, it is recommended to perform all three key diagnostic tests. |

**Core Recommendations for Treatment of AADC Deficiency (per 2017 iNTD Guidelines)**

The core recommendations for treatment of AADCD are below - In general, multiple drug classes will be needed:

- First line treatment with selective dopamine agonists, MAO-inhibitors, and pyridoxine.
- Additional symptomatic treatment agents with anticholinergic agents, melatonin, benzodiazepines, and alpha-adrenoreceptor blockers.

| STATUS | DATE REVISED | REVIEW DATE | APPROVED/REVIEWED BY | EFFECTIVE DATE |
|---|---|---|---|---|
| Created | 9/19/2025 | 9/19/2025 | Tamara Chinarian, PharmD, Clinical Pharmacist | N/A |
| Approved | N/A | 11/13/2025 | Pharmacy & Therapeutics (P&T) Committee | 11/13/2025 |
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# Kisunla *(donanemab-azbt)*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses (FDA approved indication)** | Kisunla is an amyloid beta-directed antibody indicated for the treatment of Alzheimer's disease. Treatment with Kisunla should be initiated in patients with mild cognitive impairment or mild dementia stage of disease, the population in which treatment was initiated in the clinical trials. |
| **Exclusion Criteria** | None. |
| **Required Medical Information** | Medical records supporting the request must be provided, including documentation of registry participation and follow-up. |
| **Other Criteria** | Must follow NCD: Monoclonal Antibodies Directed Against Amyloid for the Treatment of Alzheimer's Disease. https://www.cms.gov/medicare-coverage-database/view/ncacal-decision-memo.aspx?proposed=N&ncaid=305 |
| **Age Restriction** | None. |
| **Prescriber Restrictions** | None. |
| **Coverage Duration** | Six months initial and reauthorization. Dose will be approved according to the FDA- approved labeling or within accepted standards of medical practice.<br><br>Patient's physician must be participating in a registry (attestation required). |
| **Other Criteria/Information** | Refer to the Gold Coast Health Plan Medicare Part B Reference and Summary of Evidence document. |

| HCPCS | Description | Billing Units/How Supplied |
|---|---|---|
| J0175 | Kisunla (donanemab-azbt) | **Billing unit: 2 mg**<br><br>350 mg/20 mL SDV |

| STATUS | DATE REVISED | REVIEW DATE | APPROVED/REVIEWED BY | EFFECTIVE DATE |
|---|---|---|---|---|
| Created | 3/26/2025 | 3/26/2025 | Dawn Shojai, PharmD, Senior Pharmacy Benefit Consultant (PSG) | N/A |
| Approved | N/A | 5/15/2025 | Pharmacy & Therapeutics (P&T) Committee | 5/15/2025 |
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# Kymriah *(tisagenlecleucel)*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses (FDA approved indication)** | Kymriah is a CD19-directed genetically modified autologous T-cell immunotherapy indicated for the treatment of:<br>1. Patients up to 25 years of age with B-cell precursor acute lymphoblastic leukemia (ALL) that is refractory or in second or later relapse.<br>2. Adult patients with relapsed or refractory (r/r) large B-cell lymphoma after two or more lines of systemic therapy, including diffuse large B-cell lymphoma (DLBCL) not otherwise specified, high grade B-cell lymphoma and DLBCL arising from follicular lymphoma. |
| **Exclusion Criteria** | None. |
| **Required Medical Information** | Medical records supporting the request must be provided. |
| **Other Criteria** | Must follow NCD 110.24 for Chimeric Antigen Receptor (CAR) T-Cell Therapy. https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?ncdid=374 |
| **Age Restriction** | None. |
| **Prescriber Restrictions** | None. |
| **Coverage Duration** | In accordance with the FDA approved labeling or accepted standards of medical practice. |
| **Other Criteria/Information** | Refer to the Gold Coast Health Plan Medicare Part B Reference and Summary of Evidence document. |

| HCPCS | Description | Billing Units/How Supplied |
|---|---|---|
| Q2042 | Kymriah (tisagenlecleucel) | **Billing unit: per dose**<br><br>SD infusion bag |

| STATUS | DATE REVISED | REVIEW DATE | APPROVED/REVIEWED BY | EFFECTIVE DATE |
|---|---|---|---|---|
| Created | 3/26/2025 | 3/26/2025 | Dawn Shojai, PharmD, Senior Pharmacy Benefit Consultant (PSG) | N/A |
| Approved | N/A | 5/15/2025 | Pharmacy & Therapeutics (P&T) Committee | 5/15/2025 |
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# Lamzede *(velmanase alfa-tycv)*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses (FDA approved indication)** | Lamzede is indicated for the treatment of non-central nervous system manifestations of alpha-mannosidosis in adult and pediatric patients. |
| **Exclusion Criteria** | Lamzede is not covered for patients with CNS disease manifestations or rapidly progressive disease, patients who cannot walk without support, and/or patients with a history of a HSCT or bone marrow transplant. |
| **Required Medical Information** | Medical records supporting the request must be provided.<br>For alpha-mannosidosis, documentation of the diagnosis confirmed by one of the following must also be provided:<br>• biallelic pathogenic variants in MAN2B1 gene OR<br>• enzyme assay demonstrating alpha-mannosidase activity <10% of normal activity. |
| **Age Restriction** | None. |
| **Prescriber Restrictions** | Must be prescribed by or in consultation with a physician who specializes in the management of patients with alphamannosidosis, or in the administration of other enzyme replacement therapies for lysosomal storage disorders. |
| **Coverage Duration** | Initial coverage and reauthorization: one year. Dose will be approved according to the FDA approved labeling or within accepted standards of medical practice.<br><br>For reauthorization: Must have documentation of clinically significant improvement or stabilization in clinical signs and symptoms of disease (e.g. motor function, FVC, rate of infections, serum oligosaccharides, etc.) compared to the predicted natural history trajectory of disease; AND the patient continues to have an absence of exclusion criteria. |
| **Other Criteria/Information** | Refer to the Gold Coast Health Plan Medicare Part B Reference and Summary of Evidence document. |

| HCPCS | Description | Billing Units/How Supplied |
|---|---|---|
| J0217 | Lamzede (velmanase alfa) | **Billing unit: 1 mg**<br><br>10 mg SD Kit |

| STATUS | DATE REVISED | REVIEW DATE | APPROVED/REVIEWED BY | EFFECTIVE DATE |
|---|---|---|---|---|
| Created | 3/26/2025 | 3/26/2025 | Dawn Shojai, PharmD, Senior Pharmacy Benefit Consultant (PSG) | N/A |
| Approved | N/A | 5/15/2025 | Pharmacy & Therapeutics (P&T) Committee | 5/15/2025 |
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# Lantidra *(donislecel-jujn)*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses (FDA approved indication)** | Lantidra for hepatic portal vein infusion is an allogeneic pancreatic islet cellular therapy indicated for the treatment of adults with Type 1 diabetes who are unable to approach target HbA1c because of current repeated episodes of severe hypoglycemia despite intensive diabetes management and education. |
| **Exclusion Criteria** | None. |
| **Required Medical Information** | The following are required for approval:<br>1. Medical records supporting the request<br>2. Diagnosis of type 1 diabetes<br>3. Patient has had intensive insulin management that includes the appropriate use of a CGM (i.e., with insulin pump or with an automated insulin delivery system)<br>4. Patient has been unable to reach target HbA1c despite intensive diabetes education and insulin management due to current, repeated episodes of severe hypoglycemia defined by the ADA as Level 3 hypoglycemia (a severe event characterized by altered mental and/or physical functioning that requires assistance from another person for recovery, regardless of glucose level)<br>5. Lantidra must be taken with concomitant immunosuppressants<br>6. Approval of the patient's islet cell transplant must be on file prior to determination of Lantidra's use in any patient. |
| **Age Restriction** | Patient is at least 18 years of age. |
| **Prescriber Restrictions** | None. |
| **Coverage Duration** | Initial: one infusion. Reauthorization: up to two additional infusions.<br><br>For reauthorization: Patient has not achieved independence from exogenous insulin within one year of infusion - or - within one year after losing independence from exogenous insulin after a previous infusion. A third infusion may be performed using the same criteria as for the second infusion. There are no data regarding the effectiveness or safety for patients receiving more than three infusions. |
| **Other Criteria/Information** | Refer to the Gold Coast Health Plan Medicare Part B Reference and Summary of Evidence document. |

| HCPCS | Description | Billing Units/How Supplied |
|---|---|---|
| J3590*, C9399* | Lantidra (donislecel-jujn) | Additional information required: National Drug Code (NDC), Strength, Dosage administered, Route of administration.<br><br>400 mL infusion bag containing not more than 10 cc of estimated packed islet tissue and not more than 1 x 106 EIN |

| STATUS | DATE REVISED | REVIEW DATE | APPROVED/REVIEWED BY | EFFECTIVE DATE |
|---|---|---|---|---|
| Created | 3/26/2025 | 3/26/2025 | Dawn Shojai, PharmD, Senior Pharmacy Benefit Consultant (PSG) | N/A |
| Approved | N/A | 5/15/2025 | Pharmacy & Therapeutics (P&T) Committee | 5/15/2025 |
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# Leqembi *(lecanemab-irmb)*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses (FDA approved indication)** | Leqembi is indicated for the treatment of Alzheimer's disease (AD). Treatment with Leqembi should be initiated in patients with mild cognitive impairment (MCI) or mild dementia stage of disease, the population in which treatment was initiated in clinical trials. |
| **Exclusion Criteria** | None. |
| **Required Medical Information** | Medical records supporting the request must be provided, including documentation of registry participation and follow-up. |
| **Other Criteria** | Must follow National Coverage Determination (NCD) 200.3 for Monoclonal Antibodies Directed Against Amyloid for the Treatment of Alzheimer's Disease (AD).<br>https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?ncdid=375&ncdver=1 |
| **Age Restriction** | None. |
| **Prescriber Restrictions** | None. |
| **Coverage Duration** | Six months initial and reauthorization. Dose will be approved according to the FDA-approved labeling or within accepted standards of medical practice.<br><br>Patient's physician must be participating in a registry (attestation required). |
| **Other Criteria/Information** | Refer to the Gold Coast Health Plan Medicare Part B Reference and Summary of Evidence document. |

| HCPCS | Description | Billing Units/How Supplied |
|---|---|---|
| J0174 | Leqembi (lecanemab-irmb) 1 mg injection | **Billing unit: 1 mg**<br><br>200 mg/2 ml SDV<br>500 mg/5 ml SDV |

| STATUS | DATE REVISED | REVIEW DATE | APPROVED/REVIEWED BY | EFFECTIVE DATE |
|---|---|---|---|---|
| Created | 3/26/2025 | 3/26/2025 | Dawn Shojai, PharmD, Senior Pharmacy Benefit Consultant (PSG) | N/A |
| Approved | N/A | 5/15/2025 | Pharmacy & Therapeutics (P&T) Committee | 5/15/2025 |
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# Leqvio *(inclisiran)*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses (FDA approved indication)** | Leqvio is a small interfering RNA (siRNA) directed to PCSK9 (proprotein convertase subtilisin kexin type 9) mRNA indicated as an adjunct to diet and maximally tolerated statin therapy for the treatment of adults with heterozygous familial hypercholesterolemia (HeFH) or clinical atherosclerotic cardiovascular disease (ASCVD), who require additional lowering of low density lipoprotein cholesterol (LDL-C). |
| **Exclusion Criteria** | Must not be used in combination with a PCSK9 inhibitor (e.g., Repatha), Nexletol, or Nexlizet. |
| **Required Medical Information** | Must submit most recent LDL-C level. Medical records supporting the request must be provided. |
| **Age Restriction** | None. |
| **Prescriber Restrictions** | Must be prescribed by, or in consultation with, a cardiologist, endocrinologist, or board- certified lipidologist. |
| **Coverage Duration** | Initial Coverage: one year. Reauthorization: two years. Dose will be approved according to the FDA approved labeling or within accepted standards of medical practice. |
| **Other Criteria/Information** | Refer to the Gold Coast Health Plan Medicare Part B Reference and Summary of Evidence document. |

| HCPCS | Description | Billing Units/How Supplied |
|---|---|---|
| J1306 | Leqvio (inclisiran) | **Billing unit: 1 mg**<br><br>284 mg/1.5 mL prefilled syringe |

| STATUS | DATE REVISED | REVIEW DATE | APPROVED/REVIEWED BY | EFFECTIVE DATE |
|---|---|---|---|---|
| Created | 3/26/2025 | 3/26/2025 | Dawn Shojai, PharmD, Senior Pharmacy Benefit Consultant (PSG) | N/A |
| Approved | N/A | 8/21/2025 | Pharmacy & Therapeutics (P&T) Committee | 8/21/2025 |
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# Lumizyme *(alglucosidase alfa)*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses (FDA approved indication)** | Lumizyme is a hydrolytic lysosomal glycogen-specific enzyme indicated for patients with Pompe disease [acid α-glucosidase (GAA) deficiency]. |
| **Exclusion Criteria** | Must not be used in combination with another ERT (e.g., Nexviazyme, Pombiliti). |
| **Required Medical Information** | Medical records supporting the request must be provided, including the following:<br>• Patient's current weight.<br>• For initial coverage: Confirmation of diagnosis by enzyme assay or genetic testing. |
| **Age Restriction** | None. |
| **Prescriber Restrictions** | Must be prescribed by or in consultation with a specialist for the condition (such as genetic and metabolic specialists, neurologist, cardiologist, pediatrician). |
| **Coverage Duration** | One year initial; two years reauthorization. Dose will be approved according to the FDA- approved labeling or within accepted standards of medical practice.<br><br>For reauthorization, must have documented response to therapy evidenced by improvement or stabilization in condition (such as improved or stable muscle strength, motor function, cardiac involvement, FVC, and/or 6MWT). |
| **Other Criteria/Information** | Refer to the Gold Coast Health Plan Medicare Part B Reference and Summary of Evidence document. |

| HCPCS | Description | Billing Units/How Supplied |
|---|---|---|
| J0221 | Lumizyme (alglucosidase alfa) | **Billing unit: 10 mg**<br><br>50 mg SDV |

| STATUS | DATE REVISED | REVIEW DATE | APPROVED/REVIEWED BY | EFFECTIVE DATE |
|---|---|---|---|---|
| Created | 3/26/2025 | 3/26/2025 | Dawn Shojai, PharmD, Senior Pharmacy Benefit Consultant (PSG) | N/A |
| Approved | N/A | 5/15/2025 | Pharmacy & Therapeutics (P&T) Committee | 5/15/2025 |
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# Lyfgenia *(lovotibeglogene autotemcel)*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses (FDA approved indication)** | Lyfgenia is an autologous hematopoietic stem cell-based gene therapy indicated for the treatment of patients 12 years of age or older with sickle cell disease and a history of vaso-occlusive events. |
| **Exclusion Criteria** | Lyfgenia is not covered in patients with prior HSCT or prior gene therapy. |
| **Required Medical Information** | Before the drug is covered, the patient must meet the following requirements:<br>1. Patient has a diagnosis of Sickle Cell Disease (SCD) with ßS/ßS, ßS/ß0, or ßS/ß+ genotype confirmed by genetic testing;<br>2. Patient has a history of at least four severe vaso-occlusive events within the previous two years;<br>3. Patient's current weight has been provided;<br>4. Patient has adequate organ function and is eligible for HSCT (stem cell transplant);<br>5. Patient does not have a contraindication to any product or procedure required for successful gene therapy treatment;<br>6. Patient has tried and failed hydroxyurea, or if not tolerated, at least one other SCD treatment such as Endari (L-Glutamine). |
| **Age Restriction** | Patient is at least 12 years of age. |
| **Prescriber Restrictions** | Must be prescribed by or in consultation with a hematologist or other clinically appropriate provider. |
| **Coverage Duration** | Six months authorization duration with a limit of one dose (treatment) per lifetime. |
| **Other Criteria/Information** | Refer to the Gold Coast Health Plan Medicare Part B Reference and Summary of Evidence document. |

| HCPCS | Description | Billing Units/How Supplied |
|---|---|---|
| J3394 | Lyfgenia (lovotibeglogene autotemcel) | **Billing unit: per therapy**<br><br>f 3 × $10^6$ CD34+ cells/kg of body weight, in one to four infusion bags. |

| STATUS | DATE REVISED | REVIEW DATE | APPROVED/REVIEWED BY | EFFECTIVE DATE |
|---|---|---|---|---|
| Created | 3/26/2025 | 3/26/2025 | Dawn Shojai, PharmD, Senior Pharmacy Benefit Consultant (PSG) | N/A |
| Approved | N/A | 5/15/2025 | Pharmacy & Therapeutics (P&T) Committee | 5/15/2025 |
| | | | | |
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# LYNOZYFIC™ *(linvoseltamab-gcpt)* injection, for IV use

<table>
<tr><th>PA Criteria</th><th>Criteria Details</th></tr>
<tr><td>Description</td><td>LYNOZYFIC™ is a bispecific B-cell maturation antigen (BCMA) directed CD3 T-cell engager.</td></tr>
<tr><td>Covered Uses<br>(FDA approved indication)</td><td>LYNOZYFIC is indicated for the treatment of adult patients with relapsed or refractory multiple myeloma who have received at least four prior lines of therapy, including a proteasome inhibitor, an immunomodulatory agent, and an anti CD38 monoclonal antibody* (see Appendix).<br><br>*This indication is approved under accelerated approval based on response rate and durability of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trial(s).</td></tr>
<tr><td>Dosing and Administration</td><td>
<table>
<tr><th>Indication</th><th>Dosing Regimen</th><th>Maximum Dose</th></tr>
<tr><td>Multiple Myeloma</td><td>The recommended dosage of LYNOZYFIC is:<ul><li>Step-up doses of 5 mg, 25 mg, and 200 mg, followed by 200 mg weekly for 10 doses, followed by 200 mg every two weeks.</li><li>In patients who have achieved and maintained VGPR or better at or after Week 24 and received at least 17 doses of 200 mg, decrease the dosing frequency to 200 mg every four weeks.</li><li>Patients must be hospitalized for 24 hours after administration of Day one and Day eight Step-Up doses.</li><li>Continue until disease progression or unacceptable toxicity.</li></ul></td><td>1.8 x $10^{11}$ vector genomes</td></tr>
</table>
<table>
<tr><th>Dosing Schedule</th><th>Day[a]</th><th>LYNOZYFIC Dose</th><th>Infusion Time</th></tr>
<tr><td rowspan="3">Step-Up Dosing</td><td>Day 1</td><td>5 mg</td><td rowspan="3">Four hours</td></tr>
<tr><td>Day 8</td><td>25 mg</td></tr>
<tr><td>Day 15</td><td>200 mg (1st treatment dose)</td></tr>
<tr><td>Weekly Dosing</td><td>Start one week from Day 15<br><br>Weekly from Weeks 4-13 for 10 treatment doses</td><td>200 mg</td><td>First weekly dose: one hour<br><br>Subsequent doses[b]: 30 min</td></tr>
<tr><td>Q2 weeks Dosing</td><td>Week 14 and q2 weeks thereafter</td><td>200 mg</td><td>30 min</td></tr>
<tr><td colspan="4">Patients who achieve and maintain VGPR or better at or after Week 24 AND receive at least 17 doses of 200 mg</td></tr>
<tr><td>Q4 weeks Dosing</td><td>Week 24 or after and q4 weeks thereafter</td><td>200 mg</td><td>30 min</td></tr>
</table>
[a] Weekly doses should be at least five days apart; q2 weeks dosing at least 10 days apart; q4 weeks dosing at least 24 days apart.<br>[b] For patients who experience CRS with a dose, duration of infusion should be maintained at the duration of the previously tolerated infusion.
</td></tr>
</table>

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**Recommended Premedications Prior to EACH dose of LYNOZYFIC:**

| Medication | Dose | PO or IV | Timing Prior to LYNOZYFIC infusion |
|---|---|---|---|
| Acetaminophen (or equivalent) | 650-1000 mg | PO | 30-60 min prior |
| Diphenhydramine (or equivalent) | 25 mg | PO/IV | 30-60 min prior |
| Dexamethasone (or equivalent) | 40 mg – Step-up Day 1, 8 and 15<br><br>IF no CRS and/or IRR with 40 mg after Day 15, decrease to 10 mg for all subsequent doses | IV | one-three hours prior |

Pre-treatment medications *may be discontinued* once a treatment dose of 200 mg is tolerated without CRS and/or IRR following pre-treatment with 10 mg dexamethasone (or equivalent), acetaminophen (or equivalent), and diphenhydramine (or equivalent) as described.

**Billing and Coding Information**

| | 10-digit NDC | 11-digit NDC |
|---|---|---|
| 5 mg/2.5 ML SDV | 61755-054-01 | 61755-0054-01 |
| 200 mg/10 mL SDV | 61755-056-01 | 61755-0056-01 |

| HCPCS Code | Description |
|---|---|
| C9399 | Unclassified drugs or biologicals |
| J9999 | Not otherwise classified, antineoplastic drug |

| CPT Procedural Codes | Description |
|---|---|
| 96413 | Chemotherapy IV infusion, up to one hour |
| 96415 | Chemotherapy IV infusion, additional hour* |

* Used as an add-on code for every hour of infusion that is more than 30 min past the initial one hour.

**Product Availability**

*Single-dose vial:* IV use only

- 5 mg/2.5 mL (2 mg/mL) SDV
- 200 mg/10 mL (20 mg/mL) SDV

**Contraindications**

None.

| | |
|---|---|
| **Recommended Medical Monitoring** | **BLACK BOX WARNING: Cytokine Release Syndrome (CRS) and Neurological Toxicities, including Immune Effector Cell-Associated Neurotoxicity Syndrome (ICANS)** – LYNOZYFIC is only available through **REMS** program.<br>• Due to the risk of CRS and neurologic toxicity, including ICANS, patients should be hospitalized for 24 hours after administration of Day one and Day eight Step-Up doses.<br><br>Further information about the **LYNOZYFIC REMS program** is available at www.lynozyficREMS.com or by telephone at 1-855-212-6391.<br><br>In addition to black box warnings, LYNOZYFIC has been associated with:<br>a. Infections, including serious or fatal<br>b. Neutropenia<br>c. Hepatotoxicity<br>d. Embryo-Fetal Toxicity<br><br>Patients should be monitored for any of these reactions. LYNOZYFIC dose may be delayed, reduced or permanently discontinued based on the severity of adverse reactions.<br><br>LYNOZYFIC can cause fetal harm when administered to a pregnant woman. Verify pregnancy status in females of reproductive potential prior to initiating LYNOZYFIC treatment. Female patients of reproductive potential should be advised to use effective contraception during treatment with Datroway and for **three months** after the last dose. |
| **Approval Criteria** | A. Physician administered IV infusion<br>i. Cannot be self-administered<br>B. Multiple Myeloma **(must meet all)**:<br>i. Diagnosis of relapsed or refractory multiple myeloma<br>ii. Prescribed by or in consultation with an oncologist<br>iii. Patient age ≥ 18 years<br>iv. Patient has ONE of the following:<br>1. Patient has measurable disease as evidenced by one of the following assessed within the last 28 days:<br>a. Serum M-protein ≥ 0.5 g/dL<br>b. Urine M-protein ≥ 200 mg/24 hr<br>c. Serum free light chain (FLC) assay: involved FLC level ≥ 10 mg/dL<br>2. Patient has progressive disease as defined by International Myeloma Working Group (IMWG) response criteria (see Appendix), assessed within 60 days following last dose of last anti-myeloma drug regimen received.<br>v. Member has documented intolerance to ≥ four prior lines of therapy (see Appendix for examples). Prior therapies must include **one of each** of the following:<br>1. *Proteasome Inhibitor* (e.g., bortezomib, Kyprolis, Ninlaro)<br>2. *Immunomodulatory Agent* (e.g., Revlimid, Pomalyst, Thalomid)<br>3. *Anti-CD38 monoclonal Antibody* (e.g., Darzalex, Sarclisa) |

| | |
|---|---|
| | vi. Member does not have known multiple myeloma brain lesions or meningeal involvement (these patients were excluded from the clinical trial)<br>vii. Request meets **one** of the following:<br>1. Dose does not exceed recommended dose for current week of therapy (see Dosing Schedule); **OR**<br>2. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (prescriber must submit supporting evidence) |
| **Age Restriction** | Adults ≥ 18 years old. |
| **Coverage Duration** | Initial: six months. Reauthorization: 12 months.<br><br>Dose will be approved according to the FDA approved labeling or within accepted standards of medical practice. |
| **Appendix** | **Examples of Prior Alternative Therapies for Multiple Myeloma**<br>• Bendamustine + Bortezomib + Dexamethasone<br>• Bendamustine + Revlimid + Dexamethasone<br>• Bortezomib + Cyclophosphamide + Dexamethasone<br>• Bortezomib + Dexamethasone<br>• Bortezomib + Doxorubicin (or liposomal doxorubicin) + dexamethasone<br>• Bortezomib + Revlimid + Dexamethasone<br>• Bortezomib + Thalomid + Dexamethasone<br>• Cyclophosphamide + Revlimid + Dexamethasone<br>• Darzalex (or Darzalex Faspro)<br>• Darzalex (or Darzalex Faspro) + Bortezomib + Dexamethasone<br>• Darzalex (or Darzalex Faspro) + Pomalidomide + Dexamethasone<br>• Darzalex (or Darzalex Faspro) + Revlimid + Dexamethasone<br>• Empliciti + Bortezomib + Dexamethasone<br>• Empliciti + Pomalidomide + Dexamethasone<br>• Empliciti + Revlimid + Dexamethasone<br>• Kyprolis + Cyclophosphamide + Dexamethasone<br>• Kyprolis + Dexamethasone<br>• Kyprolis + Revlimid + Dexamethasone<br>• Ninlaro + Pomalidomide + Dexamethasone<br>• Ninlaro + Revlimid + Dexamethasone<br>• Pomalidomide + Bortezomib + Dexamethasone<br>• Pomalidomide + Cyclophosphamide + Dexamethasone<br>• Pomalidomide + Dexamethasone<br>• Pomalidomide + Kyprolis + Dexamethasone<br>• Revlimid + Dexamethasone<br>• Revlimid + low-dose Dexamethasone<br>• Sarclisa + Pomalidomide + Dexamethasone<br>• VTD-PACE (Dexamethasone + Thalomid + Cisplatin + Doxorubicin + Cyclophosphamide + Etoposide + Bortezomib) |

| STATUS | DATE REVISED | REVIEW DATE | APPROVED/REVIEWED BY | EFFECTIVE DATE |
|---|---|---|---|---|
| Created | 9/19/2025 | 9/19/2025 | Tamara Chinarian, PharmD, Clinical Pharmacist | N/A |
| Approved | N/A | 11/13/2025 | Pharmacy & Therapeutics (P&T) Committee | 11/13/2025 |
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# Margenza *(margetuximab-cmkb)*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses (FDA approved indication)** | Margenza is a receptor antagonist that targets HER2 receptors on tumor cells that overexpress the protein, preventing further cell growth, ultimately leading to programmed cell death. |
| **Exclusion Criteria** | None. |
| **Required Medical Information** | Medical records supporting the request must be provided. |
| **Other Criteria** | Must follow LCD L37205: Chemotherapy Drugs and their Adjuncts. https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdId=37205&ver=15 |
| **Age Restriction** | None. |
| **Prescriber Restrictions** | None. |
| **Coverage Duration** | One year. Dose will be approved according to the FDA-approved labeling or within accepted standards of medical practice. |
| **Other Criteria/Information** | Refer to the Gold Coast Health Plan Medicare Part B Reference and Summary of Evidence document. |

| HCPCS | Description | Billing Units/How Supplied |
|---|---|---|
| J9353 | Margenza (margetuximab-cmkb) | **Billing unit: 5 mg**<br><br>250 mg/10 mL SDV |

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# Monovisc *(hyaluronan/ hyaluronic acid)*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses (FDA approved indication)** | Hyaluronic acid injections are indicated to treat osteoarthritis pain of the knee when conservative nonpharmacologic therapy and non-steroidal anti-inflammatory drugs (NSAIDs) or simple analgesics, such as acetaminophen, have failed. |
| **Exclusion Criteria** | None. |
| **Required Medical Information** | Medical records supporting the request must be provided, including documentation of prior therapies and responses to treatment. |
| **Other Criteria** | Must follow LCD L39529 (Intraarticular Knee Injections of Hyaluronan). https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdid=39529 |
| **Age Restriction** | None. |
| **Prescriber Restrictions** | None. |
| **Coverage Duration** | One treatment series every six months. Dose will be approved according to the FDA approved labeling or within accepted standards of medical practice. |
| **Other Criteria/Information** | Refer to the Gold Coast Health Plan Medicare Part B Reference and Summary of Evidence document. |

| HCPCS | Description | Billing Units/How Supplied |
|---|---|---|
| J7327 | Monovisc (hyaluronan/ hyaluronic acid) for intra-articular injection | **Billing unit: per dose**<br><br>88 mg/4 mL SD syringe |

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# Neupogen *(filgrastim)*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses (FDA approved indication)** | Colony-stimulating factors (CSFs) are hematopoietic growth factors that regulate the growth and differentiation of cells towards the myeloid and erythroid lineages. Myeloid growth factors (MGFs), such as granulocyte colony-stimulating factors (G-CSF), are primarily used to reduce the incidence of febrile neutropenia (FN) in patients with non-myeloid malignancies receiving myelosuppressive chemotherapy. |
| **Exclusion Criteria** | None. |
| **Required Medical Information** | Medical records supporting the request must be provided. |
| **Age Restriction** | None. |
| **Prescriber Restrictions** | None. |
| **Coverage Duration** | One year. Dose will be approved according to the FDA approved labeling or within accepted standards of medical practice. |
| **Other Criteria/Information** | Refer to the Gold Coast Health Plan Medicare Part B Reference and Summary of Evidence document. |

| HCPCS | Description | Billing Units/How Supplied |
|---|---|---|
| J1442 | Neupogen (filgrastim) | **Billing unit: 1 mcg**<br><br>300 mcg/0.5 mL, 300 mcg/1 mL, 480 mcg/0.8 mL, 480 mcg/1.6 mL SD vial/syringe |

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# Nexviazyme *(avalglucosidase alfangpt)*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses (FDA approved indication)** | Nexviazyme is a hydrolytic lysosomal glycogen-specific enzyme indicated for patients with Pompe disease [acid α-glucosidase (GAA) deficiency]. |
| **Exclusion Criteria** | Must not be used in combination with another ERT (e.g., Lumizyme, Pombiliti). |
| **Required Medical Information** | Medical records supporting the request must be provided, including the following:<br>1. Patient's current weight.<br>2. For initial coverage: Confirmation of diagnosis by enzyme assay or genetic testing. |
| **Age Restriction** | None. |
| **Prescriber Restrictions** | Must be prescribed by or in consultation with a specialist for the condition (such as genetic and metabolic specialists, neurologist, cardiologist, pediatrician). |
| **Coverage Duration** | One year initial; two years reauthorization. Dose will be approved according to the FDA- approved labeling or within accepted standards of medical practice.<br><br>For reauthorization, must have a documented response to therapy evidenced by improvement or stabilization in condition (such as improved or stable muscle strength, motor function, cardiac involvement, FVC, and/or 6MWT). |
| **Other Criteria/Information** | Refer to the Gold Coast Health Plan Medicare Part B Reference and Summary of Evidence document. |

| HCPCS | Description | Billing Units/How Supplied |
|---|---|---|
| J0219 | Nexviazyme (avalglucosidase alfa-ngpt) | **Billing unit: 4 mg**<br><br>100mg SDV |

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# Nucala *(mepolizumab)*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses (FDA approved indication)** | Nucala is an interleukin-5 (IL-5) antagonist indicated for several conditions including severe eosinophilic asthma, eosinophilic granulomatosis with polyangiitis (EGPA) and hypereosinophilic syndrome (HES). |
| **Exclusion Criteria** | Must not be used in combination with other biologic drugs. |
| **Required Medical Information** | **For initial coverage of severe eosinophilic asthma:**<br>1. Medical records supporting the request, including documentation of prior therapies and responses to treatment must be provided - AND -<br>2. Must have an elevated eosinophil level greater than or equal to 150 cells/mcL within six weeks (prior to the immediate start of treatment with Nucala) - OR - greater than or equal to 300 cells/mcL in the previous 12 months - AND -<br>3. Must try and fail 1 ICS/LABA inhaler drug in the past six months (fail is defined as an intolerance or inability to improve the condition on required therapy for at least four weeks).<br><br>**For reauthorization requests for severe eosinophilic asthma:**<br>1. Medical records supporting the request, including documentation of prior therapies and responses to treatment must be provided.<br>2. Must have clinical benefit (e.g., decrease in exacerbations, improvement in symptoms, decrease in oral steroid use).<br><br>**For initial coverage of Hypereosinophilic Syndrome (HES):**<br>1. Medical records supporting the request, including documentation of prior therapies and responses to treatment must be provided.<br>2. Must have a blood eosinophil count at least 1,000 cells/mcL.<br>3. Must have had HES for at least six months.<br>4. Must have had at least two flares of HES in the past year defined as symptoms requiring a steroid or increase in current steroid.<br>5. The provider attests that there is NO identifiable non-hematologic secondary cause of HES.<br>6. Must try and fail (defined as an inability to improve symptoms) a generic steroid- sparing drug (e.g., methotrexate, hydroxyurea).<br><br>**For reauthorization requests for Hypereosinophilic Syndrome (HES):**<br>1. Medical records supporting the request, including documentation of prior therapies and responses to treatment must be provided.<br>2. Must have clinical benefit (e.g., decrease in exacerbations, improvement in symptoms, decrease in steroid use). |
| **Age Restriction** | None. |
| **Prescriber Restrictions** | Prescriber is a specialist or has consulted with a specialist for the condition being treated. |
| **Coverage Duration** | Initial: one year; reauthorization: two years. Dose will be approved according to the FDA approved labeling or within accepted standards of medical practice. |

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|---|---|
| **Other Criteria/Information** | Refer to the Gold Coast Health Plan Medicare Part B Reference and Summary of Evidence document. |

| HCPCS | Description | Billing Units/How Supplied |
|---|---|---|
| J2182 | Nucala (mepolizumab) Vial | **Billing unit: 1 mg**<br><br>100mg SDV |

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# Nulojix *(belatacept)*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses (FDA approved indication)** | Nulojix is a selective T-cell co-stimulation blocker and is indicated for the prophylaxis of organ rejection in patient receiving kidney transplant, for patients who are Epstein-Barr virus (EBV) seropositive. |
| **Exclusion Criteria** | None. |
| **Required Medical Information** | Medical records supporting the request must be provided. |
| **Other Criteria** | Must follow LCD L33824 Immunosuppressive Drugs and LCA A52474 Immunosuppressive Drugs – Policy Article. https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdid=33824 |
| **Age Restriction** | None. |
| **Prescriber Restrictions** | None. |
| **Coverage Duration** | One year. Dose will be approved according to the FDA-approved labeling or within accepted standards of medical practice. |
| **Other Criteria/Information** | Refer to the Gold Coast Health Plan Medicare Part B Reference and Summary of Evidence document. |

| HCPCS | Description | Billing Units/How Supplied |
|---|---|---|
| J0485 | Nulojix (belatacept) | **Billing unit: 1 mg**<br><br>250mg SDV |

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# Nypozi *(filgrastim-txid)*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses (FDA approved indication)** | Colony-stimulating factors (CSFs) are hematopoietic growth factors that regulate the growth and differentiation of cells towards the myeloid and erythroid lineages. Myeloid growth factors (MGFs), such as granulocyte colony-stimulating factors (G-CSF), are primarily used to reduce the incidence of febrile neutropenia (FN) in patients with non-myeloid malignancies receiving myelosuppressive chemotherapy. |
| **Exclusion Criteria** | None. |
| **Required Medical Information** | Medical records supporting the request must be provided, including documentation of prior therapies and responses to treatment. |
| **Age Restriction** | None. |
| **Prescriber Restrictions** | None. |
| **Coverage Duration** | One year. Dose will be approved according to the FDA approved labeling or within accepted standards of medical practice. |
| **Other Criteria/Information** | Refer to the Gold Coast Health Plan Medicare Part B Reference and Summary of Evidence document. |

| HCPCS | Description | Billing Units/How Supplied |
|---|---|---|
| Q5148 | Nypozi (filgrastim-txid) biosimilar | **Billing unit: 1 mcg**<br><br>300 mcg/0.5mL, 480 mcg/0.8 mL prefilled syringe |

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# Ohtuvayre *(ensifentrine)*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses (FDA approved indication)** | Ohtuvayre is a nebulized phosphodiesterase inhibitor (PDE3/PDE4) indicated for the maintenance treatment of Chronic Obstructive Pulmonary Disease (COPD). |
| **Exclusion Criteria** | Must not be used in combination with roflumilast. |
| **Required Medical Information** | Diagnosis and administration information will be reviewed to determine if coverage is available as a Medicare Part B or Part D benefit.<br><br>For initial requests, medical records supporting the request must be provided and include the following:<br>1. Diagnosis of moderate-to-severe COPD defined as an FEV1 between 30-70% .<br>2. Trial and failure of dual or triple therapy in the past six months that included a LABA/LAMA therapy (e.g., Trelegy Ellipta, Anoro Ellipta, Stiolto Respimat).<br><br>Failure is defined as no improvement, worsening of the condition, or an intolerance after trying the required therapy at the maximum dosages for at least 4 weeks consistently. |
| **Age Restriction** | Patient is at least 18 years of age. |
| **Prescriber Restrictions** | Prescriber is or has consulted a pulmonologist. |
| **Coverage Duration** | Initial: one year. Reauthorization: two years. Dose will be approved according to the FDA-approved labeling or within accepted standards of medical practice.<br><br>For reauthorization, documentation supporting a decrease in symptoms, improvement in lung function, and/or reduced COPD exacerbations with Ohtuvayre compared to baseline must be provided. |
| **Other Criteria/Information** | Refer to the Gold Coast Health Plan Medicare Part B Reference and Summary of Evidence document. |

| HCPCS | Description | Billing Units/How Supplied |
|---|---|---|
| J7601 | Ohtuvayre (ensifentrine) | **Billing unit: 3 mg**<br><br>3 mg/2.5mL ampule |

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# Omvoh *(mirikizumab-mrkz)*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses (FDA approved indication)** | Omvoh is an interleukin-23 antagonist indicated for the treatment of moderately to severely active ulcerative colitis in adults. The intravenous solution is only indicated for induction treatment. |
| **Exclusion Criteria** | Must not be used in combination with other biologic drugs, Otezla, or Janus Kinase Inhibitor (JAKis). |
| **Required Medical Information** | Medical records supporting the request must be provided, including documentation of prior therapies and responses to treatment. |
| **Age Restriction** | Patient is at least 18 years of age. |
| **Prescriber Restrictions** | Prescriber is a specialist or has consulted with a specialist for the condition being treated. |
| **Coverage Duration** | Three induction doses (week zero, week four and week eight) will be covered. Doses are approved according to the FDA-approved labeling or within accepted standards of medical practice. |
| **Other Criteria/Information** | Refer to the Gold Coast Health Plan Medicare Part B Reference and Summary of Evidence document. |

| HCPCS | Description | Billing Units/How Supplied |
|---|---|---|
| J2267 | Omvoh (mirikizumab-mrkz) | **Billing unit: 1 mg**<br><br>300 mg/15 mL SDV |

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# Onpattro *(patisiran)*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses (FDA approved indication)** | Onpattro lipid complex injection contains a transthyretin-directed small interfering RNA and is indicated for the treatment of the polyneuropathy of hereditary transthyretin- mediated (hATTR) amyloidosis. |
| **Exclusion Criteria** | Must not be used in combination with TTR stabilizers (e.g., tafamidis) or TTR-lowering agents (e.g., Amvuttra) – and – Patient must not have had a liver transplant. |
| **Required Medical Information** | 1. Medical records supporting the request must be provided.<br>2. Must provide patient's current weight.<br>3. Must have documentation of a transthyretin (TTR) mutation (e.g., V30M).<br>4. Must have documentation of a baseline polyneuropathy disability (PND) score less than or equal to IIIb and/or baseline FAP Stage 1 or 2.<br>5. Must have documentation of clinical signs and symptoms of the condition (e.g., motor disability, peripheral/autonomic neuropathy, etc.). |
| **Age Restriction** | Must be at least 18 years of age. |
| **Prescriber Restrictions** | None. |
| **Coverage Duration** | One year initial and reauthorization. Dose will be approved according to the FDA-approved labeling or within accepted standards of medical practice.<br><br>**For reauthorization:** Must have a positive clinical response to Onpattro compared to baseline (e.g., improved neuropathy symptoms, motor function, quality of life; slowing of disease progression). |
| **Other Criteria/Information** | Refer to the Gold Coast Health Plan Medicare Part B Reference and Summary of Evidence document. |

| HCPCS | Description | Billing Units/How Supplied |
|---|---|---|
| J0222 | Onpattro (patisiran) | **Billing unit: 0.1 mg**<br><br>10 mg/5 mL SDV |

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# Ontruzant *(trastuzumab-dttb)*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses (FDA approved indication)** | Ontruzant is a trastuzumab biosimilar.<br>Ontruzant is indicated for adjuvant treatment of HER2-overexpressing node-positive or node-negative (ER/PR-negative or with one high-risk feature) breast cancer:<br>• As part of a treatment regimen consisting of doxorubicin, cyclophosphamide, and either paclitaxel or docetaxel.<br>• As part of a treatment regimen with docetaxel and carboplatin.<br>• As a single agent following multi-modality anthracycline-based therapy. |
| **Exclusion Criteria** | None. |
| **Required Medical Information** | Medical records supporting the request must be provided, including documentation of prior therapies and responses to treatment. |
| **Other Criteria** | Must follow LCD L37205: Chemotherapy Drugs and their Adjuncts.<br>https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdId=37205&ver=15 |
| **Age Restriction** | None. |
| **Prescriber Restrictions** | None. |
| **Coverage Duration** | One year. Dose will be approved according to the FDA-approved labeling or within accepted standards of medical practice. |
| **Other Criteria/Information** | Refer to the Gold Coast Health Plan Medicare Part B Reference and Summary of Evidence document. |

| HCPCS | Description | Billing Units/How Supplied |
|---|---|---|
| Q5112 | Ontruzant (trastuzumab-dttb) biosimilar | **Billing unit: 10 mg**<br><br>150 mg, 420 mg SDV |

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# Orencia IV *(abatacept)*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses (FDA approved indication)** | Orencia is a biologic disease-modifying agent that functions as a selective T-cell co- stimulation blocker indicated for several inflammatory conditions including psoriatic arthritis (PsA) and rheumatoid arthritis (RA). |
| **Exclusion Criteria** | Must not be used in combination with other biologic drugs, Otezla, or Janus Kinase Inhibitor (JAKis). |
| **Required Medical Information** | Medical records supporting the request must be provided, including documentation of prior therapies and responses to treatment. |
| **Age Restriction** | None. |
| **Prescriber Restrictions** | Prescriber is a specialist or has consulted with a specialist for the condition being treated. |
| **Coverage Duration** | Two years. Dose will be approved according to the FDA approved labeling or within accepted standards of medical practice. |
| **Other Criteria/Information** | Refer to the Gold Coast Health Plan Medicare Part B Reference and Summary of Evidence document. |

| HCPCS | Description | Billing Units/How Supplied |
|---|---|---|
| J0129 | Orencia IV (abatacept) Vial | **Billing unit: 10 mg**<br><br>250 mg SDV |

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# Orthovisc *(hyaluronan / hyaluronic acid)*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses (FDA approved indication)** | Hyaluronic acid injections are indicated to treat osteoarthritis pain of the knee when conservative nonpharmacologic therapy and non-steroidal anti-inflammatory drugs (NSAIDs) or simple analgesics, such as acetaminophen, have failed. |
| **Exclusion Criteria** | None. |
| **Required Medical Information** | Medical records supporting the request must be provided, including documentation of prior therapies and responses to treatment. |
| **Other Criteria** | Must follow LCD L39529 (Intraarticular Knee Injections of Hyaluronan). https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdid=39529 |
| **Age Restriction** | None. |
| **Prescriber Restrictions** | None. |
| **Coverage Duration** | One treatment series every six months. Dose will be approved according to the FDA approved labeling or within accepted standards of medical practice. |
| **Other Criteria/Information** | Refer to the Gold Coast Health Plan Medicare Part B Reference and Summary of Evidence document. |

| HCPCS | Description | Billing Units/How Supplied |
|---|---|---|
| J7324 | Orthovisc (hyaluronan/ hyaluronic acid) for intra-articular injection | **Billing unit: per dose**<br><br>30 mg/2 mL SD syringe |

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# Oxlumo *(lumasiran)*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses (FDA approved indication)** | Oxlumo is a HAO1-directed small interfering ribonucleic acid (siRNA) indicated for the treatment of primary hyperoxaluria type 1 (PH1) to lower urinary and plasma oxalate levels in pediatric and adult patients. |
| **Exclusion Criteria** | Coverage will not be provided in the following situations: (1) Patient has a history of kidney or liver transplant; AND (2) Patient will be using in combination with Rivfloza. |
| **Required Medical Information** | 1. Medical records supporting the request must be provided;<br>2. Must have a diagnosis of primary hyperoxaluria type 1 (PH1) confirmed by genetic testing of the AGXT mutation or by liver enzyme analysis;<br>3. For reauthorization requests, must have documented clinical benefit with Oxlumo compared to baseline. |
| **Age Restriction** | None. |
| **Prescriber Restrictions** | Prescribed by or in consultation with a nephrologist or urologist. |
| **Coverage Duration** | Initial: one year. Reauthorization: two years. Dose will be approved according to the FDA-approved labeling or within accepted standards of medical practice. |
| **Other Criteria/Information** | Refer to the Gold Coast Health Plan Medicare Part B Reference and Summary of Evidence document. |

| HCPCS | Description | Billing Units/How Supplied |
|---|---|---|
| J0224 | Oxlumo (lumasiran) | **Billing unit: 0.5 mg**<br><br>94.5 mg/0.5 mL SDV |

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# Ozurdex *(dexamethasone, intravitreal implant)*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses (FDA approved indication)** | Ozurdex is indicated for: the treatment of macular edema following branch retinal vein occlusion (BRVO) or central retinal vein occlusion (CRVO); The treatment of non-infectious uveitis affecting the posterior segment of the eye; and The treatment of diabetic macular edema in patients who are pseudophakic or are phakic and scheduled for cataract surgery. |
| **Exclusion Criteria** | None. |
| **Required Medical Information** | Medical records supporting the request must be provided. |
| **Age Restriction** | None. |
| **Prescriber Restrictions** | None. |
| **Coverage Duration** | In accordance with the FDA-approved labeling or accepted standards of medical practice. |
| **Other Criteria/Information** | Refer to the Gold Coast Health Plan Medicare Part B Reference and Summary of Evidence document. |

| HCPCS | Description | Billing Units/How Supplied |
|---|---|---|
| J7312 | Ozurdex (dexamethasone, intravitreal implant) | **Billing unit: 0.1 mg**<br><br>0.7 mg implant |

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# Panzyga *(immune globulin)*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses (FDA approved indication)** | Intravenous immunoglobulin (IVIG) are human derived antibodies used to treat various autoimmune, infectious, and idiopathic diseases including, but not limited to: Chronic Inflammatory Demyelinating Polyneuropathy (CIDP), Chronic Lymphocytic Leukemia (CLL), multiple myeloma, myasthenia gravis, and Immune Thrombocytopenia (ITP). |
| **Exclusion Criteria** | None. |
| **Required Medical Information** | Medical records supporting the request must be provided, including documentation of prior therapies and responses to treatment. |
| **Other Criteria** | Must follow LCD L34771 for Immune Globulins.<br>https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdid=34771&ver=49&= |
| **Age Restriction** | None. |
| **Prescriber Restrictions** | None. |
| **Coverage Duration** | Two years. Dose will be approved according to the FDA-approved labeling or within accepted standards of medical practice. |
| **Other Criteria/Information** | Refer to the Gold Coast Health Plan Medicare Part B Reference and Summary of Evidence document. |

| HCPCS | Description | Billing Units/How Supplied |
|---|---|---|
| J1576 | Panzyga (immune globulin) intravenous | **Billing unit: 500 mg**<br><br>1 gm, 2.5 gm, 5 gm, 10 gm, 20 gm, 30 gm SDV |

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# Phesgo *(pertuzumab, trastuzumab, and hyaluronidase-zzxf)*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses (FDA approved indication)** | Phesgo is a combination of pertuzumab and trastuzumab, HER2/neu receptor antagonists, and hyaluronidase, an endoglycosidase, indicated for:<br>Use in combination with chemotherapy as: 1) neoadjuvant treatment of patients with HER2-positive, locally advanced, inflammatory, or early-stage breast cancer (either greater than 2 cm in diameter or node positive) as part of a complete treatment regimen for early breast cancer. 2) adjuvant treatment of patients with HER2-positive early breast cancer at high risk of recurrence.<br>Use in combination with docetaxel for treatment of patients with HER2- positive metastatic breast cancer (MBC) who have not received prior anti-HER2 therapy or chemotherapy for metastatic disease. |
| **Exclusion Criteria** | None. |
| **Required Medical Information** | Medical records supporting the request must be provided, including documentation of prior therapies and responses to treatment. |
| **Other Criteria** | Must follow LCD L37205: Chemotherapy Drugs and their Adjuncts.<br>https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdId=37205&ver=15 |
| **Age Restriction** | None. |
| **Prescriber Restrictions** | None. |
| **Coverage Duration** | One year. Dose will be approved according to the FDA-approved labeling or within accepted standards of medical practice. |
| **Other Criteria/Information** | Refer to the Gold Coast Health Plan Medicare Part B Reference and Summary of Evidence document. |

| HCPCS | Description | Billing Units/How Supplied |
|---|---|---|
| J9316 | Phesgo (pertuzumab, trastuzumab, and hyaluronidase-zzxf) | **Billing unit: 10 mg**<br><br>60 mg-60 mg-2000 unit/10 mL, 80 mg-40 mg-2000 unit/15 mL SDV |

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# PiaSky *(rovalimab-akkz)*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses (FDA approved indication)** | PiaSky is a complement C5 inhibitor indicated for the treatment of adult and pediatric patients 13 years and older with paroxysmal nocturnal hemoglobinuria (PNH) with a body weight of at least 40 kg. |
| **Exclusion Criteria** | Patient is not receiving PiaSky in combination with another complement inhibitor for the treatment of PNH (Empaveli, Soliris, Ultomiris, Fabhalta, Voydeya). |
| **Required Medical Information** | For initial coverage, medical records supporting the request must be provided and include the following:<br>1. Diagnosis confirmed by flow cytometry<br>2. Hemolysis-associated symptoms (thrombosis, organ dysfunction, pain, dyspnea, hemoglobin <10 g/dL etc.)<br>3. Patient's body weight is at least 40 kg. |
| **Age Restriction** | Must be at least 13 years of age. |
| **Prescriber Restrictions** | None. |
| **Coverage Duration** | **Initial:** One year. Reauthorization: two years. Dose will be approved according to the FDA-approved labeling or within accepted standards of medical practice.<br><br>**For reauthorization:** Must have documentation confirming a positive clinical response to PiaSky including a sustained increase in hemoglobin levels, improvement in hemolysis, or reduced transfusions compared to baseline. |
| **Other Criteria/Information** | Refer to the Gold Coast Health Plan Medicare Part B Reference and Summary of Evidence document. |

| HCPCS | Description | Billing Units/How Supplied |
|---|---|---|
| J1307 | PiaSky (crovalimab-akkz) | **Billing unit: 10 mg**<br><br>340mg/2mL SDV |

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# Pombiliti *(cipaglucosidase-alfa)*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses (FDA approved indication)** | Pombiliti is a hydrolytic lysosomal glycogen-specific enzyme indicated, in combination with Opfolda (an enzyme stabilizer) for the treatment of adult patients with late-onset Pompe disease (lysosomal acid alpha-glucosidase [GAA] deficiency) weighing ≥40 kg and who are not improving on their current enzyme replacement therapy (ERT). |
| **Exclusion Criteria** | Must not be used in combination with another ERT (such as Lumizyme or Nexviazyme). |
| **Required Medical Information** | Medical records supporting the request must be provided, including the following:<br>1. Patient's current weight.<br>2. For initial coverage: Confirmation of diagnosis by enzyme assay or genetic testing. |
| **Age Restriction** | Must be at least 13 years of age. |
| **Prescriber Restrictions** | Must be prescribed by or in consultation with a specialist for the condition (such as genetic and metabolic specialists, neurologist, cardiologist, pediatrician). |
| **Coverage Duration** | One year initial; two years reauthorization. Dose will be approved according to the FDA- approved labeling or within accepted standards of medical practice.<br><br>Must be used in combination with Opfolda. For reauthorization, must also have documented response to therapy evidenced by improvement or stabilization in the condition (such as improved or stable muscle strength, motor function, cardiac involvement, FVC, and/or 6MWT). |
| **Other Criteria/Information** | Refer to the Gold Coast Health Plan Medicare Part B Reference and Summary of Evidence document. |

| HCPCS | Description | Billing Units/How Supplied |
|---|---|---|
| J1203 | Pombiliti (cipaglucosidase-alfa) | **Billing unit: 5 mg**<br><br>105 mg SDV |

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# Prolia *(denosumab)*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses (FDA approved indication)** | Prolia is indicated for the treatment of postmenopausal women with osteoporosis at high risk for fracture, defined as a history of osteoporotic fracture, or multiple risk factors for fracture; or patients who have failed or are intolerant to other available osteoporosis therapy. |
| **Exclusion Criteria** | None. |
| **Required Medical Information** | Medical records supporting the request must be provided, including documentation of prior therapies and responses to treatment. |
| **Other Criteria** | Must follow LCD L34648 Bisphosphonate Drug Therapy<br>LCD - Bisphosphonate Drug Therapy (L34648) |
| **Age Restriction** | None. |
| **Prescriber Restrictions** | None. |
| **Coverage Duration** | Up to two years. Dose will be approved according to the FDA approved labeling or within accepted standards of medical practice. |
| **Other Criteria/Information** | Refer to the Gold Coast Health Plan Medicare Part B Reference and Summary of Evidence document. |

| HCPCS | Description | Billing Units/How Supplied |
|---|---|---|
| J0897 | Prolia (denosumab) | **Billing unit: 1 mg**<br><br>60 mg/mL SD syringe |

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# Qalsody *(tofersen)*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses (FDA approved indication)** | Qalsody is an antisense oligonucleotide indicated for the treatment of amyotrophic lateral sclerosis (ALS) in adults who have a mutation in the superoxide dismutase 1 (SOD1) gene. |
| **Exclusion Criteria** | None. |
| **Required Medical Information** | Medical records supporting the request must be provided including the following:<br>1. Documentation confirming the diagnosis;<br>2. Documentation confirming the superoxide dismutase 1 (SOD1) gene mutation;<br>3. Documentation of the patient's baseline neurofilament light chain (NfL) level |
| **Age Restriction** | Must be 18 years of age or older. |
| **Prescriber Restrictions** | Must be prescribed by a neurologist. |
| **Coverage Duration** | Initial and reauthorization: one year. Dose will be approved according to the FDA approved labeling or within accepted standards of medical practice.<br><br>For initial approval: Must have weakness associated with ALS, and Must have a vital capacity ≥50% (or ≥45% if the vital capacity has been stable defined as not declining more than 5% in the previous six months).<br><br>For reauthorization: Must have documentation of a decrease in plasma neurofilament light chains from baseline. |
| **Other Criteria/Information** | Refer to the Gold Coast Health Plan Medicare Part B Reference and Summary of Evidence document. |

| HCPCS | Description | Billing Units/How Supplied |
|---|---|---|
| J1304 | Qalsody (tofersen) | **Billing unit: 1 mg**<br><br>100 mg/15 mL (6.7 mg/mL) solution SDV |

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# Reblozyl *(luspatercept)*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses (FDA approved indication)** | Reblozyl is an erythroid maturation agent (EMA) indicated for the treatment of anemia in adults with beta thalassemia and myelodysplastic syndromes (MDS) who require red blood cell (RBC) infusions. |
| **Exclusion Criteria** | Must not be used in combination with imetelstat (Reblozyl has not been studied and there is no data to support use in combination with imetelstat [Rytelo]). |
| **Required Medical Information** | **For Beta Thalassemia initial coverage, documentation to support the following is required:**<br>1. Use of Reblozyl for the treatment of anemia in an adult with beta thalassemia who requires regular blood transfusions defined as at least six red blood cell (RBC) units in the previous 24 weeks (six months) prior to Reblozyl<br>2. The patient's current weight.<br><br>**For Myelodysplastic Syndrome initial coverage, documentation to support the following is also required:**<br>1. Use of Reblozyl for very low- to intermediate-risk myelodysplastic syndromes as defined by IPSS-R risk score<br>2. The patient's current weight<br>3. Use of Reblozyl follows current National Comprehensive Cancer Network (NCCN) Guidelines. |
| **Age Restriction** | Patient is at least 18 years of age. |
| **Prescriber Restrictions** | Must be prescribed by or in consultation with a hematologist or oncologist. |
| **Coverage Duration** | Initial and reauthorization: one year. Dose will be approved according to the FDA-approved labeling or within accepted standards of medical practice. |
| **Other Criteria/Information** | Refer to the Gold Coast Health Plan Medicare Part B Reference and Summary of Evidence document. |

| HCPCS | Description | Billing Units/How Supplied |
|---|---|---|
| J0896 | Reblozyl (luspatercept) | **Billing unit: 0.25 mg**<br><br>25 mg, 75 mg SDV |

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# Rebyota *(fecal microbiota live-jslm)*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses (FDA approved indication)** | Rebyota suspension is indicated for the prevention of recurrence of Clostridioides difficile infection (CDI) in individuals 18 years of age and older, following antibiotic treatment for recurrent CDI. Currently, there are no compendia supported uses for this therapy outside the FDA-indication(s). |
| **Exclusion Criteria** | None. |
| **Required Medical Information** | Medical records supporting the request, including documentation of prior therapies and responses to treatment must be provided. |
| **Age Restriction** | Must be 18 years of age or older. |
| **Prescriber Restrictions** | None. |
| **Coverage Duration** | One treatment course per FDA label and/or accepted standards of medical practice. |
| **Other Criteria/Information** | Refer to the Gold Coast Health Plan Medicare Part B Reference and Summary of Evidence document. |

| HCPCS | Description | Billing Units/How Supplied |
|---|---|---|
| J1440 | Rebyota (fecal microbiota live-jslm) | **Billing unit: 1 ml**<br><br>150ml Rectal Suspension |

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# Releuko *(filgrastim-ayow)*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses (FDA approved indication)** | Releuko is a biosimilar to Neupogen.<br>Colony-stimulating factors (CSFs) are hematopoietic growth factors that regulate the growth and differentiation of cells towards the myeloid and erythroid lineages. Myeloid growth factors (MGFs), such as granulocyte colony-stimulating factors (G-CSF), are primarily used to reduce the incidence of febrile neutropenia (FN) in patients with non-myeloid malignancies receiving myelosuppressive chemotherapy. |
| **Exclusion Criteria** | None. |
| **Required Medical Information** | Medical records supporting the request must be provided. |
| **Age Restriction** | None. |
| **Prescriber Restrictions** | None. |
| **Coverage Duration** | One year. Dose will be approved according to the FDA-approved labeling or within accepted standards of medical practice. |
| **Other Criteria/Information** | Refer to the Gold Coast Health Plan Medicare Part B Reference and Summary of Evidence document. |

| HCPCS | Description | Billing Units/How Supplied |
|---|---|---|
| Q5125 | Releuko (filgrastim-ayow) | **Billing unit: 0.1 mg**<br><br>300 mcg/mL SDV, 480 mcg/1.6 mL SDV, 300 mcg/0.5 mL PFS, and 480 mcg/0.8 mL PFS |

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# Remecade *(infliximab)*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses (FDA approved indication)** | Remicade is a tumor necrosis factor inhibitor (TNFi) indicated for several conditions including Crohn's Disease (CD), Ulcerative Colitis (UC), fistulizing CD, Rheumatoid Arthritis (RA), active ankylosing spondylitis (AS), psoriatic arthritis (PsA), and plaque psoriasis (PsO). |
| **Exclusion Criteria** | Must not be used in combination with other biologic drugs, Otezla, or Janus Kinase Inhibitor (JAKis). |
| **Required Medical Information** | Medical records supporting the request must be provided, including documentation of prior therapies and responses to treatment. |
| **Age Restriction** | None. |
| **Prescriber Restrictions** | Prescriber is a specialist or has consulted with a specialist for the condition being treated. |
| **Coverage Duration** | Two years. Dose will be approved according to the FDA approved labeling or within accepted standards of medical practice. |
| **Other Criteria/Information** | Refer to the Gold Coast Health Plan Medicare Part B Reference and Summary of Evidence document. |

| HCPCS | Description | Billing Units/How Supplied |
|---|---|---|
| J1745 | Remicade (infliximab)<br><br>Generic Infliximab - Janssen only | **Billing unit: 10 mg**<br><br>100 mg SDV |

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# Revcovi *(elapegademase-lvlr)*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses (FDA approved indication)** | Revcovi injection is a recombinant adenosine deaminase indicated for the treatment of adenosine deaminase severe combined immune deficiency (ADA-SCID) in pediatric and adult patients. |
| **Exclusion Criteria** | None. |
| **Required Medical Information** | Must provide the following: (1) Trough plasma ADA activity, (2) trough dAXP levels, (3) patient's current weight, (4) requested dose, and (5) medical records supporting the request. |
| **Other Criteria** | Provider attestation that treatment will follow FDA-approved labeling with dose adjusted to maintain trough ADA activity over 30 mmol/hr/L, trough dAXP level under 0.02 mmol/L, and/or to maintain adequate immune reconstitution based on clinical assessment of the patient. |
| **Age Restriction** | None. |
| **Prescriber Restrictions** | None. |
| **Coverage Duration** | Initial coverage: one year. Reauthorization: two years. |
| **Other Criteria/Information** | Refer to the Gold Coast Health Plan Medicare Part B Reference and Summary of Evidence document. |

| HCPCS | Description | Billing Units/How Supplied |
|---|---|---|
| J3590, C9399 | Revcovi (elapegademase-lvlr) | Additional information required: National Drug Code (NDC), Strength, Dosage administered, Route of administration.<br><br>2.4 mg/1.5 mL SDV |

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# Riabni *(rituximab-arrx)*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses (FDA approved indication)** | Riabni is a monoclonal antibody that induces apoptosis in DHL 4 human B cell lymphoma cells and inhibits rheumatoid factor production, antigen presentation, T-cell activation and proinflammatory cytokine production in rheumatoid arthritis.<br><br>Rituxan was the original rituximab product launched, but many biosimilars have since come to market including Riabni, Ruxience, Truxima, and Rituxan Hycela. |
| **Exclusion Criteria** | None. |
| **Required Medical Information** | Medical records supporting the request must be provided, including documentation of prior therapies and responses to treatment. |
| **Other Criteria** | Must follow LCD L35026: Rituximab.<br>https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?LCDId=35026 |
| **Age Restriction** | None. |
| **Prescriber Restrictions** | None. |
| **Coverage Duration** | Up to two years. Dose will be approved according to the FDA-approved labeling or within accepted standards of medical practice. |
| **Other Criteria/Information** | Refer to the Gold Coast Health Plan Medicare Part B Reference and Summary of Evidence document. |

| HCPCS | Description | Billing Units/How Supplied |
|---|---|---|
| Q5123 | Riabni (rituximab-arrx) biosimilar | **Billing unit: 10 mg**<br><br>100 mg/10 mL, 500 mg/50 mL SDV |

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# Rituxan *(rituximab)*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses (FDA approved indication)** | Rituxan is a monoclonal antibody that induces apoptosis in DHL 4 human B cell lymphoma cells and inhibits rheumatoid factor production, antigen presentation, T-cell activation and proinflammatory cytokine production in rheumatoid arthritis.<br><br>Rituxan was the original rituximab product launched, but many biosimilars have since come to market including Riabni, Ruxience, Truxima, and Rituxan Hycela. |
| **Exclusion Criteria** | None. |
| **Required Medical Information** | Medical records supporting the request must be provided, including documentation of prior therapies and responses to treatment. |
| **Other Criteria** | Must follow LCD L35026: Rituximab.<br>https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?LCDId=35026 |
| **Age Restriction** | None. |
| **Prescriber Restrictions** | None. |
| **Coverage Duration** | Up to two years. Dose will be approved according to the FDA-approved labeling or within accepted standards of medical practice. |
| **Other Criteria/Information** | Refer to the Gold Coast Health Plan Medicare Part B Reference and Summary of Evidence document. |

| HCPCS | Description | Billing Units/How Supplied |
|---|---|---|
| J9312 | Rituxan (rituximab) | **Billing unit: 10 mg**<br><br>100 mg/10 mL, 500 mg/50 mL SDV |

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# Rituxan Hycela *(rituximab / hyaluronidase)*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses (FDA approved indication)** | Rituxan Hycela is a monoclonal antibody that induces apoptosis in DHL 4 human B cell lymphoma cells and inhibits rheumatoid factor production, antigen presentation, T-cell activation and proinflammatory cytokine production in rheumatoid arthritis. Hyaluronidase is an enzyme that serves to promote rituximab delivery under the skin so that rituximab can be given subcutaneously (versus intravenously).<br><br>Rituxan was the original rituximab product launched, but many biosimilars have since come to market including Riabni, Ruxience, Truxima, and Rituxan Hycela. |
| **Exclusion Criteria** | None. |
| **Required Medical Information** | Medical records supporting the request must be provided, including documentation of prior therapies and responses to treatment. |
| **Other Criteria** | Must follow LCD L35026: Rituximab.<br>https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?LCDId=35026 |
| **Age Restriction** | None. |
| **Prescriber Restrictions** | None. |
| **Coverage Duration** | Up to two years. Dose will be approved according to the FDA-approved labeling or within accepted standards of medical practice. |
| **Other Criteria/Information** | Refer to the Gold Coast Health Plan Medicare Part B Reference and Summary of Evidence document. |

| HCPCS | Description | Billing Units/How Supplied |
|---|---|---|
| J9311 | Rituxan Hycela (rituximab / hyaluronidase) | **Billing unit: 10 mg**<br><br>1400 mg-23400 units/11.7 mL, 1600 mg-26800 units/13.4 mL SDV |

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# Rivfloza *(nedosiran)*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses (FDA approved indication)** | Rivfloza is an LDHA-directed small interfering RNA indicated to lower urinary oxalate levels in children 9 years of age and older and adults with primary hyperoxaluria type 1 (PH1) and relatively preserved kidney function, e.g., eGFR ≥30 mL/min/1.73 $m^2$. |
| **Exclusion Criteria** | Coverage will not be provided in the following situations: (1) Patient has a history of kidney or liver transplant; AND (2) Patient will be using in combination with Oxlumo. |
| **Required Medical Information** | 1. Medical records supporting the request must be provided;<br>2. Must have a diagnosis of primary hyperoxaluria type 1 (PH1) confirmed by genetic testing of the AGXT mutation or by liver enzyme analysis;<br>3. Must have preserved kidney function with an estimated glomerular filtrate rate (eGFR) of 30 mL/min/1.73$m^2$ or more;<br>4. For reauthorization requests, must have documented clinical benefit with Rivfloza compared to baseline. |
| **Age Restriction** | Patient is at least 9 years of age. |
| **Prescriber Restrictions** | Prescribed by or in consultation with a nephrologist or urologist. |
| **Coverage Duration** | Initial: one year. Reauthorization: two years. Dose will be approved according to the FDA-approved labeling or within accepted standards of medical practice. |
| **Other Criteria/Information** | Refer to the Gold Coast Health Plan Medicare Part B Reference and Summary of Evidence document. |

| HCPCS | Description | Billing Units/How Supplied |
|---|---|---|
| J3490*, C9399* | Rivfloza (nedosiran) | Additional information required: National Drug Code (NDC), Strength, Dosage administered, Route of administration.<br><br>128 mg/ 0.8 mL and 160 mg/mL prefilled syringe and 80 mg/0.5 mL SDV |

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# Roctavian *(valoctocogene roxaparvovec-rvox)*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses (FDA approved indication)** | Roctavian is an adeno-associated virus (AAV) vector-based gene therapy product indicated for the treatment of adults with severe hemophilia A without antibodies to adeno-associated virus serotype 5 (AAV5). |
| **Exclusion Criteria** | 1. Patient must not have any detectable antibodies to adeno-associated virus serotype 5 (AAV5)<br>– AND –<br>2. Patient must not have any FVIII inhibitors. |
| **Required Medical Information** | Medical records supporting the request must be provided and include documentation of the following:<br>1. Patient's current weight.<br>2. Confirmatory diagnosis of severe hemophilia A with a factor VIII activity level showing < 1 IU/dL. |
| **Age Restriction** | Must be 18 years of age or older. |
| **Prescriber Restrictions** | None. |
| **Coverage Duration** | One lifetime dose in accordance with the FDA-approved labeling or accepted standards of medical practice. |
| **Other Criteria/Information** | Refer to the Gold Coast Health Plan Medicare Part B Reference and Summary of Evidence document. |

| HCPCS | Description | Billing Units/How Supplied |
|---|---|---|
| J1412 | Roctavian (valoctocogene roxaparvovec-rvox) | **Billing unit: 1 mL**<br>$2 \times 10^{13}$ vector genomes/mL SD infusion bag |

| STATUS | DATE REVISED | REVIEW DATE | APPROVED/REVIEWED BY | EFFECTIVE DATE |
|---|---|---|---|---|
| Created | 3/26/2025 | 3/26/2025 | Dawn Shojai, PharmD, Senior Pharmacy Benefit Consultant (PSG) | N/A |
| Approved | N/A | 5/15/2025 | Pharmacy & Therapeutics (P&T) Committee | 5/15/2025 |
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# Rolvedon *(eflapegrastim-xnst)*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses (FDA approved indication)** | Rolvedon is indicated to decrease the incidence of infection, as manifested by febrile neutropenia, in adult patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs associated with clinically significant incidence of febrile neutropenia. |
| **Exclusion Criteria** | None. |
| **Required Medical Information** | Medical records supporting the request, including documentation of prior therapies and responses to treatment, must be provided. |
| **Age Restriction** | None. |
| **Prescriber Restrictions** | None. |
| **Coverage Duration** | One year. Dose will be approved according to the FDA approved labeling or within accepted standards of medical practice. |
| **Other Criteria/Information** | Refer to the Gold Coast Health Plan Medicare Part B Reference and Summary of Evidence document. |

| HCPCS | Description | Billing Units/How Supplied |
|---|---|---|
| J1449 | Rolvedon (eflapegrastim-xnst) | **Billing unit: 0.1 mg**<br><br>13.2 mg/0.6 mL prefilled syringe |

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| Created | 3/26/2025 | 3/26/2025 | Dawn Shojai, PharmD, Senior Pharmacy Benefit Consultant (PSG) | N/A |
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# Ryplazim *(plasminogen, human-tvmh)*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses (FDA approved indication)** | Ryplazim is plasma-derived human plasminogen indicated for the treatment of patients with plasminogen deficiency type 1 (hypoplasminogenemia), to be given 6.6 mg/kg body weight administered every two to four days. |
| **Exclusion Criteria** | None. |
| **Required Medical Information** | Must have documentation of a baseline plasminogen activity level ≤45% Patient's current weight. Genetic testing confirming diagnosis of PLGD type 1. |
| **Age Restriction** | None. |
| **Prescriber Restrictions** | Must be prescribed by or in consultation with a hematologist. |
| **Coverage Duration** | Initial: 12 weeks.<br>Reauthorization: 12 months.<br>Dose will be approved according to the FDA-approved labeling or within accepted standards of medical practice. |
| **Other Criteria/Information** | Refer to the Gold Coast Health Plan Medicare Part B Reference and Summary of Evidence document. |

| HCPCS | Description | Billing Units/How Supplied |
|---|---|---|
| J2998 | Ryplazim (plasminogen, human-tvmh) | **Billing unit: 1 mg**<br><br>68.8 mg/12.5 mL SDV |

| STATUS | DATE REVISED | REVIEW DATE | APPROVED/REVIEWED BY | EFFECTIVE DATE |
|---|---|---|---|---|
| Created | 3/26/2025 | 3/26/2025 | Dawn Shojai, PharmD, Senior Pharmacy Benefit Consultant (PSG) | N/A |
| Approved | N/A | 8/21/2025 | Pharmacy & Therapeutics (P&T) Committee | 8/21/2025 |
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# Rystiggo *(rozanolixizumab-noli)*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses (FDA approved indication)** | Rystiggo is a neonatal Fc receptor blocker indicated for the treatment of generalized myasthenia gravis (gMG) in adult patients who are anti-acetylcholine receptor (AChR-Ab+) or anti-muscle-specific tyrosine kinase (MuSK) antibody positive. |
| **Exclusion Criteria** | Must not be used in combination with similar therapies for myasthenia gravis including immune globulins, Soliris, Ultomiris, Vyvgart/Vygart Hytrulo, or Zilbrysq. (Rystiggo has not been studied and there is no data to support use in combination with other medications used to treat MG). |
| **Required Medical Information** | **For initial coverage, must have**:<br>1. Baseline Myasthenia Gravis Activities of Daily Living (MG-ADL) of at least three.<br>2. Confirmed generalized myasthenia gravis that is anti-acetylcholine receptor antibody (AChR-Ab) positive or anti-muscle-specific tyrosine kinase [MuSK] anti-body positive.<br><br>**For initial and reauthorization:** Medical records supporting the request must be provided. |
| **Age Restriction** | None. |
| **Prescriber Restrictions** | Must be prescribed by, or in consultation with, a neurologist. |
| **Coverage Duration** | One year initial; two years reauthorization. Dose will be approved according to the FDA-approved labeling or within accepted standards of medical practice.<br><br>**For Reauthorization:** Must have a documented response to therapy evidenced by a stable or improved MG-ADL total score from baseline. |
| **Other Criteria/Information** | Refer to the Gold Coast Health Plan Medicare Part B Reference and Summary of Evidence document. |

| HCPCS | Description | Billing Units/How Supplied |
|---|---|---|
| J9333 | Rystiggo (rozanolixizumab-noli) | **Billing unit: 1 mg**<br><br>280mg/2ml (140mg/ml) SDV |

| STATUS | DATE REVISED | REVIEW DATE | APPROVED/REVIEWED BY | EFFECTIVE DATE |
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# Saphnelo *(anifrolumab-fnia)*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses (FDA approved indication)** | Saphnelo is a type I interferon (IFN) receptor antagonist indicated for the treatment of adult patients with moderate to severe systemic lupus erythematosus (SLE), who are receiving standard therapy. |
| **Exclusion Criteria** | Must not be used with another biologic drug (e.g., Benlysta) or Lupkynis. |
| **Required Medical Information** | Medical records supporting the request must be provided.<br><br>**For systemic lupus erythematosus (SLE):**<br><br>1. Must have tried and failed (defined as an inability to taper the steroid dose and/or have frequent relapses) two of the following in combination: steroid, immunosuppressant, and/or hydroxychloroquine;<br>2. Must have tried and failed (defined above) Benlysta;<br>3. Must have a baseline SELENA-SLEDAI score of six or more; and<br>4. for reauthorization, must have documentation of clinical benefit compared to baseline. |
| **Age Restriction** | None. |
| **Prescriber Restrictions** | Must be prescribed by or in consultation with a rheumatologist. |
| **Coverage Duration** | One year initial; two years reauthorization. Dose will be approved according to the FDA-approved labeling or within accepted standards of medical practice. |
| **Other Criteria/Information** | Refer to the Gold Coast Health Plan Medicare Part B Reference and Summary of Evidence document. |

| HCPCS | Description | Billing Units/How Supplied |
|---|---|---|
| J0491 | Saphnelo (anifrolumab-fnia) | **Billing unit: 1 mg**<br><br>300mg/2ml |

| STATUS | DATE REVISED | REVIEW DATE | APPROVED/REVIEWED BY | EFFECTIVE DATE |
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# Signifor LAR *(pasireotide)*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses (FDA approved indication)** | Signifor LAR is a somatostatin analog indicated for the treatment of Acromegaly and Cushing's disease in adults for whom surgery has not worked well enough or who cannot have surgery. |
| **Exclusion Criteria** | None. |
| **Required Medical Information** | Medical records supporting the request must be provided. |
| **Age Restriction** | None. |
| **Prescriber Restrictions** | None. |
| **Coverage Duration** | Up to two years. Dose will be approved according to the FDA-approved labeling or within accepted standards of medical practice. |
| **Other Criteria/Information** | Refer to the Gold Coast Health Plan Medicare Part B Reference and Summary of Evidence document. |

| HCPCS | Description | Billing Units/How Supplied |
|---|---|---|
| J2502 | Signifor LAR (pasireotide) | **Billing unit: 1 mg**<br><br>10 mg, 20 mg, 30 mg, 40 mg, 60 mg SDV |

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|---|---|---|---|---|
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# Simponi Aria *(golimumab)* IV

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses (FDA approved indication)** | Simponi Aria is a tumor necrosis factor inhibitor (TNFi) indicated for several inflammatory conditions including Ulcerative Colitis (UC), Rheumatoid Arthritis (RA), ankylosing spondylitis (AS), and psoriatic arthritis (PsA). |
| **Exclusion Criteria** | Must not be used in combination with other biologic drugs, Otezla, or Janus Kinase Inhibitor (JAKis). |
| **Required Medical Information** | Medical records supporting the request must be provided, including documentation of prior therapies and responses to treatment. |
| **Age Restriction** | None. |
| **Prescriber Restrictions** | Prescriber is a specialist or has consulted with a specialist for the condition being treated. |
| **Coverage Duration** | Two years. Dose will be approved according to the FDA approved labeling or within accepted standards of medical practice. |
| **Other Criteria/Information** | Refer to the Gold Coast Health Plan Medicare Part B Reference and Summary of Evidence document. |

| HCPCS | Description | Billing Units/How Supplied |
|---|---|---|
| J1602 | Simponi Aria (golimumab) IV | **Billing unit: 1 mg**<br><br>50 mg/4 mL SDV |

| STATUS | DATE REVISED | REVIEW DATE | APPROVED/REVIEWED BY | EFFECTIVE DATE |
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# Skyrizi IV *(risankizumab-rzaa)*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses (FDA approved indication)** | Skyrizi is an IL-23 antagonist indicated for multiple inflammatory conditions including moderate to severe active Crohn's disease (CD) and moderate to severely active ulcerative colitis (UC). |
| **Exclusion Criteria** | Must not be used in combination with other biologic drugs, Otezla, or Janus Kinase Inhibitor (JAKis). |
| **Required Medical Information** | Medical records supporting the request must be provided, including documentation of prior therapies and responses to treatment. |
| **Age Restriction** | None. |
| **Prescriber Restrictions** | Prescriber is a specialist or has consulted with a specialist for the condition being treated. |
| **Coverage Duration** | Three IV induction will be approved. Subsequent maintenance doses must be approved under the pharmacy benefit. |
| **Other Criteria/Information** | Refer to the Gold Coast Health Plan Medicare Part B Reference and Summary of Evidence document. |

| HCPCS | Description | Billing Units/How Supplied |
|---|---|---|
| J2327 | Skyrizi IV (risankizumab-rzaa) 600mg/10ml vial | **Billing unit: 1 mg**<br><br>600mg/10 mL SDV |

| STATUS | DATE REVISED | REVIEW DATE | APPROVED/REVIEWED BY | EFFECTIVE DATE |
|---|---|---|---|---|
| Created | 3/26/2025 | 3/26/2025 | Dawn Shojai, PharmD, Senior Pharmacy Benefit Consultant (PSG) | N/A |
| Approved | N/A | 5/15/2025 | Pharmacy & Therapeutics (P&T) Committee | 5/15/2025 |
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# Soliris *(eculizumab)*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses (FDA approved indication)** | Soliris is a complement inhibitor indicated for the treatment of multiple indications involving the complement system including neuromyelitis optica spectrum disorder (NMOSD), generalized myasthenia gravis (gMG) in patients who are anti-acetylcholine receptor antibody positive (AChR-Ab+), atypical hemolytic uremic syndrome (aHUS), and paroxysmal nocturnal hemoglobinuria (PNH). |
| **Exclusion Criteria** | None. |
| **Required Medical Information** | Medical records supporting the request must be provided, including documentation of prior therapies and responses to treatment. |
| **Age Restriction** | None. |
| **Prescriber Restrictions** | For NMSOD and myasthenia gravis: Must be prescribed by or in consultation with a neurologist. |
| **Coverage Duration** | In accordance with the FDA-approved labeling or accepted standards of medical practice. |
| **Other Criteria/Information** | Refer to the Gold Coast Health Plan Medicare Part B Reference and Summary of Evidence document. |

| HCPCS | Description | Billing Units/How Supplied |
|---|---|---|
| J1300 | Soliris (eculizumab) | **Billing unit: 10 mg**<br><br>300 mg/30 mL SDV |

| STATUS | DATE REVISED | REVIEW DATE | APPROVED/REVIEWED BY | EFFECTIVE DATE |
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| Created | 3/26/2025 | 3/26/2025 | Dawn Shojai, PharmD, Senior Pharmacy Benefit Consultant (PSG) | N/A |
| Approved | N/A | 8/21/2025 | Pharmacy & Therapeutics (P&T) Committee | 8/21/2025 |
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# Spevigo (*spesolimab-sbzo)*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses (FDA approved indication)** | Spevigo is an interleukin-36 receptor antagonist indicated for the treatment of generalized pustular psoriasis (GPP) in adults and pediatric patients 12 years of age and older and weighing at least 40 kg. |
| **Exclusion Criteria** | Must not be used in combination with other biologic or targeted DMARDS or with Otezla. |
| **Required Medical Information** | **For GPP requests:**<br>Medical records supporting the request must be provided;<br>1. Patient has a diagnosis of generalized pustular psoriasis (GPP) confirmed by a skin biopsy, presence of systemic symptoms such as fever and fatigue, and relapsing episodes (history of GPP flares);<br>2. Patient is experiencing a GPP flare of moderate-to-severe intensity defined by all the following (a, b, c, and d):<br>a. a Generalized Pustular Psoriasis Physician Global Assessment (GPPPGA) total score of three or more;<br>b. New or worsening pustules;<br>c. a GPPPGA pustulation sub-score of two or more; and<br>d. 5% of more of body surface area (BSA) with erythema and pustules |
| **Age Restriction** | Must be age 12 or older. |
| **Prescriber Restrictions** | Prescriber is a specialist or has consulted with a specialist for the condition being treated. |
| **Coverage Duration** | Initial: 12 weeks. Dose will be approved according to the FDA approved labeling or within accepted standards of medical practice. |
| **Other Criteria/Information** | Refer to the Gold Coast Health Plan Medicare Part B Reference and Summary of Evidence document. |

| HCPCS | Description | Billing Units/How Supplied |
|---|---|---|
| J1747 | Spevigo (spesolimab-sbzo) | **Billing unit: 1 mg**<br><br>450 mg/7.5 ml SDV |

| STATUS | DATE REVISED | REVIEW DATE | APPROVED/REVIEWED BY | EFFECTIVE DATE |
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| Created | 3/26/2025 | 3/26/2025 | Dawn Shojai, PharmD, Senior Pharmacy Benefit Consultant (PSG) | N/A |
| Approved | N/A | 5/15/2025 | Pharmacy & Therapeutics (P&T) Committee | 5/15/2025 |
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# Spinraza *(nusinersen sodium)*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses (FDA approved indication)** | Spinraza intrathecal injection is a survival motor neuron-2 (SMN2)-directed antisense oligonucleotide indicated for the treatment of spinal muscular atrophy (SMA) in pediatric and adult patients. |
| **Exclusion Criteria** | None. |
| **Required Medical Information** | For initial requests: Confirmation of spinal muscular atrophy (SMA) by genetic testing. |
| **Age Restriction** | None. |
| **Prescriber Restrictions** | Must be prescribed by or in consultation with a neurologist. |
| **Coverage Duration** | Two years. Dose will be approved according to the FDA-approved labeling or within accepted standards of medical practice. |
| **Other Criteria/Information** | Refer to the Gold Coast Health Plan Medicare Part B Reference and Summary of Evidence document. |

| HCPCS | Description | Billing Units/How Supplied |
|---|---|---|
| J2326 | Spinraza (nusinersen sodium) | **Billing unit: 0.1 mg**<br><br>12 mg/5 mL SDV |

| STATUS | DATE REVISED | REVIEW DATE | APPROVED/REVIEWED BY | EFFECTIVE DATE |
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# Spravato *(esketamine)*

<table>
<tr><th>PA Criteria</th><th>Criteria Details</th></tr>
<tr><td>Covered Uses<br>(FDA approved indication)</td><td>Spravato is a non-competitive N-methyl D-aspartate (NMDA) receptor antagonist approved for its role in certain depression indications, including treatment-resistant depression and major depressive disorder with acute suicidal ideation.</td></tr>
<tr><td>Exclusion Criteria</td><td>None.</td></tr>
<tr><td>Required Medical Information</td><td>Medical records supporting the request must be provided;<br><br>Spravato must be used in combination with an oral antidepressant.</td></tr>
<tr><td>Age Restriction</td><td>Must be at least 18 years of age.</td></tr>
<tr><td>Prescriber Restrictions</td><td>Must be prescribed by or in consultation with a psychiatrist.</td></tr>
<tr><td>Coverage Duration</td><td>Six months. Dose will be approved according to the FDA- approved labeling or within accepted standards of medical practice.</td></tr>
<tr><td>Other Criteria/Information</td><td>Refer to the Gold Coast Health Plan Medicare Part B Reference and Summary of Evidence document.<br><br>
<table>
<tr><th>HCPCS</th><th>Description</th><th>Billing Units/How Supplied</th></tr>
<tr><td>G2082 - up to 56mg<br><br>G2083 - greater than 56mg</td><td>Spravato (esketamine)</td><td>Billing unit: 1 mg<br><br>56 mg, 84 mg nasal spray kit (each kit contains 28 mg unit dose)</td></tr>
</table>
</td></tr>
</table>

| STATUS | DATE REVISED | REVIEW DATE | APPROVED/REVIEWED BY | EFFECTIVE DATE |
|---|---|---|---|---|
| Created | 3/26/2025 | 3/26/2025 | Dawn Shojai, PharmD, Senior Pharmacy Benefit Consultant (PSG) | N/A |
| Approved | N/A | 5/15/2025 | Pharmacy & Therapeutics (P&T) Committee | 5/15/2025 |
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# Stelara *(ustekinumab)* IV

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses (FDA approved indication)** | Stelara is a monoclonal antibody that inhibits interleukin (IL)-12 and IL-23 and is an IL-17 receptor A antagonist indicated for several inflammatory conditions including Plaque Psoriasis (PsO), Psoriatic Arthritis (PsA), Ulcerative Colitis (UC) and Crohn's Disease (CD). |
| **Exclusion Criteria** | Must not be used in combination with other biologic drugs, Otezla, or Janus Kinase Inhibitor (JAKis). |
| **Required Medical Information** | Medical records supporting the request must be provided, including documentation of prior therapies and responses to treatment.<br><br>Patient's current weight must be provided. |
| **Age Restriction** | None. |
| **Prescriber Restrictions** | Prescriber is a specialist or has consulted with a specialist for the condition being treated. |
| **Coverage Duration** | One-time induction dose. Doses are approved according to the FDA-approved labeling or within accepted standards of medical practice. |
| **Other Criteria/Information** | Refer to the Gold Coast Health Plan Medicare Part B Reference and Summary of Evidence document. |

| HCPCS | Description | Billing Units/How Supplied |
|---|---|---|
| J3358 | Stelara IV (ustekinumab) 130mg/26ml vial | **Billing unit: 1 mg**<br><br>130 mg/26 mL SDV |

| STATUS | DATE REVISED | REVIEW DATE | APPROVED/REVIEWED BY | EFFECTIVE DATE |
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# Stimufend *(pegfilgrastim-fpgk)*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses (FDA approved indication)** | Stimufend is indicated to decrease the incidence of infection, as manifested by febrile neutropenia, in patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a clinically significant incidence of febrile neutropenia. |
| **Exclusion Criteria** | None. |
| **Required Medical Information** | Medical records supporting the request, including documentation of prior therapies and responses to treatment, must be provided. |
| **Age Restriction** | None. |
| **Prescriber Restrictions** | None. |
| **Coverage Duration** | One year. Dose will be approved according to the FDA approved labeling or within accepted standards of medical practice. |
| **Other Criteria/Information** | Refer to the Gold Coast Health Plan Medicare Part B Reference and Summary of Evidence document. |

| HCPCS | Description | Billing Units/How Supplied |
|---|---|---|
| Q5127 | Injection, pegfilgrastim-fpgk (stimufend), biosimilar, 0.5 mg | **Billing unit: 0.5 mg**<br><br>6 mg/0.6 mL prefilled syringe |

| STATUS | DATE REVISED | REVIEW DATE | APPROVED/REVIEWED BY | EFFECTIVE DATE |
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# Susvimo *(ranibizumab)*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses (FDA approved indication)** | Susvimo ocular implant, a vascular endothelial growth factor (VEGF) inhibitor, is indicated for the treatment of patients with neovascular (wet) age-related macular degeneration (AMD) who have previously responded to at least two intravitreal injections of a VEGF inhibitor. |
| **Exclusion Criteria** | None. |
| **Required Medical Information** | Baseline Best-Corrected Visual Acuity (BCVA) score must be provided Medical records supporting the request must be provided. |
| **Age Restriction** | None. |
| **Prescriber Restrictions** | Must be prescribed by or in consultation with an ophthalmologist. |
| **Coverage Duration** | Up to 2 years. Dose will be approved according to the FDA approved labeling or within accepted standards of medical practice. |
| **Other Criteria/Information** | Refer to the Gold Coast Health Plan Medicare Part B Reference and Summary of Evidence document. |

| HCPCS | Description | Billing Units/How Supplied |
|---|---|---|
| J2779 | Susvimo (ranibizumab) | **Billing unit: 0.1 mg**<br><br>10 mg/0.1mL SDV |

| STATUS | DATE REVISED | REVIEW DATE | APPROVED/REVIEWED BY | EFFECTIVE DATE |
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# Syfovre *(pegcetacoplan)*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses (FDA approved indication)** | Syfovre is a complement inhibitor indicated for the treatment of geographic atrophy (GA) secondary to age-related macular degeneration (AMD). Currently, there are no compendia supported uses for this therapy outside the FDA-indication(s). |
| **Exclusion Criteria** | GA (geographic atrophy) secondary to a condition other than AMD (age-related macular degeneration) is not covered. Must not be used in combination with Izervay or any other medication for GA (Syfovre has not been studied and there is no data to support use in combination with other medications used to treat GA). |
| **Required Medical Information** | Medical records supporting the request must be provided. For initial coverage, must also have documentation confirming the diagnosis. |
| **Age Restriction** | None. |
| **Prescriber Restrictions** | Must be prescribed by or in consultation with an ophthalmologist. |
| **Coverage Duration** | Initial: one year. Reauthorization: two years. Dosing is limited to a frequency of every 60 days.<br><br>For reauthorization: Documentation showing the patient has had measurable improvement or stabilization in the condition compared to pre-treatment baseline (such as GA lesion size reduction, improved visual acuity, or improved/stable disease as seen on fundus autofluorescence or OCT) must be provided. |
| **Other Criteria/Information** | Refer to the Gold Coast Health Plan Medicare Part B Reference and Summary of Evidence document. |

| HCPCS | Description | Billing Units/How Supplied |
|---|---|---|
| J2781 | Syfovre (pegcetacoplan) intravitreal injection | **Billing unit: 1 mg**<br><br>15mg/0.1mL SDV |

| STATUS | DATE REVISED | REVIEW DATE | APPROVED/REVIEWED BY | EFFECTIVE DATE |
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# Synojoynt *(hyaluronan or derivative )*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses (FDA approved indication)** | Hyaluronic acid injections are indicated to treat osteoarthritis pain of the knee when conservative nonpharmacologic therapy and non-steroidal anti-inflammatory drugs (NSAIDs) or simple analgesics, such as acetaminophen, have failed. |
| **Exclusion Criteria** | None. |
| **Required Medical Information** | Medical records supporting the request must be provided, including documentation of prior therapies and responses to treatment. |
| **Other Criteria** | Must follow LCD L39529 (Intraarticular Knee Injections of Hyaluronan). https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdid=39529 |
| **Age Restriction** | None. |
| **Prescriber Restrictions** | None. |
| **Coverage Duration** | One treatment series every six months. Dose will be approved according to the FDA approved labeling or within accepted standards of medical practice. |
| **Other Criteria/Information** | Refer to the Gold Coast Health Plan Medicare Part B Reference and Summary of Evidence document. |

| HCPCS | Description | Billing Units/How Supplied |
|---|---|---|
| J7331 | Synojoynt (hyaluronan or derivative for intra-articular injection) | **Billing unit: 1 mg**<br><br>20 mg/2 mL |

| STATUS | DATE REVISED | REVIEW DATE | APPROVED/REVIEWED BY | EFFECTIVE DATE |
|---|---|---|---|---|
| Created | 3/26/2025 | 3/26/2025 | Dawn Shojai, PharmD, Senior Pharmacy Benefit Consultant (PSG) | N/A |
| Approved | N/A | 5/15/2025 | Pharmacy & Therapeutics (P&T) Committee | 5/15/2025 |
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# Synvisc/Synvisc One *(hyaluronan / hyaluronic acid)*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses (FDA approved indication)** | Hyaluronic acid injections are indicated to treat osteoarthritis pain of the knee when conservative nonpharmacologic therapy and non-steroidal anti-inflammatory drugs (NSAIDs) or simple analgesics, such as acetaminophen, have failed. |
| **Exclusion Criteria** | None. |
| **Required Medical Information** | Medical records supporting the request must be provided, including documentation of prior therapies and responses to treatment. |
| **Other Criteria** | Must follow LCD L39529 (Intraarticular Knee Injections of Hyaluronan). https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdid=39529 |
| **Age Restriction** | None. |
| **Prescriber Restrictions** | None. |
| **Coverage Duration** | One treatment series every six months. Dose will be approved according to the FDA approved labeling or within accepted standards of medical practice. |
| **Other Criteria/Information** | Refer to the Gold Coast Health Plan Medicare Part B Reference and Summary of Evidence document. |

| HCPCS | Description | Billing Units/How Supplied |
|---|---|---|
| J7325 | Synvisc/Synvisc One (hyaluronan / hyaluronic acid) for intra-articular injection | **Billing unit: 1 mg**<br><br>16 mg/2 mL SD syringe (Synvisc); 48 mg/6 mL SD syringe (Synvisc-One) |

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# Tecartus *(brexucabtagene autoleucel)*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses (FDA approved indication)** | Tecartus is a CD19-directed genetically modified autologous T cell immunotherapy indicated for the treatment of adult patients with relapsed or refractory B-cell precursor acute lymphoblastic leukemia (ALL). |
| **Exclusion Criteria** | None. |
| **Required Medical Information** | Medical records supporting the request must be provided. |
| **Other Criteria** | Must follow NCD 110.24 for Chimeric Antigen Receptor (CAR) T-Cell Therapy. https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?ncdid=374 |
| **Age Restriction** | None. |
| **Prescriber Restrictions** | None. |
| **Coverage Duration** | In accordance with the FDA-approved labeling or accepted standards of medical practice. |
| **Other Criteria/Information** | Refer to the Gold Coast Health Plan Medicare Part B Reference and Summary of Evidence document. |

| HCPCS | Description | Billing Units/How Supplied |
|---|---|---|
| Q2053 | Tecartus (brexucabtagene autoleucel) | **Billing unit: per dose**<br><br>Up to $2x10^8$ CAR+ t cells per SD infusion bag |

| STATUS | DATE REVISED | REVIEW DATE | APPROVED/REVIEWED BY | EFFECTIVE DATE |
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| Approved | N/A | 5/15/2025 | Pharmacy & Therapeutics (P&T) Committee | 5/15/2025 |
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# Tepezza *(teprotumumab-trbw)*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses (FDA approved indication)** | Tepezza for injection is an insulin-like growth factor-1 receptor inhibitor indicated for the treatment of Thyroid Eye Disease (TED). |
| **Exclusion Criteria** | None. |
| **Required Medical Information** | Medical records supporting the request, including documentation of prior therapies and responses to treatment must be provided. |
| **Age Restriction** | None. |
| **Prescriber Restrictions** | None. |
| **Coverage Duration** | In accordance with the FDA-approved labeling or accepted standards of medical practice. |
| **Other Criteria/Information** | Refer to the Gold Coast Health Plan Medicare Part B Reference and Summary of Evidence document. |

| HCPCS | Description | Billing Units/How Supplied |
|---|---|---|
| J3241 | Tepezza (teprotumumab-trbw) | **Billing unit: 10 mg**<br><br>500 mg SDV |

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# Tezspire *(tezepelumab-ekko)*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses (FDA approved indication)** | Tezspire is a thymic stromal lymphopoietin (TSLP) blocker, human monoclonal antibody (IgG2λ), indicated for the add-on maintenance treatment of severe asthma. TSLP is a cytokine involved in the asthma immune response and is over-expressed in asthma patients. |
| **Exclusion Criteria** | Must not be used in combination with other biologic drugs. |
| **Required Medical Information** | Medical records supporting the request, including documentation of prior therapies and responses to treatment must be provided. |
| **Age Restriction** | None. |
| **Prescriber Restrictions** | Prescriber is a specialist or has consulted with a specialist for the condition being treated. |
| **Coverage Duration** | Initial: one year; reauthorization: two years. Dose will be approved according to the FDA approved labeling or within accepted standards of medical practice. |
| **Other Criteria/Information** | Refer to the Gold Coast Health Plan Medicare Part B Reference and Summary of Evidence document. |

| HCPCS | Description | Billing Units/How Supplied |
|---|---|---|
| J2356 | Tezspire (tezepelumab-ekko)<br>Pre-filled Autoinjector Pen | **Billing unit: 1 mg**<br><br>210 mg/1.91 mL Pen-injector |

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# Tofidence *(tocilizumab-bavi)*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses (FDA approved indication)** | Tofidence is a biosimilar to Actemra (tocilizumab). Tocilizumab is an interleukin-6 inhibitor (IL-6i) indicated for multiple inflammatory conditions. |
| **Exclusion Criteria** | Must not be used in combination with other biologic drugs, Otezla, or Janus Kinase Inhibitor (JAKis). |
| **Required Medical Information** | Medical records supporting the request must be provided, including documentation of prior therapies and responses to treatment. |
| **Age Restriction** | None. |
| **Prescriber Restrictions** | Prescriber is a specialist or has consulted with a specialist for the condition being treated. |
| **Coverage Duration** | Up to two years. Dose will be approved according to the FDA approved labeling or within accepted standards of medical practice. |
| **Other Criteria/Information** | Refer to the Gold Coast Health Plan Medicare Part B Reference and Summary of Evidence document. |

| HCPCS | Description | Billing Units/How Supplied |
|---|---|---|
| Q5133 | Tofidence (tocilizumab-bavi) biosimilar | **Billing unit: 1 mg**<br><br>80 mg/4 mL, 200 mg/10 mL, 400 mg/20 mL SDV |

| STATUS | DATE REVISED | REVIEW DATE | APPROVED/REVIEWED BY | EFFECTIVE DATE |
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# Tremfya *(guselkumab)* IV

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses (FDA approved indication)** | Tremfya is an interleukin-23 (IL-23) inhibitor and is available in both a subcutaneous (SC) injection and an intravenous (IV) infusion. The IV formulation is currently indicated for the induction phase of ulcerative colitis treatment in adults. The SC formulation is indicated in the maintenance phase of treatment in ulcerative colitis, as well as other inflammatory conditions such as psoriatic arthritis and plaque psoriasis. |
| **Exclusion Criteria** | Must not be used in combination with other biologic drugs, Otezla, or Janus Kinase Inhibitor (JAKis). |
| **Required Medical Information** | Medical records supporting the request must be provided, including documentation of prior therapies and responses to treatment. |
| **Age Restriction** | None. |
| **Prescriber Restrictions** | Prescriber is a specialist or has consulted with a specialist for the condition being treated. |
| **Coverage Duration** | Three IV induction doses will be approved in accordance with the FDA-approved labeling. Subsequent maintenance doses must be approved under the pharmacy benefit. |
| **Other Criteria/Information** | Refer to the Gold Coast Health Plan Medicare Part B Reference and Summary of Evidence document. |

| HCPCS | Description | Billing Units/How Supplied |
|---|---|---|
| J1628 | Tremfya (guselkumab)<br>200mg/20ml vial<br>(IV infusion) | **Billing unit: 1 mg**<br><br>200mg20 mL SDV |

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# Triluron *(hyaluronan / hyaluronic acid)*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses (FDA approved indication)** | Hyaluronic acid injections are indicated to treat osteoarthritis pain of the knee when conservative nonpharmacologic therapy and non-steroidal anti-inflammatory drugs (NSAIDs) or simple analgesics, such as acetaminophen, have failed. |
| **Exclusion Criteria** | None. |
| **Required Medical Information** | Medical records supporting the request must be provided, including documentation of prior therapies and responses to treatment. |
| **Other Criteria** | Must follow LCD L39529 (Intraarticular Knee Injections of Hyaluronan). https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdid=39529 |
| **Age Restriction** | None. |
| **Prescriber Restrictions** | None. |
| **Coverage Duration** | One treatment series every six months. Dose will be approved according to the FDA approved labeling or within accepted standards of medical practice. |
| **Other Criteria/Information** | Refer to the Gold Coast Health Plan Medicare Part B Reference and Summary of Evidence document. |

| HCPCS | Description | Billing Units/How Supplied |
|---|---|---|
| J7332 | Triluron (hyaluronan / hyaluronic acid) for intra-articular injection | **Billing unit: 1 mg**<br><br>20 mg/2 mL SD syringe |

| STATUS | DATE REVISED | REVIEW DATE | APPROVED/REVIEWED BY | EFFECTIVE DATE |
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# Trivisc *(hyaluronan / hyaluronic acid)*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses (FDA approved indication)** | Hyaluronic acid injections are indicated to treat osteoarthritis pain of the knee when conservative nonpharmacologic therapy and non-steroidal anti-inflammatory drugs (NSAIDs) or simple analgesics, such as acetaminophen, have failed. |
| **Exclusion Criteria** | None. |
| **Required Medical Information** | Medical records supporting the request must be provided, including documentation of prior therapies and responses to treatment. |
| **Other Criteria** | Must follow LCD L39529 (Intraarticular Knee Injections of Hyaluronan). https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdid=39529 |
| **Age Restriction** | None. |
| **Prescriber Restrictions** | None. |
| **Coverage Duration** | One treatment series every 6 months. Dose will be approved according to the FDA approved labeling or within accepted standards of medical practice. |
| **Other Criteria/Information** | Refer to the Gold Coast Health Plan Medicare Part B Reference and Summary of Evidence document. |

| HCPCS | Description | Billing Units/How Supplied |
|---|---|---|
| J7329 | Trivisc (hyaluronan / hyaluronic acid) for intra-articular injection | **Billing unit: 1 mg**<br><br>25 mg/2.5 mL SD syringe |

| STATUS | DATE REVISED | REVIEW DATE | APPROVED/REVIEWED BY | EFFECTIVE DATE |
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| Approved | N/A | 5/15/2025 | Pharmacy & Therapeutics (P&T) Committee | 5/15/2025 |
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# Tyenne *(tocilizumab-aazg)*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses (FDA approved indication)** | Tyenne is a biosimilar to Actemra (tocilizumab).<br><br>Tocilizumab (including biosimilars) is an interleukin-6 inhibitor (IL-6i) indicated for multiple inflammatory conditions, including rheumatoid arthritis (RA), giant cell arteritis, and juvenile idiopathic arthritis (JIA). |
| **Exclusion Criteria** | Must not be used in combination with other biologic drugs, Otezla, or Janus Kinase Inhibitor (JAKis). |
| **Required Medical Information** | Medical records supporting the request must be provided, including documentation of prior therapies and responses to treatment. |
| **Age Restriction** | None. |
| **Prescriber Restrictions** | Prescriber is a specialist or has consulted with a specialist for the condition being treated. |
| **Coverage Duration** | Two years. Dose will be approved according to the FDA approved labeling or within accepted standards of medical practice. |
| **Other Criteria/Information** | Refer to the Gold Coast Health Plan Medicare Part B Reference and Summary of Evidence document. |

| HCPCS | Description | Billing Units/How Supplied |
|---|---|---|
| Q5135 | Tyenne IV (tocilizumab-aazg) | **Billing unit: 1 mg**<br><br>80 mg/4 mL, 200 mg/10 mL, 400 mg/20 mL SDV |

| STATUS | DATE REVISED | REVIEW DATE | APPROVED/REVIEWED BY | EFFECTIVE DATE |
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| Created | 3/26/2025 | 3/26/2025 | Dawn Shojai, PharmD, Senior Pharmacy Benefit Consultant (PSG) | N/A |
| Approved | N/A | 5/15/2025 | Pharmacy & Therapeutics (P&T) Committee | 5/15/2025 |
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GOLD COAST HEALTH PLAN TOTAL Care ADVANTAGE℠

TOTAL CARE ADVANTAGE PART B CLINICAL GUIDELINES

# Tyvaso *(treprostinil)* inhalation

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses (FDA approved indication)** | Tyvaso is a prostacyclin mimetic indicated for the treatment of pulmonary arterial hypertension (PAH; WHO Group 1) and pulmonary hypertension associated with interstitial lung disease (PH-ILD; WHO Group 3). |
| **Exclusion Criteria** | None. |
| **Required Medical Information** | **For initial coverage of PAH (WHO Group 1):**<br>• Medical records supporting the request must be provided, including documentation of prior therapies and responses to treatment.<br>• Must have confirmation of diagnosis by right heart catheterization.<br><br>**For initial coverage of PH-ILD (WHO Group 3):**<br>• Medical records supporting the request must be provided - AND -<br>• Must have confirmation of diagnosis by right heart catheterization<br>• Must provide the patient's baseline six-minute walk test (6MWT) - AND<br>• Must have PH-ILD associated with IPF, CTD, or combined IPF and emphysema (CPFE). PH-ILD associated with other phenotypes such as COPD is not covered based on the current 2022 ESC/ERS Guidelines. |
| **Age Restriction** | None. |
| **Prescriber Restrictions** | Prescriber is a specialist or has consulted with a specialist for the condition being treated. |
| **Coverage Duration** | **For PAH:** two years initial and reauthorization.<br><br>**For PH-ILD:** one year initial and two years reauthorization. Dose will be approved according to the FDA approved labeling or within accepted standards of medical practice. |
| **Other Criteria/Information** | Refer to the Gold Coast Health Plan Medicare Part B Reference and Summary of Evidence document. |

| HCPCS | Description | Billing Units/How Supplied |
|---|---|---|
| J7686 | Tyvaso (treprostinil) inhalation | **Billing unit: 1.74 mg**<br><br>1.74 mg/2.9 mL SD ampule |

| STATUS | DATE REVISED | REVIEW DATE | APPROVED/REVIEWED BY | EFFECTIVE DATE |
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# Tzield *(teplizumab-mzwv)*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses (FDA approved indication)** | Tzield injection is a CD3-directed antibody indicated to delay the onset of Stage 3 type 1 diabetes (T1D) in adults and pediatric patients aged 8 years and older with Stage 2 T1D, to be given with dosing based on body surface area and administered once daily for 14 days. Currently, there are no compendia supported uses for this therapy outside the FDA-indication(s). |
| **Exclusion Criteria** | Must not have a history of type 2 diabetes. |
| **Required Medical Information** | Medical records supporting the request must be provided, including autoantibody test results – AND – Must provide patient's current weight and height.<br><br>For approval, the following must be met:<br>• Must have documentation of at least two of the following autoantibodies:<br>» Glutamic acid decarboxylase 65 (GAD) autoantibody:<br>» Insulin autoantibody (IAA)<br>» Insulinoma-associated antigen 2 autoantibody (IA-2A)<br>» Zinc transporter 8 autoantibody (ZnT8A)<br>» Islet cell autoantibody (ICA)<br><br>• Must have documentation of dysglycemia defined as meeting one of the following:<br>» A fasting glucose level of 110 to 125 mg/dL – or –<br>» A two-hour postprandial plasma glucose level of at least 140 mg/dL but less than 200 mg/dL – or – A postprandial glucose level more than 200 mg/dL on two occasions |
| **Age Restriction** | Must be 8 years of age or older. |
| **Prescriber Restrictions** | Must be prescribed by, or in consultation with, an endocrinologist. |
| **Coverage Duration** | One, 14-day course in accordance with the FDA-approved labeling. |
| **Other Criteria/Information** | Refer to the Gold Coast Health Plan Medicare Part B Reference and Summary of Evidence document. |

| HCPCS | Description | Billing Units/How Supplied |
|---|---|---|
| J9381 | Tzield (teplizumab-mzwv) injection | **Billing unit: 5 mcg**<br><br>2mg/2mL SDV |

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# Udenyca *(pegfilgrastim-cbqv)*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses (FDA approved indication)** | Udenyca is a leukocyte growth factor indicated to decrease the incidence of infection, as manifested by febrile neutropenia, in patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a clinically significant incidence of febrile neutropenia. |
| **Exclusion Criteria** | None. |
| **Required Medical Information** | Medical records supporting the request, including documentation of prior therapies and responses to treatment, must be provided. |
| **Age Restriction** | None. |
| **Prescriber Restrictions** | None. |
| **Coverage Duration** | One year. Dose will be approved according to the FDA approved labeling or within accepted standards of medical practice. |
| **Other Criteria/Information** | Refer to the Gold Coast Health Plan Medicare Part B Reference and Summary of Evidence document. |

| HCPCS | Description | Billing Units/How Supplied |
|---|---|---|
| Q5111 | Udenyca (pegfilgrastim-cbqv) biosimilar | **Billing unit: 0.5 mg**<br><br>6 mg/0.6 mL SD syringe |

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# Ultomiris *(ravulizumab-cwvz)*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses (FDA approved indication)** | Ultomiris is a complement inhibitor indicated for the treatment of multiple indications involving the complement system including neuromyelitis optica spectrum disorder (NMOSD) in patients who are anti-aquaporin-4 (AQP4) antibody positive, generalized myasthenia gravis (gMG) in patients who are anti-acetylcholine receptor antibody-positive (AChR-Ab+), atypical hemolytic uremic syndrome (aHUS) and paroxysmal nocturnal hemoglobinuria (PNH). |
| **Exclusion Criteria** | None. |
| **Required Medical Information** | **For neuromyelitis optica spectrum disorder (NMOSD):**<br>1. Patient has anti-aquaporin-4 (AQP4) antibody positive disease;<br>2. Patient is exhibiting one of the following core clinical characteristics: optic neuritis, acute myelitis, area postrema syndrome, acute brainstem syndrome, symptomatic narcolepsy or acute diencephalic clinical syndrome with NMOSD-typical diencephalic MRI lesions, or symptomatic cerebral syndrome with NMOSD-typical brain lesions;<br>3. Ultomiris will not be used in combination with Soliris, Uplizna, Enspryng, or other medications for NMOSD;<br>4. Must have an Expanded Disability Status Scale (EDSS) score of ≤7; Medical records supporting the request must be provided;<br><br>For reauthorization: Ultomiris must not be used in combination with Soliris, Uplizna, Enspryng, or other medications for neuromyelitis optica spectrum disorder (NMOSD); AND Documentation of a decrease in relapse rate must be provided.<br><br>**For myasthenia gravis:**<br>1. Must have a baseline Myasthenia Gravis Activities of Daily Living (MG-ADL) of six or more;<br>2. Confirmed diagnosis of generalized myasthenia gravis that is anti-acetylcholine receptor antibody (AChR-Ab) positive;<br>3. Must not be used in combination with similar therapies for myasthenia gravis including immune globulins, Vyvgart, Soloris, Rystiggo, or Zilbrysq. (Ultomiris has not been studied and there is no data to support use in combination with other medications used to treat MG);<br>4. Medical records supporting the request must be provided;<br><br>For reauthorization, must have documentation of improvement in the MG-ADL total score from baseline - must not be used in combination with similar therapies for myasthenia gravis including immune globulins, Vyvgart, Soloris, Rystiggo, or Zilbrysq.<br><br>**For paroxysmal nocturnal hemoglobinuria (PNH):**<br>1. Must have diagnosis confirmed by flow cytometry;<br>2. Must have hemolysis-associated symptoms (thrombosis, organ dysfunction, pain);<br>3. Must not be used in combination with other complement drug therapy including Fabhalta, Soliris, Empaveli. (Ultomiris has not been studied and there is no data to support use in combination with other medications used for PHN);<br>4. Medical records supporting the request must be provided; |

GOLD COAST HEALTH PLAN
TOTAL Care ADVANTAGE℠

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<tr><td></td><td>For reauthorization: Must have documentation of improvement in PNH-related symptoms (e.g., fatigue, dyspnea) compared to baseline - AND - a sustained increase in hemoglobin levels, improvement in hemolysis, or reduced transfusions compared to baseline - AND - must not be used in combination with other complement drug therapy including Fabhalta, Soliris, Empaveli.</td></tr>
<tr><td>Age Restriction</td><td>None</td></tr>
<tr><td>Prescriber Restrictions</td><td>For NMSOD: Must be prescribed by or in consultation with a neurologist.</td></tr>
<tr><td>Coverage Duration</td><td>One year (initial); two years (reauthorization). Dose will be approved according to the FDA approved labeling or within accepted standards of medical practice.</td></tr>
<tr><td>Other Criteria/Information</td><td>Refer to the Gold Coast Health Plan Medicare Part B Reference and Summary of Evidence document.</td></tr>
<tr><td>Other Criteria/Information</td><td>Refer to the Gold Coast Health Plan Medicare Part B Reference and Summary of Evidence document.
<table>
<tr><th>HCPCS</th><th>Description</th><th>Billing Units/How Supplied</th></tr>
<tr><td>J1303</td><td>Ultomiris (ravulizumab-cwvz)</td><td>Billing unit: 10 mg<br><br>300 mg/3 mL, 1100 mg/11 mL SDV</td></tr>
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| STATUS | DATE REVISED | REVIEW DATE | APPROVED/REVIEWED BY | EFFECTIVE DATE |
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| Created | 3/26/2025 | 3/26/2025 | Dawn Shojai, PharmD, Senior Pharmacy Benefit Consultant (PSG) | N/A |
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# Uplizna *(inebilizumab-cdon)*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses (FDA approved indication)** | Uplizna is a CD19-directed cytolytic antibody indicated for the treatment of neuromyelitis optica spectrum disorder (NMOSD) in adult patients who are anti-aquaporin- 4 (AQP4) antibody positive. |
| **Exclusion Criteria** | None. |
| **Required Medical Information** | Medical records supporting the request must be provided. |
| **Age Restriction** | None. |
| **Prescriber Restrictions** | None. |
| **Coverage Duration** | Up to two years. Dose will be approved according to the FDA approved labeling or within accepted standards of medical practice. |
| **Other Criteria/Information** | Refer to the Gold Coast Health Plan Medicare Part B Reference and Summary of Evidence document. |

| HCPCS | Description | Billing Units/How Supplied |
|---|---|---|
| J1823 | Uplizna (inebilizumab-cdon) | **Billing unit: 1 mg**<br><br>100 mg/10 mL SDV |

| STATUS | DATE REVISED | REVIEW DATE | APPROVED/REVIEWED BY | EFFECTIVE DATE |
|---|---|---|---|---|
| Created | 3/26/2025 | 3/26/2025 | Dawn Shojai, PharmD, Senior Pharmacy Benefit Consultant (PSG) | N/A |
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# Vegzelma *(bevacizumab-adcd)*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses (FDA approved indication)** | Vegzelma is a biosimilar to Avastin® (bevacizumab). Bevacizumab is a vascular endothelial growth factor inhibitor indicated for the treatment of multiple cancers including:<br>A. metastatic colorectal cancer, in combination with intravenous fluorouracil-based chemotherapy for first- or second-line treatment;<br>B. metastatic colorectal cancer, in combination with fluoropyrimidine-irinotecan- or luoropyrimidine oxaliplatin-based chemotherapy for second-line treatment in patients who have progressed on a first-line bevacizumab product-containing regimen;<br>C. Unresectable, locally advanced, recurrent or metastatic non-squamous non-small cell lung cancer, in combination with carboplatin and paclitaxel for first-line treatment;<br>D. recurrent glioblastoma in adult;<br>E. metastatic renal cell carcinoma in combination with interferon alfa, and more. |
| **Exclusion Criteria** | None. |
| **Required Medical Information** | Medical records supporting the request must be provided, including documentation of prior therapies and responses to treatment. |
| **Other Criteria** | Must follow (LCD) L37205: Chemotherapy Drugs and their Adjuncts. https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdId=37205&ver=15 |
| **Age Restriction** | None. |
| **Prescriber Restrictions** | None. |
| **Coverage Duration** | Up to one year. Dose will be approved according to the FDA approved labeling or within accepted standards of medical practice. |
| **Other Criteria/Information** | Refer to the Gold Coast Health Plan Medicare Part B Reference and Summary of Evidence document. |

| HCPCS | Description | Billing Units/How Supplied |
|---|---|---|
| Q5129 | Injection, bevacizumab-adcd (vegzelma), biosimilar, 10 mg | **Billing unit: 10 mg**<br><br>100 mg/4 mL SDV<br>400 mg/16 mL SDV |

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# Veopoz *(pozelimab-bbfg)*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses (FDA approved indication)** | Veopoz injection is a complement inhibitor indicated for the treatment of adult and pediatric patients 1-year-of-age and older with CD55-deficient protein-losing enteropathy (PLE), also known as CHAPLE disease to be administered 30 mg/kg once followed by 10 mg/kg as a subcutaneous injection once weekly starting on day eight. Currently, there are no compendia supported uses for this therapy outside the FDA-indication(s). |
| **Exclusion Criteria** | Must not be used in combination with eculizumab. |
| **Required Medical Information** | Medical records supporting the request must be provided and include the following:<br>1. clinical diagnosis of CHAPLE disease that includes symptoms of the condition (such as diarrhea, vomiting, abdominal pain, etc.) and a low serum albumin;<br>2. confirmation of CD55 loss-of function mutation by genetic testing;<br>3. baseline serum albumin; and<br>4. patient's current weight. |
| **Age Restriction** | Must be at least 1-year-of-age. |
| **Prescriber Restrictions** | Must be prescribed by or in consultation with hematologists, gastroenterologists, or those who specialize in rare genetic hematologic diseases. |
| **Coverage Duration** | Initial: one year; Reauthorization: two years. Dose will be approved according to the FDA- approved labeling or within accepted standards of medical practice.<br><br>For reauthorization, documentation of a positive clinical response must be provided. |
| **Other Criteria/Information** | Refer to the Gold Coast Health Plan Medicare Part B Reference and Summary of Evidence document. |

| HCPCS | Description | Billing Units/How Supplied |
|---|---|---|
| J9376 | Veopoz (pozelimab-bbfg) | **Billing unit: 1 mg**<br><br>400 mg/2 mL SDV |

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# Vivimusta *(bendamustine)*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses (FDA approved indication)** | Vivimusta is an alkylating agent with a unique mechanism indicated for the treatment of chronic lymphocytic leukemia (CLL) and indolent B-cell non-Hodgkin lymphoma (NHL) that has progressed during or within six months of treatment with rituximab or a rituximab-containing regimen. |
| **Exclusion Criteria** | None. |
| **Required Medical Information** | Medical records supporting the request must be provided, including documentation of prior therapies and responses to treatment. |
| **Other Criteria** | Must follow LCD L37205: Chemotherapy Drugs and their Adjuncts. https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdId=37205&ver=15 |
| **Age Restriction** | None. |
| **Prescriber Restrictions** | None. |
| **Coverage Duration** | One year. Dose will be approved according to the FDA approved labeling or within accepted standards of medical practice. |
| **Other Criteria/Information** | Refer to the Gold Coast Health Plan Medicare Part B Reference and Summary of Evidence document. |

| HCPCS | Description | Billing Units/How Supplied |
|---|---|---|
| J9056 | Vivimusta (bendamustine hydrochloride), Injection, 1 mg | **Billing unit: 1 mg**<br><br>100mg / 4 ml MDV |

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# Vyalev *(foscarbidopa and foslevodopa)*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses (FDA approved indication)** | Vyalev injection is a combination of prodrugs foscarbidopa and foslevodopa and is indicated for the treatment of motor fluctuations in adults with advanced Parkinson's disease (PD). |
| **Exclusion Criteria** | None. |
| **Required Medical Information** | Medical records to support the request, including documentation of the following:<br>1. Patient has levodopa-responsive advanced PD with clearly defined "on" periods;<br>2. Patient is receiving optimal carbidopa/levodopa therapy;<br>3. Patient has persistent motor fluctuations despite therapy with the following: levodopa or levodopa-carbidopa AND one other class of anti-Parkinson's therapy including dopamine agonists (e.g., pramipexole, ropinirole), MAO-B inhibitors (e.g., rasagiline, selegiline), COMT inhibitors (e.g., entacapone). |
| **Other Criteria** | Must follow Local Coverage Determination (LCD) L33374 External Infusion Pumps.<br>LCD - External Infusion Pumps (L33794) |
| **Age Restriction** | Patient is at least 18 years of age. |
| **Prescriber Restrictions** | Must be prescribed by, or in consultation with, a neurologist. |
| **Coverage Duration** | Initial: one year. Reauthorization: two years. Dose will be approved according to the FDA-approved labeling or within accepted standards of medical practice.<br><br>For reauthorization: Documentation of positive clinical response to Vyalev therapy. |
| **Other Criteria/Information** | Refer to the Gold Coast Health Plan Medicare Part B Reference and Summary of Evidence document. |

| HCPCS | Description | Billing Units/How Supplied |
|---|---|---|
| J7356 | Vyalev (foscarbidopa 0.25 mg / foslevodopa 5 mg) | **Billing unit: 5.25 mg**<br><br>120 mg/2,400 mg per 10 mL SDV |

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# Vyepti *(eptinezumab-jjmr)*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses (FDA approved indication)** | Vyepti is indicated for the preventive treatment of migraine in adults. It is a humanized monoclonal antibody (mAb) that binds to calcitonin gene-related peptide (CGRP) ligand and blocks its binding to the receptor. Currently, there are no compendia supported uses for this therapy outside the FDA-indication(s). |
| **Exclusion Criteria** | Must not be used in combination with other CGRP antagonist therapy. |
| **Required Medical Information** | For initial requests:<br>1. Medical records supporting the request must be provided;<br>2. Patient must be evaluated for and determined not to have medication overuse headache (MOH); |
| **Age Restriction** | None. |
| **Prescriber Restrictions** | None. |
| **Coverage Duration** | Six months initial coverage; two years reauthorization. Dose will be approved according to the FDA approved labeling or within accepted standards of medical practice.<br><br>For reauthorization: Must provide evidence of clinical improvement including a reduction in monthly migraine days compared to baseline. |
| **Other Criteria/Information** | Refer to the Gold Coast Health Plan Medicare Part B Reference and Summary of Evidence document. |

| HCPCS | Description | Billing Units/How Supplied |
|---|---|---|
| J3032 | Vyepti (eptinezumab-jjmr) | **Billing unit: 1 mg**<br><br>100 mg/mL SDV |

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# Vyvgart *(efgartigimod alfa-fcab)*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses (FDA approved indication)** | Vyvgart is a neonatal Fc receptor blocker indicated for the treatment of generalized myasthenia gravis (gMG) in adult patients who are anti-acetylcholine receptor antibody positive (AChR-Ab+). |
| **Exclusion Criteria** | Must not be used in combination with similar therapies for myasthenia gravis including immune globulins, Soliris, Ultomiris, Rystiggo, or Zilbrysq. (Vyvgart has not been studied and there is no data to support use in combination with other medications used to treat MG) |
| **Required Medical Information** | **For initial coverage:**<br>Medical records supporting the request must be provided.<br>1. Baseline Myasthenia Gravis Activities of Daily Living (MG-ADL) of at least five.<br>2. Confirmed diagnosis of generalized myasthenia gravis that is anti-acetylcholine receptor antibody (AChR-Ab) positive.<br><br>**For reauthorization:**<br>Must have a documented response to therapy evidenced by a stable or improved MG-ADL total score from baseline. |
| **Age Restriction** | None. |
| **Prescriber Restrictions** | Must be prescribed by, or in consultation with, a neurologist. |
| **Coverage Duration** | One year initial; two years reauthorization. Dose will be approved according to the FDA- approved labeling or within accepted standards of medical practice. |
| **Other Criteria/Information** | Refer to the Gold Coast Health Plan Medicare Part B Reference and Summary of Evidence document. |

| HCPCS | Description | Billing Units/How Supplied |
|---|---|---|
| J9332 | Vyvgart (efgartigimod alfa-fcab) | **Billing unit: 2 mg**<br><br>400mg/20ml SDV |

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# Winrevair *(sotatercept)*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses (FDA approved indication)** | Winrevair subcutaneous powder for solution is an activin signaling inhibitor indicated for the treatment of adults with pulmonary arterial hypertension (PAH, World Health Organization [WHO] Group 1) to increase exercise capacity, improve WHO functional class (FC), and reduce the risk of clinical worsening events. |
| **Exclusion Criteria** | None. |
| **Required Medical Information** | For initial requests, documentation of the following is required:<br>1. Must have a confirmed diagnosis of Pulmonary Arterial Hypertension (PAH), World Health Organization Group 1, by right heart catheterization.<br>2. Must have WHO functional class II or III symptoms.<br><br>For reauthorization requests: Documentation must be provided demonstrating that the patient has had a beneficial response to Winrevair compared to pretreatment baseline in one or more of the following: improvement in WHO functional class, risk status, or 6MWD. |
| **Age Restriction** | Patient is at least 18 years of age. |
| **Prescriber Restrictions** | Must be prescribed by or in consultation with a specialist for the condition. |
| **Coverage Duration** | Initial: one year; Reauthorization: two years. Dose will be approved according to the FDA-approved labeling or within accepted standards of medical practice. |
| **Other Criteria/Information** | Refer to the Gold Coast Health Plan Medicare Part B Reference and Summary of Evidence document. |

| HCPCS | Description | Billing Units/How Supplied |
|---|---|---|
| J3590*,<br>C9399* | Winrevair (sotatercept-csrk) | Additional information required: National Drug Code (NDC), Strength, Dosage administered, Route of administration.<br><br>45mg, 60mg SDV |

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# Xenpozyme *(olipudase alfa-rpcp)*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses (FDA approved indication)** | Xenpozyme for injection is a hydrolytic lysosomal sphingomyelin-specific enzyme indicated for treatment of non–central nervous system manifestations of acid sphingomyelinase deficiency (ASMD) in adult and pediatric patients. |
| **Exclusion Criteria** | Patient must not have ASMD Type A. |
| **Required Medical Information** | Must provide medical records supporting the request and patient's current weight and height.<br><br>For initial coverage, must also provide the following:<br><br>1. Documentation of a diagnosis of acid sphingomyelinase deficiency (ASMD) Type A/B or Type B.<br>2. Confirmation of ASMD by enzyme assay demonstrating low ASM enzyme activity (<10% of controls).<br>3. Clinical symptoms of ASMD including low diffusion capacity of the lungs for carbon monoxide (DLCO) and splenomegaly.<br>4. Baseline DLCO.<br><br>For reauthorization: Documentation of a clinical response to therapy compared to pretreatment baseline in one or more of the following: reduction in spleen or liver volume, improvement in lung function (e.g., DLCO) or improvement in symptoms (shortness of breath, fatigue, etc.). |
| **Age Restriction** | None. |
| **Prescriber Restrictions** | Must be prescribed by, or in consultation with, a specialist familiar with the treatment of lysosomal storage disorders. |
| **Coverage Duration** | Initial coverage and reauthorization: one year. Dose will be approved according to the FDA approved labeling or within accepted standards of medical practice. |
| **Other Criteria/Information** | Refer to the Gold Coast Health Plan Medicare Part B Reference and Summary of Evidence document. |

| HCPCS | Description | Billing Units/How Supplied |
|---|---|---|
| J0218 | Xenpozyme (olipudase alfa-rpcp) | **Billing unit: 1 mg**<br><br>20mg SDV |

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# Xgeva *(denosumab)*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses (FDA approved indication)** | Xgeva is indicated for the prevention of skeletal-related events in patients with multiple myeloma and in patients with bone metastases from solid tumors. |
| **Exclusion Criteria** | None. |
| **Required Medical Information** | Medical records supporting the request must be provided. |
| **Age Restriction** | None. |
| **Prescriber Restrictions** | None. |
| **Coverage Duration** | Up to two years. Doses will be approved according to the FDA-approved labeling or within accepted standards of medical practice. |
| **Other Criteria/Information** | Refer to the Gold Coast Health Plan Medicare Part B Reference and Summary of Evidence document. |

| HCPCS | Description | Billing Units/How Supplied |
|---|---|---|
| J0897 | Xgeva (denosumab) | **Billing unit: 1 mg**<br><br>120 mg/1.7 mL SDV |

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# Xipere *(triamcinolone)*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses (FDA approved indication)** | Xipere is a corticosteroid indicated for the treatment of ophthalmic conditions which include temporal arteritis, uveitis, and sympathetic ophthalmia, and ocular inflammatory conditions unresponsive to topical corticosteroids. |
| **Exclusion Criteria** | None. |
| **Required Medical Information** | Medical records supporting the request must be provided. |
| **Age Restriction** | None. |
| **Prescriber Restrictions** | None. |
| **Coverage Duration** | In accordance with the FDA-approved labeling or accepted standards of medical practice. |
| **Other Criteria/Information** | Refer to the Gold Coast Health Plan Medicare Part B Reference and Summary of Evidence document. |

| HCPCS | Description | Billing Units/How Supplied |
|---|---|---|
| J3299 | Xipere (triamcinolone) | **Billing unit: 1 mg**<br><br>40 mg/mL SDV |

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# Xolair *(omalizumab)*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses (FDA approved indication)** | Xolair is a monoclonal antibody that specifically targets immunoglobulin E (IgE) indicated for the treatment of moderate to severe asthma inadequately controlled by inhaled corticosteroids and presence of a positive skin test or in vitro reactivity to a perennial aeroallergen, chronic urticaria (CU) refractory to H1 antihistamine treatment, chronic rhinosinusitis with nasal polyps (CRSwNP) inadequately controlled with nasal corticosteroids as add-on maintenance treatment, and IgE-mediated food allergy. |
| **Exclusion Criteria** | Must not be used in combination with other biologic drugs (e.g., Dupixent, Nucala, Fasenra). |
| **Required Medical Information** | **For initial coverage of asthma:**<br>1. Medical records supporting the request must be provided, including documentation of prior therapies and responses to treatment must be provided.<br>2. Must have tried and failed 1 ICS/LABA inhaler in combination with one other asthma controller drug in the past six months (failed is defined as an intolerance or inability to improve the condition on required therapy for at least four weeks).<br>3. Must provide patient's current weight and baseline IgE level.<br>4. A baseline IgE level of at least 30 IU/mL (baseline is defined as before treatment with Xolair or another therapy that lowers IgE levels).<br>5. A baseline (defined above) positive skin test or in vitro reactivity to a perennial aeroallergen.<br><br>**For reauthorization requests for asthma:**<br>1. Medical records supporting the request must be provided, including documentation of prior therapies and responses to treatment must be provided.<br>2. Must provide patient's current weight and baseline IgE level.<br>3. (2) Must have documented clinical benefit (e.g., decrease in exacerbations, improvement in symptoms).<br><br>**For initial coverage of chronic urticaria:**<br>1. Medical records supporting the request must be provided, including documentation of prior therapies and responses to treatment must be provided.<br>2. Patient has a confirmed diagnosis of chronic urticaria defined as urticaria occurring for more than six weeks.<br>3. Must try and fail (defined as inability to improve symptoms) with at least two H1 antihistamines (e.g., levocetirizine, desloratadine) - OR - one H1 antihistamine and at least one of the following: H2 antihistamine (e.g., famotidine), oral steroid, or leukotriene modifier.<br><br>**For reauthorization requests for chronic urticaria:**<br>1. Medical records supporting the request must be provided, including documentation of prior therapies and responses to treatment must be provided.<br>2. Must have documented clinical benefit (e.g., decrease in exacerbations, improvement in symptoms, decrease in steroid use). |

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| | **For initial coverage of nasal polyps:**<br>1. Medical records supporting the request must be provided, including documentation of prior therapies and responses to treatment must be provided.<br>2. Patient has a baseline IgE level of at least 30 IU/mL (baseline is defined as before treatment with Xolair or another therapy that lowers IgE levels).<br>3. Must try and fail (defined as an inability to improve symptoms for least four weeks) intranasal steroids.<br>4. Must be used in combination with an intranasal steroid.<br>5. Must provide patient's current weight and baseline IgE level.<br><br>**For reauthorization requests for nasal polyps:**<br>1. Medical records supporting the request must be provided, including documentation of prior therapies and responses to treatment must be provided.<br>2. Must have documented clinical benefit (e.g., decrease in exacerbations, improvement in symptoms, decrease in steroid use).<br>3. Must provide patient's current weight and baseline IgE level.<br>4. Must continue to be used in combination with an intranasal steroid.<br><br>**For initial coverage of food allergy:**<br>1. Medical records supporting the request must be provided.<br>2. Patient has a diagnosis of an IgE-mediated food allergy confirmed by both a positive in vitro test for IgE to the specified foods AND a positive skin prick test to the specified foods.<br>3. Patient has a clinical history of a significant allergic reaction to the specified foods.<br>4. Patient has a baseline IgE level of at least 30 IU/mL.<br>5. Xolair must be used in conjunction with a food allergen-avoidant diet.<br>6. Patient's current weight and baseline IgE level have been provided.<br>7. Patient is at least 1 year of age.<br><br>**For reauthorization requests for food allergy:**<br>1. Medical records supporting the request must be provided.<br>2. Xolair must continue to be used in conjunction with a food allergen-avoidant diet.<br>3. The patient's current weight and baseline IgE level must be provided. |
| **Age Restriction** | None. |
| **Prescriber Restrictions** | Prescriber is a specialist or has consulted with a specialist for the condition being treated. |
| **Coverage Duration** | One year initial and reauthorization for food allergy; one year initial and two years reauthorization for all others. Dose will be approved according to the FDA-approved labeling or within accepted standards of medical practice. |

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| **Other Criteria/Information** | Refer to the Gold Coast Health Plan Medicare Part B Reference and Summary of Evidence document. |

| HCPCS | Description | Billing Units/How Supplied |
|---|---|---|
| J2357 | Xolair (omalizumab)<br>Vial/Prefilled syringe | **Billing unit: 5 mg**<br><br>150 mg SDV; 75 mg, 150 mg SD syringe |

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# Yescarta *(axicabtagene ciloleucel)*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses (FDA approved indication)** | Yescarta is a CD19-directed genetically modified autologous T cell immunotherapy indicated for the treatment of:<br>• Adult patients with large B-cell lymphoma that is refractory to first-line chemoimmunotherapy or that relapses within 12 months of first-line chemoimmunotherapy.<br>• Adult patients with relapsed or refractory large B-cell lymphoma after two or more lines of systemic therapy, including diffuse large B-cell lymphoma (DLBCL) not otherwise specified, primary mediastinal large B-cell lymphoma, high grade B-cell lymphoma, and DLBCL arising from follicular lymphoma. |
| **Exclusion Criteria** | None. |
| **Required Medical Information** | Medical records supporting the request must be provided. |
| **Other Criteria** | Must follow NCD 110.24 for Chimeric Antigen Receptor (CAR) T-Cell Therapy.<br>https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?ncdid=374 |
| **Age Restriction** | None. |
| **Prescriber Restrictions** | None. |
| **Coverage Duration** | In accordance with the FDA approved labeling or accepted standards of medical practice. |
| **Other Criteria/Information** | Refer to the Gold Coast Health Plan Medicare Part B Reference and Summary of Evidence document. |

| HCPCS | Description | Billing Units/How Supplied |
|---|---|---|
| Q2041 | Yescarta (axicabtagene ciloleucel) | **Billing unit: per dose**<br>Up to 2 x $10^8$ CAR+ T-cells per SD infusion bag |

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# Yupelri *(revefenacin)*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses (FDA approved indication)** | Yupelri is an anticholinergic indicated for the maintenance treatment of patients with chronic obstructive pulmonary disease (COPD). |
| **Exclusion Criteria** | None. |
| **Required Medical Information** | Medical records supporting the request must be provided, including documentation of prior therapies and responses to treatment. |
| **Age Restriction** | None. |
| **Prescriber Restrictions** | None. |
| **Coverage Duration** | Up to two years. Dose will be approved according to the FDA-approved labeling or within accepted standards of medical practice. |
| **Other Criteria/Information** | Refer to the Gold Coast Health Plan Medicare Part B Reference and Summary of Evidence document. |

| HCPCS | Description | Billing Units/How Supplied |
|---|---|---|
| J7677 | Yupelri (revefenacin) | **Billing unit: 1mcg**<br><br>175 mcg/3 mL SDV |

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# Yupelri *(revefenacin)*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses (FDA approved indication)** | Yupelri is an anticholinergic indicated for the maintenance treatment of patients with chronic obstructive pulmonary disease (COPD). |
| **Exclusion Criteria** | None. |
| **Required Medical Information** | Medical records supporting the request must be provided, including documentation of prior therapies and responses to treatment. |
| **Age Restriction** | None. |
| **Prescriber Restrictions** | None. |
| **Coverage Duration** | Up to two years. Dose will be approved according to the FDA-approved labeling or within accepted standards of medical practice. |
| **Other Criteria/Information** | Refer to the Gold Coast Health Plan Medicare Part B Reference and Summary of Evidence document. |

| HCPCS | Description | Billing Units/How Supplied |
|---|---|---|
| J7677 | Yupelri (revefenacin) | **Billing unit: 1mcg**<br><br>175 mcg/3 mL SDV |

| STATUS | DATE REVISED | REVIEW DATE | APPROVED/REVIEWED BY | EFFECTIVE DATE |
|---|---|---|---|---|
| Created | 3/26/2025 | 3/26/2025 | Dawn Shojai, PharmD, Senior Pharmacy Benefit Consultant (PSG) | N/A |
| Approved | N/A | 8/21/2025 | Pharmacy & Therapeutics (P&T) Committee | 8/21/2025 |
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# Yutiq *(fluocinolone)* implant

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses (FDA approved indication)** | Yutiq is approved for the treatment of chronic non-infectious uveitis affecting the posterior segment of the eye. |
| **Exclusion Criteria** | None. |
| **Required Medical Information** | Medical records supporting the request must be provided. |
| **Age Restriction** | None. |
| **Prescriber Restrictions** | None. |
| **Coverage Duration** | In accordance with the FDA-approved labeling or accepted standards of medical practice.<br>For reauthorization, must have disease response indicated by stability or improvement in condition compared to baseline. |
| **Other Criteria/Information** | Refer to the Gold Coast Health Plan Medicare Part B Reference and Summary of Evidence document. |

| HCPCS | Description | Billing Units/How Supplied |
|---|---|---|
| J7314 | Yutiq (fluocinolone implant) | **Billing unit: 0.01 mg**<br><br>0.18 mg implant |

| STATUS | DATE REVISED | REVIEW DATE | APPROVED/REVIEWED BY | EFFECTIVE DATE |
|---|---|---|---|---|
| Created | 3/26/2025 | 3/26/2025 | Dawn Shojai, PharmD, Senior Pharmacy Benefit Consultant (PSG) | N/A |
| Approved | N/A | 8/21/2025 | Pharmacy & Therapeutics (P&T) Committee | 8/21/2025 |
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# Ziextenzo *(pegfilgrastim-bmez)*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses (FDA approved indication)** | Ziextenzo is a leukocyte growth factor indicated to:<br>• Decrease the incidence of infection, as manifested by febrile neutropenia, in patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a clinically significant incidence of febrile neutropenia.<br>• Increase survival in patients acutely exposed to myelosuppressive doses of radiation (Hematopoietic Subsyndrome of Acute Radiation Syndrome).<br><br>Ziextenzo is a biosimilar to Neulasta. |
| **Exclusion Criteria** | None. |
| **Required Medical Information** | Medical records supporting the request, including documentation of prior therapies and responses to treatment, must be provided. |
| **Age Restriction** | None. |
| **Prescriber Restrictions** | None. |
| **Coverage Duration** | One year. Dose will be approved according to the FDA approved labeling or within accepted standards of medical practice. |
| **Other Criteria/Information** | Refer to the Gold Coast Health Plan Medicare Part B Reference and Summary of Evidence document. |

| HCPCS | Description | Billing Units/How Supplied |
|---|---|---|
| Q5120 | Ziextenzo Injection, pegfilgrastim-bmez (ziextenzo), biosimilar, 0.5 mg | **Billing unit: 0.5 mg**<br><br>6 mg/0.6 mL SD syringe |

| STATUS | DATE REVISED | REVIEW DATE | APPROVED/REVIEWED BY | EFFECTIVE DATE |
|---|---|---|---|---|
| Created | 3/26/2025 | 3/26/2025 | Dawn Shojai, PharmD, Senior Pharmacy Benefit Consultant (PSG) | N/A |
| Approved | N/A | 5/15/2025 | Pharmacy & Therapeutics (P&T) Committee | 5/15/2025 |
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# ZIIHERA® *(zanidatamab-hrii)* injection, for IV use

<table>
<tr><th>PA Criteria</th><th>Criteria Details</th></tr>
<tr><td>Description</td><td>ZIIHERA® is a bispecific HER2-directed antibody.</td></tr>
<tr><td>Covered Uses<br>(FDA approved indication)</td><td>ZIIHERA is indicated for the treatment of adults with previously treated, unresectable or metastatic HER2-positive (IHC 3+) biliary tract cancer (BTC) including intra-hepatic cholangiocarcinoma, extra-hepatic cholangiocarcinoma, and gallbladder cancer, as detected by an FDA-approved test*.<br><br>Information on FDA-approved tests for HER2 protein expression in biliary tract cancers is available at: http://www.fda.gov/CompanionDiagnostics.<br><br>*This indication is approved under accelerated approval based on objective response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in the confirmatory trial.</td></tr>
<tr><td>Dosing and Administration</td><td>
<table>
<tr><th>Indication</th><th>Dosing Regimen</th><th>Maximum Dose</th></tr>
<tr><td>Biliary Tract Cancer (BTC)</td><td>20 mg/kg IV infusion every two weeks<br><br>Continue until disease progression or unacceptable toxicity.<br><br>
<table>
<tr><th>Dose</th><th>Infusion Time</th></tr>
<tr><td>1st and 2nd</td><td>120-150 min</td></tr>
<tr><td>3rd and 4th</td><td>90 min<br>(if previous infusions well tolerated)</td></tr>
<tr><td>Subsequent</td><td>60 min<br>(if previous infusions well tolerated)</td></tr>
</table>
</td><td>20 mg/kg/dose</td></tr>
</table>
</td></tr>
<tr><td>Billing and Coding Information</td><td>
<table>
<tr><th>10-digit NDC</th><th>11-digit NDC</th></tr>
<tr><td>Vial: 68727-950-01<br>Carton: 68727-950-02</td><td>Vial: 68727-0950-01<br>Carton: 68727-0950-02</td></tr>
</table>
<table>
<tr><th>HCPCS Code</th><th>Description</th></tr>
<tr><td>J9276</td><td>Injection, zanidatamab-hrii, 2 mg</td></tr>
</table>
<table>
<tr><th>CPT Procedural Codes</th><th>Description</th></tr>
<tr><td>96413</td><td>Chemotherapy IV infusion, up to one hour</td></tr>
<tr><td>96415</td><td>Chemotherapy IV infusion, additional hour*</td></tr>
</table>
* Used as an add-on code for every hour of infusion that is more than 30 min past the initial one hour.
</td></tr>
<tr><td>Product Availability</td><td>Single-dose vial: 300 mg lyophilized powder<br><br>Each carton contains two 300 mg single-dose vials.</td></tr>
<tr><td>Contraindications</td><td>None.</td></tr>
</table>

| | |
|---|---|
| **Recommended Medical Monitoring** | **BLACK BOX WARNING: Embryo-Fetal Toxicity** – Based on the mechanism of action, ZIIHERA can cause fetal harm when administered to pregnant women; there are no human or animal data on the use of ZIIHERA in pregnancy. In literature reports, HER2-directed antibody use during pregnancy resulted in cases of pediatric pulmonary hypoplasia, skeletal abnormalities, and neonatal death.<br>a. Advise patients of potential risk to fetus; verify pregnancy status of females of reproductive potential prior to initiation of therapy<br>b. Recommend effective contraception during treatment and for four months after last dose.<br><br>ZIIHERA has been associated with:<br>• Left Ventricular Dysfunction<br>• Infusion Related Reactions (IRR)<br>• Diarrhea<br><br>Patients should be monitored for any of these reactions. ZIIHERA dose may be delayed, reduced or permanently discontinued based on the severity of adverse reactions. |
| **Approval Criteria** | A. Physician administered IV infusion; in-office or HOPD<br>i. Cannot be self-administered<br>B. Biliary Tract Cancer **(must meet all)**:<br>i. Diagnosis of Biliary Tract Cancer<br>ii. Prescribed by or in consultation with an oncologist<br>iii. Patient age ≥ 18 years<br>iv. Disease is HER2-positive (IHC 3+) determined by FDA-approved test<br>v. Disease is unresectable, resected gross residual (R2) or metastatic<br>vi. Patient does NOT have untreated or symptomatic CNS metastases<br>vii. Failure of at least one prior systemic treatment (see Appendix)<br>viii. LVEF ≥ 50% prior to start of therapy<br>ix. Prescribed as a single agent<br>x. Request meets one of the following:<br>1. Dose does not exceed 20 mg/kg every two weeks<br>2. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (prescriber must submit supporting evidence) |
| **Age Restriction** | Adults ≥ 18 years old. |
| **Coverage Duration** | Initial: six months. Reauthorization: 12 months.<br><br>Dose will be approved according to the FDA approved labeling or within accepted standards of medical practice. |

| Appendix | Examples of Prior Systemic Therapies for BTC:<br>• 5-FU<br>• Capecitabine<br>• Capecitabine + Oxaliplatin<br>• FOLFOX (5-FU + leucovorin + Oxaliplatin)<br>• Gemcitabine<br>• Gemcitabine + Abraxane<br>• Gemcitabine + Capecitabine<br>• Gemcitabine + Cisplatin<br>• Gemcitabine + Imfinzi + cisplatin<br>• Gemcitabine + Keytruda + Cisplatin<br>• Gemcitabine + Oxaliplatin |
|---|---|

| STATUS | DATE REVISED | REVIEW DATE | APPROVED/REVIEWED BY | EFFECTIVE DATE |
|---|---|---|---|---|
| Created | 9/22/2025 | 9/22/2025 | Tamara Chinarian, PharmD, Clinical Pharmacist | N/A |
| Approved | N/A | 11/13/2025 | Pharmacy & Therapeutics (P&T) Committee | 11/13/2025 |
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# Zilbrysq *(zilucoplan)*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses (FDA approved indication)** | Zilbrysq is a complement inhibitor indicated for the treatment of generalized myasthenia gravis (gMG) in adult patients who are antiacetylcholine receptor antibody positive (AChR-Ab+). |
| **Exclusion Criteria** | Must not be used in combination with similar therapies for myasthenia gravis including immune globulins, Soliris, Ultomiris, Vyvgart/Vygart Hytrulo, or Rystiggo. (Zilbrysq has not been studied and there is no data to support use in combination with other medications used to treat MG). |
| **Required Medical Information** | **For initial requests, must have:**<br>1. Medical records supporting the request must be provided.<br>2. Confirmed generalized myasthenia gravis that is anti-acetylcholine receptor antibody (AChR-Ab) positive.<br>3. Baseline Myasthenia Gravis Activities of Daily Living (MG-ADL) of six or more.<br><br>For reauthorization: Must have a documented response to therapy evidenced by a stable or improved MG-ADL total score from baseline. |
| **Age Restriction** | Must be at least 18 years old. |
| **Prescriber Restrictions** | Must be prescribed by, or in consultation with, a neurologist. |
| **Coverage Duration** | Twelve weeks (initial); one year (reauthorization). Dose will be approved according to the FDA approved labeling or within accepted standards of medical practice. |
| **Other Criteria/Information** | Refer to the Gold Coast Health Plan Medicare Part B Reference and Summary of Evidence document. |

| HCPCS | Description | Billing Units/How Supplied |
|---|---|---|
| J3490*, C9399* | Zilbrysq (zilucoplan) | Additional information required: National Drug Code (NDC), Strength, Dosage administered, Route of administration.<br><br>16.6 mg/0.416 mL, 23 mg/0.574 mL, and 32.4 mg/0.81 mL prefilled syringes |

| STATUS | DATE REVISED | REVIEW DATE | APPROVED/REVIEWED BY | EFFECTIVE DATE |
|---|---|---|---|---|
| Created | 3/26/2025 | 3/26/2025 | Dawn Shojai, PharmD, Senior Pharmacy Benefit Consultant (PSG) | N/A |
| Approved | N/A | 5/15/2025 | Pharmacy & Therapeutics (P&T) Committee | 5/15/2025 |
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# Zolgensma *(onasemnogene abeparvovec)*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses (FDA approved indication)** | Zolgensma in indicated for the treatment of pediatric patients less than 2 years of age with spinal muscular atrophy (SMA) with bi-allelic mutations in the survival motor neuron 1 (SMN1) gene. |
| **Exclusion Criteria** | None. |
| **Required Medical Information** | Medical records supporting the request must be provided. |
| **Other Criteria** | Must follow NCD 110.24 for Chimeric Antigen Receptor (CAR) T-Cell Therapy. https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?ncdid=374 |
| **Age Restriction** | None. |
| **Prescriber Restrictions** | None. |
| **Coverage Duration** | In accordance with the FDA-approved labeling or accepted standards of medical practice. |
| **Other Criteria/Information** | Refer to the Gold Coast Health Plan Medicare Part B Reference and Summary of Evidence document. |

| HCPCS | Description | Billing Units/How Supplied |
|---|---|---|
| J3399 | Zolgensma (onasemnogene abeparvovec) | **Billing unit: per each kit**<br><br>5.5 mL or 8.3 mL SDV (each kit will provide sufficient number of vials based on patient weight) |

| STATUS | DATE REVISED | REVIEW DATE | APPROVED/REVIEWED BY | EFFECTIVE DATE |
|---|---|---|---|---|
| Created | 3/26/2025 | 3/26/2025 | Dawn Shojai, PharmD, Senior Pharmacy Benefit Consultant (PSG) | N/A |
| Approved | N/A | 5/15/2025 | Pharmacy & Therapeutics (P&T) Committee | 5/15/2025 |
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# Zymfentra *(infliximab-dyyb)*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses (FDA approved indication)** | Zymfentra is a tumor necrosis factor inhibitor (TNFi) currently indicated for maintenance treatment of moderately to severe Crohn's disease (CD) and Ulcerative Colitis (UC) in those who have completed induction therapy with an intravenous infliximab product. |
| **Exclusion Criteria** | Must not be used in combination with other biologic drugs, Otezla, or Janus Kinase Inhibitor (JAKis). |
| **Required Medical Information** | Medical records supporting the request must be provided;<br>A diagnosis of moderately to severely active ulcerative colitis or moderately to severely active Crohn's disease following treatment with an infliximab product administered intravenously; |
| **Age Restriction** | None. |
| **Prescriber Restrictions** | Prescriber is a specialist or has consulted with a specialist for the condition being treated. |
| **Coverage Duration** | Two years. Dose will be approved according to the FDA approved labeling or within accepted standards of medical practice. |
| **Other Criteria/Information** | Refer to the Gold Coast Health Plan Medicare Part B Reference and Summary of Evidence document. |

| HCPCS | Description | Billing Units/How Supplied |
|---|---|---|
| J1748 | Zymfentra (infliximab-dyyb) | **Billing unit: 10 mg**<br><br>120 mg/mL prefilled syringe and prefilled pen |

| STATUS | DATE REVISED | REVIEW DATE | APPROVED/REVIEWED BY | EFFECTIVE DATE |
|---|---|---|---|---|
| Created | 3/26/2025 | 3/26/2025 | Dawn Shojai, PharmD, Senior Pharmacy Benefit Consultant (PSG) | N/A |
| Approved | N/A | 5/15/2025 | Pharmacy & Therapeutics (P&T) Committee | 5/15/2025 |
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# Zynteglo *(betibeglogene autotemcel)*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses (FDA approved indication)** | Zynteglo is a autologous hematopoietic stem cell-based gene therapy for treatment of adult and pediatric patients with beta-thalassemia who require regular red blood cell (RBC) transfusions. Zynteglo is a one-time therapy. It is administered as a single dose and is a customized treatment created using an individual's own cells that are genetically modified to produce functional beta-globin. |
| **Exclusion Criteria** | Must not have a prior hematopoietic stem cell transplant (HSCT) or history of previous gene therapy (the safety and efficacy of Zynteglo following a previous HSCT or gene therapy has not been established). |
| **Required Medical Information** | 1. Medical records supporting the request must be provided;<br>2. Must have a diagnosis of transfusion dependent beta thalassemia (defined as a history of at least 100 mL/kg/year of packed red blood cells (pRBC) in the previous two years OR at least eight transfusions of pRBCs per year in the previous two years;<br>3. Must not have a known and available HLA matched donor as determined by the hematologist and/or transplant specialist;<br>4. Provider attests that, in the absence of a known or available HLA-matched family donor, the patient would be otherwise clinically stable and eligible to undergo HSCT. |
| **Age Restriction** | None. |
| **Prescriber Restrictions** | Must be prescribed by or in consultation with a hematologist, transplant specialist, or another board-certified prescriber with qualifications to treat specified condition. |
| **Coverage Duration** | One lifetime dose (safety and effectiveness of repeat administration have not been evaluated). |
| **Other Criteria/Information** | Refer to the Gold Coast Health Plan Medicare Part B Reference and Summary of Evidence document. |

| HCPCS | Description | Billing Units/How Supplied |
|---|---|---|
| J3393 | Zynteglo (betibeglogene autotemcel) | **Billing unit: per dose**<br><br>20 mL infusion bag |

| STATUS | DATE REVISED | REVIEW DATE | APPROVED/REVIEWED BY | EFFECTIVE DATE |
|---|---|---|---|---|
| Created | 3/26/2025 | 3/26/2025 | Dawn Shojai, PharmD, Senior Pharmacy Benefit Consultant (PSG) | N/A |
| Approved | N/A | 5/15/2025 | Pharmacy & Therapeutics (P&T) Committee | 5/15/2025 |
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# References & Clinical Criteria

**For Medicare Part B Prior Authorization**

Gold Coast Health Plan complies with National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), Local Coverage Article (LCA), and other coverage and benefit conditions included in Traditional Medicare law for Part B drugs. These resources contain coverage criteria set by the Centers of Medicare & Medicaid Services (CMS) or a Medicare Administrative Contractor (MAC) to determine if a drug is reasonable and necessary for the treatment of a condition.

When coverage criteria do not exist or are not fully established in an NCD, LCD/LCA, or other Medicare statute or regulation, Gold Coast Health Plan may create internal coverage criteria based on CMS-approved compendium and current evidence in widely used treatment guidelines or clinical literature.

In accordance with Medicare law, when internal coverage criteria are created, Gold Coast Health Plan provides a publicly accessible summary of evidence considered during the development of the internal coverage criteria, a list of the sources of such evidence, and an explanation of the rationale supporting the adoption of the internal coverage criteria. This document presents this information.

A Medicare Administrative Contractor (MAC) establishes LCDs for Medicare Part A and Part B (A/B) medical drugs and services and Medicare Durable Medical Equipment (DME) for defined geographic areas or jurisdictions.

# BIZENGRI® (zenocutuzumab-zbco) injection, for IV use

**Additional Gold Coast Health Plan Part B Criteria:** No

The FDA has granted accelerated approval for the use of BIZENGRI®, a bispecific HER2- and HER3-directed antibody, for the treatment of patients with advanced, unresectable or metastatic non-small cell lung cancer (NSCLC) or pancreatic adenocarcinoma harboring a neuregulin 1 (NRG1) gene fusion with disease progression on or after prior systemic therapy.

*Pancreatic adenocarcinoma:* Accelerated FDA approval was based on an open-label, multi-cohort, multicenter phase II basket trial (eNRGy) that included 36 patients with advanced or metastatic NRG1 fusion-positive pancreatic adenocarcinoma who progressed on prior systemic therapy (either FOLFIRINOX, gemcitabine plus taxane-based therapy, or both), responses were seen in 15 patients (ORR of 42%). The median duration of response was seven months (ranging from 2 to 21 months).

*Non-small cell lung cancer (NCSLC):* Accelerated FDA approval was based on an open-label, multi-cohort, multicenter phase II basket trial (eNRGy). The study enrolled adult patients with advanced or metastatic NRG1 fusion-positive NSCLC who had disease progression following standard of care treatment for their disease. In the subset of 93 patients with NSCLC, the response rate was 29% with a median duration of response of 12.7 months.

The safety of zenocutuzumab was evaluated in 204 patients with *NRG1*-positive cancers; grade 3 or 4 adverse events occurred in 35%, with fatal adverse events in 4%, although these were not considered to be treatment-related. Treatment-related grade 3 or 4 events occurred in 7% including anemia, nausea, diarrhea, vomiting, abdominal pain, and elevated aspartate transaminase or alanine transaminase (1% or less for each). Other toxicities of concern with zenocutuzumab include infusion-related reactions, interstitial lung disease, and left ventricular dysfunction.

**References:**


1. Bizengri Prescribing Information. Cambridge, MA: Merus US, Inc.; 2025. Available at: https://bizengri.com/pdf/BIZENGRI_Full_Prescribing_Information_2025.pdf. Accessed September 9, 2025.
2. National Comprehensive Cancer Network Guidelines. Non-Small Cell Lung Cancer Version 2.2025. Available at: https://www.nccn.org/professionals/physician_gls/pdf/nscl.pdf. Accessed September 9, 2025.
3. National Comprehensive Cancer Network Guidelines. Pancreatic Adenocarcinoma Version 2.2025. Available at: https://www.nccn.org/professionals/physician_gls/pdf/pancreatic.pdf. Accessed September 9, 2025.
4. Neal, J, Lovely, C. Personalized, genotype-directed therapy for advanced non-small cell lung cancer. In: UpToDate, Connor RF (Ed), Wolters Kluwer. (Accessed on September 9, 2025.)
5. Singh, H, Cardin, D. Second- and later-line systemic therapy for metastatic exocrine pancreatic cancer. In: UpToDate, Connor RF (Ed), Wolters Kluwer. (Accessed on September 9, 2025.)

# **BORUZU®** (bortezomib) injection, for IV or subcutaneous use

**Additional Gold Coast Health Plan Part B Criteria:** No

BORUZU is a newly approved ready-to-use formulation for the brand drug VELCADE (bortezomib), a drug which was originally FDA approved in 2003. VELCADE requires reconstitution prior to injecting.

BORUZU is a proteosome inhibitor approved for the treatment of adult patients with multiple myeloma or mantle cell lymphoma. It is for subcutaneous (SC) or intravenous (IV) administration only. Because each route of administration has a different final concentration, caution should be used when calculating the volume to be administered.

BORUZU is contraindicated in patients with hypersensitivity to bortezomib, boron or mannitol, including anaphylactic reactions. It is also contraindicated for intrathecal administration.

The most commonly reported adverse reactions (≥ 20%) in clinical studies include nausea, diarrhea, thrombocytopenia, neutropenia, peripheral neuropathy, fatigue, neuralgia, anemia, leukopenia, constipation, vomiting, lymphopenia, rash, pyrexia, and anorexia.

BORUZU is a major substrate for cytochrome P450 3A4; patients will have to be monitored for concurrent drug-drug interactions. Concurrent use with strong 3A4 inducers is NOT recommended and should be avoided as it can decrease patient exposure to BORUZU. Patients on concurrent strong 3A4 inhibitors should be monitored closely for any signs of BORUZU toxicity, as it can increase exposure to BORUZU.

**References:**


1. *Boruzu* Prescribing Information. Telangana, India: Amneal Oncology Private Limited; 2024. Available at: https://doc-isolation-prod.prod.fire.glass/api/wopi/downloads/docisolation-viewer/v2/?fileAccessId=g_b98d244c-c904-4582-b2e9-23ac5c4c1577&statusCode=1000&operationRestriction=3 <bad link> . Accessed September 10, 2025.
2. National Comprehensive Cancer Network Guidelines. Multiple Myeloma Version 2.2026. Available at: https://www.nccn.org/professionals/physician_gls/pdf/myeloma.pdf. Accessed September 10, 2025.
3. National Comprehensive Cancer Network Guidelines. B-Cell Lymphomas Version 3.2025. Available at: https://www.nccn.org/professionals/physician_gls/pdf/b-cell.pdf. Accessed September 10, 2025.
4. Velcade Prescribing Information. Cambridge, MA. Millennium Pharmaceuticals, Inc. 2008. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2008/021602s015lbl.pdf. Accessed September 22, 2025.

# **DATROWAY®** (datopotamab deruxtecan-dlnk) injection, for IV use

**Additional Gold Coast Health Plan Part B Criteria:** No

The FDA has granted accelerated approval for the use of Datroway®, a Trop-2-directed antibody and topoisomerase inhibitor conjugate, for the treatment of patients with locally advanced or metastatic epidermal growth factor receptor *(EGFR)*-positive non-small cell lung cancer (NSCLC) who have received prior *EGFR*-directed therapy and platinum-based chemotherapy.

Approval is based on objective response rate (44 percent) and duration of response (7 months) in a phase II study in such patients, but it may be contingent on results of a confirmatory trial. The most common grade ≥3 treatment related adverse event with this agent is stomatitis (which occurred in 9.5 percent in the trial). For those with *EGFR*-positive NSCLC who have progressed on both platinum-based chemotherapy and a next-generation tyrosine kinase inhibitor, we consider Datroway® to be an appropriate option.

Datroway® is also approved for the treatment of unresectable or metastatic, hormone receptor (HR) positive, human epidermal growth factor receptor 2 (HER2) negative (IHC 0, IHC 1+ or IHC 2+/ISH-) breast cancer in adults who have received prior endocrine-based therapy and chemotherapy for unresectable or metastatic disease.

**References:**


1. Datroway Coding and Reimbursement Guide. Basking Ridge, NJ: Daiichi Sankyo, Inc.; Available at: https://www.datroway4u.com/hcp/coding-and-reimbursement. Accessed August 28, 2025.
2. Datroway Prescribing Information. Basking Ridge, NJ: Daiichi Sankyo, Inc.; June 2025. Available at: https://daiichisankyo.us/prescribing-information-portlet/getPIContent?productName=Datroway&inline=true. Accessed August 28, 2025.
3. Eichler, AF. What's New in Oncology. In: UpToDate, Connor RF (Ed), Wolters Kluwer. (Accessed on September 5, 2025.)
4. National Comprehensive Cancer Network (NCCN) Guidelines. Breast Cancer Version 4.2025. Available at https://www.nccn.org/professionals/physician_gls/pdf/breast.pdf. Accessed August 28, 2025.
5. National Comprehensive Cancer Network (NCCN) Guidelines. Non-Small Cell Lung Cancer Version 8.2025. Available at https://www.nccn.org/professionals/physician_gls/pdf/nscl.pdf. Accessed August 28, 2025.

# EMRELISY™ (telisotuzumab vedotin-tllv) injection, for IV use

**Additional Gold Coast Health Plan Part B Criteria:** No

EMRELIS is a c-Met-directed antibody and microtubule inhibitor conjugate indicated for the treatment of adult patients with locally advanced or metastatic non-squamous non-small cell lung cancer (NSCLC) with high c-Met protein overexpression (defined as ≥50% of tumor cells) with strong (3+) staining, as determined by an FDA-approved test, who have received a prior systemic therapy.

This indication is FDA approved under accelerated approval based on overall response rate (ORR) and duration of response (DOR). Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s).

EMRELIS was studied in the LUMINOSITY trial, a multicenter, open-label, non-randomized, single-arm, muti-cohort phase 2 study. It evaluated EMRELIS monotherapy in 84 patients with locally advanced or metastatic EGFR wild-type non-squamous NSCLC with high c-Met protein overexpression who received prior systemic therapy.

The most common adverse reactions (≥20%) were peripheral neuropathy, fatigue, decreased appetite, and peripheral edema. (6.1) The most common Grade 3 or 4 laboratory abnormalities (≥2%) were decreased lymphocytes, increased glucose, increased alanine aminotransferase, increased gamma glutamyl transferase, decreased phosphorus, decreased sodium, decreased hemoglobin and decreased calcium.

Concomitant use with strong CYP3A inhibitors may increase unconjugated MMAE AUC, which may increase the risk of EMRELIS adverse reactions. Monitor patients for adverse reactions when EMRELIS is given concomitantly with strong CYP3A inhibitors.

**References:**


1. *Emrelis* Billing and Coding Guide. North Chicago, IL. AbbVie, Inc. Available at: https://www.emrelishcp.com/content/dam/emrelishcp/docs/emr-billing-coding-guide.pdf. Accessed September 12, 2025.
2. *Emrelis* Prescribing Information. North Chicago, IL. AbbVie, Inc. 2025. Available at: https://www.rxabbvie.com/pdf/emrelis_pi.pdf. Accessed September 12, 2025.
3. National Comprehensive Cancer Network (NCCN) Guidelines. Non-Small Cell Lung Cancer Version 8.2025. Available at https://www.nccn.org/professionals/physician_gls/pdf/nscl.pdf. Accessed September 12, 2025.

# ENCELTO™ (revakinagene taroretcel-lwey) implant, for intravitreal use

**Additional Gold Coast Health Plan Part B Criteria:** No

ENCELTO™ is an allogeneic encapsulated cell-based gene therapy indicated for the treatment of adults with idiopathic macular telangiectasia type 2 (MacTel). It is intended for surgical intravitreal implantation under aseptic conditions by a qualified ophthalmologist.

ENCELTO secretes recombinant human ciliary neurotrophic factor (rhCNTF), which is one of several neurotrophic factors endogenously produced by neurons and supporting glial cells. Exogenous CNTF is though to initially target Müller glia to trigger a cascade of signaling events that may promote photoreceptor survival. The exact mechanism of action of ENCELTO, however, is not completely understood.

The efficacy of ENCELTO was evaluated in 2 studies: Study NTMT-03-A and Study NTMT-03-B. The most common adverse reactions (incidence ≥ 2%) were conjunctival hemorrhage, delayed dark adaptation, foreign body sensation, eye pain, suture related complications, miosis, conjunctival hyperemia, eye pruritus, ocular discomfort, vitreous hemorrhage, blurred vision, headache, dry eye, eye irritation, cataract progression or formation, vitreous floaters, severe vision loss, eye discharge, anterior chamber cell and iridocyclitis.

ENCELTO is contraindicated in patients with active or suspected ocular or periocular infections, and in patients with known hypersensitivity to Endothelial Serum Free Media (Endo-SFM). There is currently no data on the use of ENCELTO in pregnant women or during lactation.

**References:**


1. *Encelto* Billing and Coding Guide. Cumberland, RI. Neurotech Pharmaceuticals, Inc. Available at: https://www.encelto.com/ecp/Billing-And-Coding-Guide.pdf. Accessed September 17, 2025.
2. *Encelto* Prescribing Information. Cumberland, RI. Neurotech Pharmaceuticals, Inc. 2025. Available at: https://www.neurotechpharmaceuticals.com/wp-content/uploads/ENCELTO-PRESCRIBING-INFORMATION.pdf. Accessed September 17, 2025.

# **IMAAVY™** (nipocalimab-aahu) injection, for IV use

**Additional Gold Coast Health Plan Part B Criteria:** No

IMAAVY™ is a neonatal Fc receptor blocker indicated for the treatment of generalized myasthenia gravis (gMG) in adult and pediatric patients 12 years of age and older who are anti-acetylcholine receptor (AChR) or anti-muscle-specific tyrosine kinase (MuSK) antibody positive.

The efficacy of IMAAVY for the treatment of gMG in adults who are anti-AChR or anti-MuSK antibody positive was established in a 24-week, multicenter, randomized, double-blind, placebo-controlled study (Study 1; NCT04951622). Patients were treated with IMAAVY with the recommended dosage regimen. Study 1 enrolled patients with gMG who met the following criteria: Myasthenia Gravis Foundation of America (MGFA) Clinical Classification Class II to IV, Myasthenia Gravis-Activities of Daily Living (MG-ADL) total score of at least 6, and on stable dose of standard of care MG therapy prior to baseline that included acetylcholinesterase (AChE) inhibitors, steroids or non-steroidal immunosuppressive therapies (NSISTs), either in combination or alone.

In Study 1 and its extension study the safety of IMAAVY was evaluated in 186 patients with gMG who received at least one dose of IMAAVY. Of those patients, 168 patients were exposed to IMAAVY every 2 weeks for at least 6 months, and 140 patients were exposed for at least 12 months. The most common adverse reactions (reported in at least 10% of patients treated with IMAAVY) were respiratory tract infection, peripheral edema, and muscle spasms.

IMAAVY is contraindicated in patients with a history of serious hypersensitivity reaction to nipocalimab or to any of the excipients in IMAAVY.

**References:**


1. Antozzi C, Vu T, Ramchandren S, et al. Safety and efficacy of nipocalimab in adults with generalized myasthenia gravis (Vivacity-MG3): a phase 3, randomized, double-blind, placebo-controlled study. Lancet Neurol. 2025;24:105-116.
2. Bird, SJ. Overview of the treatment of myasthenia gravis. In: UpToDate, Connor RF (Ed), Wolters Kluwer. (Accessed on September 18, 2025.)
3. Hibberd, PL, Kotton CN. Immunizations in adults with cancer: live-virus vaccines. In: UpToDate, Connor RF (Ed), Wolters Kluwer. (Accessed on September 18, 2025.)
4. *Imaavy* Billing and Coding Guide. Horsham, PA. Janssen Biotech, Inc. Available at: https://asset.jnjwithme.com/document/imaavy-billing-and-coding-guide.pdf. Accessed September 18, 2025.
5. Imaavy Prescribing Information. Horsham, PA. Janssen Biotech, Inc. 2025. Available at: https://www.janssenlabels.com/package-insert/product-monograph/prescribing-information/IMAAVY-pi.pdf. Accessed September 18, 2025.
6. Narayanaswami P, Sanders DB, Wolfe G, et al. International Consensus Guidance for Management of Myasthenia Gravis: 2020 Update. Neurology. 2021;96(3):114-122.

# KEBILIDI™ (eladocagene exuparvovec-tneq) suspension, for intraputaminal infusion

**Additional Gold Coast Health Plan Part B Criteria:** No

KEBILIDI is a gene therapy indicated for the treatment of adult and pediatric patients with aromatic L-amino acid decarboxylase (AADC) deficiency. Eladocagene exuparvovec gene therapy was previously available in Europe and the UK under the brand name Upstaza. The FDA has granted KEBILIDI accelerated approval based on a change from baseline in gross motor milestone achievement at 48 weeks post-treatment. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory clinical trial.

The efficacy of Kebilidi was evaluated in a 48-week, Phase 2, open-label, single arm study (NCT04903288). The trial consisted of a trial phase (8 weeks), an extension phase (to 48 weeks), and an ongoing long-term extension phase (to 260 weeks). All patients (n = 13) received a total dose of 1.8 x 1011 vector genome given as 4 intraputaminal infusions in a single stereotactic neurosurgical procedure. Select outcomes were compared to an external untreated natural history cohort of 44 pediatric patients with severe AADC deficiency with ≥ 1 motor milestone assessment after 2 years of age. Included patients were ages 1 to < 18 years old with genetically confirmed, severe AADC deficiency, decreased AADC enzyme activity in the plasma, and skull maturity appropriate for the procedure. Patients were also required to have persistent neurological defects secondary to AADC deficiency despite standard medical therapy and be unable to ambulate independently.

The most common adverse reactions (≥ 15%) were dyskinesia, pyrexia, hypotension, anemia, salivary hypersecretion, hypokalemia, hypophosphatemia, insomnia, hypomagnesemia, and procedural complications.

**References:**


1. *Kebilidi* Prescribing Information. Warren, NJ. PTC Therapeutics, Inc. 2024. Available at: https://www.kebilidi.com/prescribing-information.pdf. Accessed September 19, 2025.
2. Wassenberg T, Molero-Luis M, Jeltsch K, et al. Consensus guideline for the diagnosis and treatment of aromatic l-amino acid decarboxylase (AADC) deficiency. Orphanet Journal of Rare Diseases. 2017 Jan 18;12(1):12.

# LYNOZYFIC™ (linvoseltamab-gcpt) injection, for IV use

**Additional Gold Coast Health Plan Part B Criteria:** No

LYNOZYFIC is indicated for the treatment of adult patients with relapsed or refractory multiple myeloma (MM) who have received at least four prior lines of therapy, including a proteasome inhibitor, an immunomodulatory agent, and an anti-CD38 monoclonal antibody. This indication was FDA approved under accelerated approval based on response rate and durability of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trial(s).

Support for LYNOZYFIC comes from an open-label, phase 2 multicenter study (LINKER-MM1) that evaluated linvoseltamab 200 mg in 117 patients with relapsed or refractory MM who had received at least three prior therapies, including an anti-CD38 monoclonal antibody, a proteasome inhibitor, and an immunomodulatory agent, or were triple-class refractory. Patients could not have received prior BCMA-targeted therapy.

The study ***excluded*** patients with known multiple myeloma brain lesions or meningeal involvement, history of a neurodegenerative condition, history of seizure within 12 months prior to study enrollment, active infection, a history of an allogeneic or autologous stem cell transplantation within 12 weeks, prior BCMA-directed bispecific antibody therapy, prior bispecific T-cell engaging therapy, or prior BCMA CAR-T cell therapy. After a median follow-up of 14.3 months, the overall response rate was 71 percent, with one-half of patients achieving a complete response (CR) or better. The estimated median duration of response was 29.4 months.

The most common adverse reactions (≥20%) were musculoskeletal pain, cytokine release syndrome, cough, upper respiratory tract infection, diarrhea, fatigue, pneumonia, nausea, headache, and dyspnea. The most common Grade 3 to 4 laboratory abnormalities (≥30%) were decreased lymphocyte count, decreased neutrophil count, decreased hemoglobin, and decreased white blood cell count.

Serious adverse reactions occurred in 74% of patients who received LYNOZYFIC. Serious adverse reactions that occurred in >5% of patients included cytokine release syndrome (27%), pneumonia (13%), COVID-19 (7%), and acute kidney injury (5%). Fatal adverse reactions occurred in 7% of patients, and included sepsis (3.4%), chronic kidney disease (0.9%), pneumonia (0.9%), tumor lysis syndrome (0.9%), and encephalopathy (0.9%).

LYNOZYFIC is available only through the LYNOZYFIC REMS program because of the risks of CRS and neurologic toxicity, including ICANS.

**References:**


1. *Lynozific* Prescribing Information. Tarrytown, NY. Regeneron Pharmaceuticals, Inc. Available at: https://www.regeneron.com/downloads/lynozyfic_fpi.pdf. Accessed September 19, 2025.
2. National Comprehensive Cancer Network. Multiple Myeloma Version 2.2026. Available at: https://www.nccn.org/professionals/physician_gls/pdf/myeloma.pdf. Accessed September 19, 2025.

# ZIIHERA® (zanidatamab-hrii) injection, for IV use

**Additional Gold Coast Health Plan Part B Criteria:** No

ZIIHERA is indicated for the treatment of adults with previously treated, unresectable or metastatic HER2-positive (immunohistochemistry [IHC] 3+) biliary tract cancer (BTC), as detected by an FDA-approved test. This indication was FDA approved under accelerated approval based on overall response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s).

The efficacy of ZIIHERA was evaluated in 62 patients with HER2-positive (IHC 3+ by central assessment) BTC in Cohort 1 of HERIZON-BTC-01 (NCT04466891), an open-label, multicenter, single arm trial in patients with unresectable or metastatic disease. Patients were required to have received at least one prior gemcitabine-containing systemic chemotherapy regimen in the advanced disease setting and adequate cardiac function (defined as LVEF ≥ 50%).

Serious adverse reactions occurred in 53% of 80 patients with unresectable or metastatic HER2-positive BTC who received ZIIHERA. Serious adverse reactions in >2% of patients included biliary obstruction (15%), biliary tract infection (8%), sepsis (8%), pneumonia (5%), diarrhea (3.8%), gastric obstruction (3.8%), and fatigue (2.5%). A fatal adverse reaction of hepatic failure occurred in one patient who received ZIIHERA. Most common adverse reactions (≥ 20%) are diarrhea, infusion-related reaction, abdominal pain, and fatigue.

**References:**


1. National Comprehensive Cancer Network. Biliary Tract Cancers 2.2025. Available at: https://www.nccn.org/professionals/physician_gls/pdf/btc.pdf. Accessed September 22, 2025.
2. Ziihera Prescribing Information. Palo Alto, CA. Jazz Pharmaceuticals, Inc. Available at: https://pp.jazzpharma.com/pi/ziihera.en.USPI.pdf. Accessed on September 22, 2025.

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