Gold Coast Health Plan
Total Care Advantage
(HMO D-SNP)
Part B Clinical Guidelines

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Contract #: H9623-001-000, CMS Approved/File & Use [date]

Drug	Generic	HCPCS Code
Abecma (Idecabtagene Vicleucel)	idecabtagene vicleucel	Q2055
Actemra IV (tocilizumab) solution vial	tocilizumab	J3262
Adakveo (crizanlizumab)	crizanlizumab	J0791
Adzynma (ADAMTS13, recombinant-krhn)	ADAMTS13, recombinant-krhn	J7171
Alyglo (immune globulin intravenous, human-stwk)	IVIG	J1552
Alymsys (bevacizumab-maly)	bevacizumab	Q5126
Amvuttra (vutrisiran) injection	vutrisiran	J0225
Apretude (cabotegravir)	cabotegravir	J0739
Aucatzyl (obecabtagene autoleucel)	obecabtagene autoleucel	Q2058
Avastin (bevacizumab)	bevacizumab	J9035
Avsola (infliximab-axxq)	infliximab	Q5121
Benlysta IV (belimumab)	belimumab	J0490
Bivigam (immune globulin) intravenous	IVIG	J1556
Boniva IV (ibandronate sodium)	ibandronate	J1740
Botox (onabotulinumtoxinA)	OnabotulinumtoxinA	J0585
Breyanzi (lisocabtagene maraleucel)	lisocabtagene maraleucel	Q2054
Carvykti (ciltacabtagene autoleucel)	ciltacabtagene autoleucel	Q2056
Casgevy (exagamglogene autotemcel)	exagamglogene autotemcel	J3392
Cimzia (certolizumab pegol) lyophilized powder	certolizumab pegol	J0717
Cinqair (reslizumab)	reslizumab	J2786
Cinryze (C-1 esterase inhibitor [human])	C-1 esterase inhibitor human	J0598
Cosentyx IV (secukinumab)	secukinumab	J3247
Daxxify (daxibotulinumtoxinA)	daxibotulinumtoxinA	J0589
Docivyx (docetaxel)	docetaxel	J9172
Durysta (bimatoprost implant)	bimatoprost	J7351
Dysport (abobotulinumtoxin A)	AbobotulinumtoxinA	J0586
Elevidys (delandistrogene moxeparvovec-rokl)	delandistrogene moxeparvovec-rokl	J1413
Enjaymo (sutimlimab-jome)	sutimlimab	J1302
Entyvio IV (vedolizumab)	vedolizumab	J3380
Erzofri (paliperidone palmitate ER) injection	paliperidone	J2428
Evenity (romosozumab-aqqg)	romosozumab-aqqg	J3111
Evkeeza (evinacumab-dgnb)	evinacumab	J1305
Fasenra (benralizumab) prefilled syringe	benralizumab	J0517
Fylnetra (pegfilgrastim-pbbk biosimilar) injection	pegfilgrastim	Q5130
Gel-One (hyaluronan/ hyaluronic acid) for intra-articular injection	hyaluronate sodium/ hyaluronic acid	J7326
GenVisc 850 (hyaluronan/ hyaluronic acid) for intra-articular injection	hyaluronate sodium/ hyaluronic acid	J7320
Granix (tbo-filgrastim)	filgrastim	J1447
Hemgenix (etranacogene dezaparvovec-drlb) injection	etranacogene dezaparvovec-drlb	J1411
Herceptin (trastuzumab)	trastuzumab	J9355
Herceptin Hylecta (trastuzumab and hyaluronidase)	trastuzumab and hyaluronidase	J9356
Hercessi (trastuzumab-strf)	trastuzumab	Q5146
Herzuma (trastuzumab-pkrb) injection, biosimilar	trastuzumab	Q5113
Hyalgan (hyaluronan/ hyaluronic acid) for intra-articular injection	hyaluronate sodium/ hyaluronic acid	J7321
Hymovis (hyaluronan/ hyaluronic acid) for intra-articular injection	hyaluronate sodium/ hyaluronic acid	J7322
Hympavzi (marstacimab-hncq) injection	marstacimab-hncq	J7172
iDose TR (travoprost intracameral implant) injection	travoprost intracameral implant	J7355
Ilaris (canakinumab) injection	canakinumab	J0638
Ilumya (tildrakizumab) injection	tildrakizumab	J3245
Infugem (gemcitabine HCl) injection	gemcitabine	J9198
Izervay (avacincaptad pegol)	avacincaptad pegol	J2782
Kanjinti (trastuzumab-anns) injection, biosimilar	trastuzumab	Q5117
Kisunla (donanemab-azbt) injection	donanemab	J0175
Kymriah (tisagenlecleucel)	tisagenlecleucel	Q2042
Lamzede (velmanase alfa-tycv) injection	velmanase alfa-tycv	J0217
Lantidra (donislecel-jujn)	donislecel-jujn	J3590, C9399
Leqembi (lecanemab-irmb) injection	lecanemab	J0174
Leqvio (inclisiran) injection	inclisiran	J1306
Lumizyme (alglucosidase alfa) injection	alglucosidase alfa	J0221
Lyfgenia (lovotibeglogene autotemcel) injection	lovotibeglogene autotemcel	J3394
Margenza (margetuximab-cmkb) injection	margetuximab-cmkb	J9353
Monovisc (hyaluronan/ hyaluronic acid) for intra-articular injection	hyaluronate sodium/ hyaluronic acid	J7327
Myobloc (rimabotulinumtoxinB) injection	rimabotulinumtoxinB	J0587
Neupogen (filgrastim g-csf) injection - excludes biosimilars	filgrastim g-csf	J1442
Nexviazyme (avalglucosidase alfa-ngpt) injection	avalglucosidase alfa	J0219
Nucala (mepolizumab) injection	mepolizumab	J2182
Nulojix (belatacept) injection	belatacept	J0485
Nypozi (filgrastim-txid) injection, biosimilar	filgrastim-txid, biosimilar	Q5148
Ohtuvayre (ensifentrine) inhaled suspension	ensifentrine	J7601
Omvoh (mirikizumab-mrkz) injection	mirikizumab	J2267
Onpattro (patisiran) injection	patisiran	J0222
Ontruzant (trastuzumab-dttb) injection	trastuzumab	Q5112
Orencia IV (abatacept) injection	abatacept	J0129
Orthovisc (hyaluronan/ hyaluronic acid) for intra-articular injection	hyaluronate sodium/ hyaluronic acid	J7324
Oxlumo (lumasiran) injection	lumasiran	J0224
Ozurdex (dexamethasone, intravitreal implant) injection	dexamethasone, IVIT implant	J7312
Panzyga (immune globulin) intravenous injection, non-lyophilized	IVIG	J1576
Phesgo (pertuzumab, trastuzumab, and hyaluronidase-zzxf) injection	pertuzumab, trastuzumab, and hyaluronidase	J9316
PiaSky (crovalimab-akkz) injection	crovalimab-akkz	J1307
Pombiliti (cipaglucosidase alfa-atga) injection	cipaglucosidase alfa-atga	J1203
Prolia (denosumab) injection	denosumab	J0897
Qalsody (tofersen) injection	tofersen	J1304

Reblozyl (luspatercept) injection	luspatercept	J0896
Rebyota (fecal microbiota, live-jslm)	fecal microbiota	J1440
Releuko (filgrastim-ayow) injection, biosimilar	filgrastim-ayow	Q5125
Remicade (Infliximab) - **Janssen manufacturer ONLY**	infliximab	J1745
Revcovi (elapegademase-lvlr)	elapegademase	J3590, C9399
Riabni (rituximab-arrx) injection, biosimilar	rituximab-arrx	Q5123
Rituxan (rituximab) injection	rituximab	J9312
Rituxan Hycela (rituximab/ hyaluronidase) injection	rituximab/hyaluronidase	J9311
Rivfloza (nedosiran) injection	nedosiran	J3490, C9399
Roctavian (valoctocogene roxaparvovec-rvox) injection	valoctocogene roxaparvovec	J1412
Rolvedon (eflapegrastim-xnst) injection	eflapegrastim-xnst	J1449
Ryplazim (plasminogen, human-tvmh) injection	plasminogen, human-tvmh	J2998
Rystiggo (rozanolixizumab-noli) injection	rozanolixizumab-noli	J9333
Saphnelo (anifrolumab-fnia) injection	anifrolumab-fnia	J0491
Signifor LAR (pasireotide long-acting) injection	pasireotide long-acting	J2502
Simponi Aria (golimumab) injection	golimumab	J1602
Skyrizi IV (risankizumab-rzaa) injection	risankizumab	J2327
Soliris (eculizumab) injection	eculizumab	J1300
Spevigo (spesolimab-sbzo) injection	spesolimab-sbzo	J1747
Spinraza (nusinersen) injection	nusinersen	J2326
Spravato (esketamine) nasal spray	esketamine	G2082 - up to 56mg | G2083 - greater than 56mg
Stelara IV (ustekinumab) injection	ustekinumab	J3358
Stimufend (pegfilgrastim-fpgk) injection, biosimilar	pegfilgrastim-fpgk	Q5127
Susvimo (ranibizumab intravitreal implant), injection	ranibizumab IVIT implant	J2779
Syfovre (pegcetacoplan) intravitreal injection	pegcetacoplan	J2781
Synojoynt (hyaluronan or derivative for intra-articular injection)	hyaluronate sodium/ hyaluronic acid	J7331
Synvisc/Synvisc One (hyaluronan or derivative for intra-articular injection)	hyaluronate sodium/ hyaluronic acid	J7325
Tecartus (brexucabtagene autoleucel)	brexucabtagene autoleucel	Q2053
Tepezza (teprotumumab-trbw) injection	teprotumumab-trbw	J3241
Tezspire (tezepelumab-ekko) injection	tezepelumab-ekko	J2356
Tofidence (tocilizumab-bavi) injection, biosimilar	tocilizumab-bavi	Q5133
Tremfya IV (guselkumab) injection	guselkumab	J1628
Triluron (hyaluronan or derivative) for intra-articular injection	hyaluronate sodium/ hyaluronic acid	J7332
Trivisc (hyaluronan or derivative) for intra-articular injection	hyaluronate sodium/ hyaluronic acid	J7329
Tyenne IV (tocilizumab-aazg) injection, biosimilar	tocilizumab-aazg	Q5135
Tyvaso (treprostinil) inhalation	treprostinil	J7686
Tzield (teplizumab-mzwv) injection	teplizumab-mzwv	J9381
Udenyca (pegfilgrastim-cbqv) injection, biosimilar	pegfilgrastim-cbqv	Q5111
Ultomiris (ravulizumab-cwvz) injection	ravulizumab	J1303
Uplizna (inebilizumab-cdon)	inebilizumab-cdon	J1823
Vegzelma (bevacizumab-adcd) injection, biosimilar	bevacizumab-adcd	Q5129
Veopoz (pozelimab-bbfg) injection	pozelimab-bbfg	J9376
Vivimusta (bendamustine hcl) injection	bendamustine	J9056
Vyalev (foscarbidopa/foslevodopa) injection	foscarbidopa/foslevodopa	J7356
Vyepti (eptinezumab-jjmr) injection	eptinezumab-jjmr	J3032
Vyvgart (efgartigimod alfa-fcab) injection	efgartigimod alfa-fcab	J9332
Winrevair (sotatercept-csrk) injection	sotatercept-csrk	J3590, C9399
Xenpozyme (olipudase alfa-rpcp) injection	olipudase alfa-rpcp	J0218
Xeomin (incobotulinumtoxin A)	incobotulinumtoxin A	J0588
Xgeva (denosumab) injection	denosumab	J0897
Xipere (triamcinolone acetonide) injection	triamcinolone acetonide (suprachoroidal)	J3299
Xolair (omalizumab) injection	omalizumab	J2357
Yescarta (axicabtagene ciloleucel)	axicabtagene ciloleucel	Q2041
Yupelri (revefenacin) inhaled solution	revefenacin	J7677
Yutiq (fluocinolone acetonide intravitreal implant) injection	Fluocinolone acetonide, IVIT implant	J7314
Ziextenzo (pegfilgrastim-bmez) injection, biosimilar	pegfilgrastim-bmez	Q5120
Zilbrysq (zilucoplan)	zilucoplan	J3490, C9399
Zolgensma (onasemnogene abeparvovec-xioi) injection	onasemnogene abeparvovec-xioi	J3399
Zymfentra (infliximab-dyyb) injection	infliximab-dyyb	J1748
Zynteglo (betibeglogene autotemcel) injection	elivaldogene autotemcel	J3393

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GCHP 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
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
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 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, SD infusion bag

STATUS	DATE REVISED	REVIEW DATE	APPROVED/REVIEWED BY	EFFECTIVE DATE
Created	3/26/25	3/26/25	Dawn Shojai, Senior Pharmacy Benefit Consultant (PSG)	N/A
Approved	N/A	5/15/25	Pharmacy & Therapeutics (P&T) Committee	5/15/25

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GCHP Clinical Guidelines:

Actemra IV (*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	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
J3262	Actemra IV (tocilizumab) solution vial	1 mg billing Unit, 80 mg/4 mL, 200 mg/10 mL, 400 mg/20 mL SDV

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GCHP Clinical Guidelines:

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 aged 16 years 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 6 months or have an intolerance or contraindication.
Age Restriction	None
Prescriber Restrictions	None
Coverage Duration	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
J0791	Adakveo (crizanlizumab)	Billing unit: 5 mg, 100 mg/10 mL SDV

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GCHP Clinical Guidelines:

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. **For initial requests:** Must also have (1) genetic testing confirming the diagnosis of congenital thrombotic thrombocytopenic purpura (cTTP); and (2) 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. **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.

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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
J7171	Adzynma (ADAMTS13, recombinant-krhn)	Billing Unit 10 IU, 500 IU SDV, 1500 IU SDV

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GCHP Clinical Guidelines:

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	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
J1552	Alyglo (immune globulin intravenous, human-stwk)	Billing unit: 500 mg, 5 g/50 mL, 10g/ 100 mL, 20 g/200 mL SDV

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GCHP Clinical Guidelines:

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: a. metastatic colorectal cancer, in combination with intravenous fluorouracil-based chemotherapy for first- or second-line treatment; b. 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; c. unresectable, locally advanced, recurrent or metastatic non-squamous non-small cell lung cancer, in combination with carboplatin and paclitaxel for first-line treatment; d. recurrent glioblastoma in adult; e. metastatic renal cell carcinoma in combination with interferon alfa, and more.
Exclusion Criteria	None
Other Critera	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 1 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

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HCPCS	Description	Billing units/How supplied
Q5126	Alymsys (bevacizumab-maly) biosimilar	**Billing unit**: 10 mg 100 mg/4 mL, 400 mg/16 mL SDV

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GCHP Clinical Guidelines:

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	1. Medical records supporting the request must be provided – **AND** – 2. Must have documentation of a transthyretin (TTR) mutation (e.g., V30M) **3.** Must have documentation of a baseline polyneuropathy disability (PND) score less than or equal to IIIb and/or baseline FAP Stage 1 or 2 4. 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	1 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 25mg/0.5ml SD syringe

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GCHP Clinical Guidelines:

Amvuttra *(vutrisiran)*

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GCHP Clinical Guidelines:

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 600mg/3ml kit

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GCHP Clinical Guidelines:

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** 10 to up to 400 x 10^6 CD19 CAR+ T cells, per infusion

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GCHP Clinical Guidelines:

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: a. metastatic colorectal cancer, in combination with intravenous fluorouracil-based chemotherapy for first- or second-line treatment; b. 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; c. unresectable, locally advanced, recurrent or metastatic non-squamous non-small cell lung cancer, in combination with carboplatin and paclitaxel for first-line treatment; d. recurrent glioblastoma in adult; e. 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 1 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

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GCHP Clinical Guidelines:

Avastin *(bevacizumab)*

HCPCS	Description	Billing units/How supplied
J9035	Avastin (bevacizumab)	**Billing unit**: 10 mg 100mg/4 mL, 400 mg/16 mL SDV

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GCHP Clinical Guidelines:

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	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
Q5121	Avsola (infliximab-axxq)	**Billing unit**: 10 mg 100 mg SDV

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GCHP Clinical Guidelines:

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 aged 5 years and older with active systemic lupus erythematosus (SLE) who are receiving standard therapy and patients aged 5 years 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. **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. **For Lupus Nephritis Initial Coverage:** Must also have a confirmed diagnosis of SLE - AND - 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	1 year initial coverage; 2 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 120 mg, 400 mg SDV

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GCHP Clinical Guidelines:

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) https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdid=34771&ver=49&=
Age Restriction	None
Prescriber Restrictions	None
Coverage Duration	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
J1556	Bivigam (immune globulin) intravenous	**Billing unit**: 500 mg 5 gm/50 ml SDV 10 gm/100 ml SDV

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GCHP Clinical Guidelines:

Bivigam *(immune globulin)*

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GCHP Clinical Guidelines:

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 LCD - Bisphosphonate Drug Therapy (L34648)
Age Restriction	None
Prescriber Restrictions	None
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
J1740	Boniva IV (ibandronate sodium)	Billing unit: 1 mg 3 mg/3 mL SD syringe

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GCHP 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. https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?LCDId=33646 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. 1 - Chronic anal fissures: Must try and fail (defined as an inadequate response) conservative treatment such as topical nitrogen. 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: Antidepressants (e.g., amitriptyline, nortriptyline) Beta blockers (e.g., propranolol, metoprolol, timolol) Anti-epileptics (e.g., valproate, topiramate) 3 - Detrusor over activity associated with a neurologic condition: (1) Must have documentation of the underlying neurological condition that

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	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). 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). 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). 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
Coverage Duration	Up to 2 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	

HCPCS	Description	Billing units/How supplied
J0585	Botox (onabotulinumtoxinA)	**1 unit billing unit,** 100 unit, 200 unit SDV
J0589	Daxxify (daxibotulinumtoxinA)	**1 unit billing unit,** 100 unit SDV

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	J0586	Dysport (abobotulinumtoxin A)	**5 units billing unit,** 300 unit, 500 unit SDV
	J0587	Myobloc (rimabotulinumtoxinB)	**100 units billing unit**, 2500 unit/0.5 mL, 5000 unit/mL, 10,000 unit/2 mL SDV
	J0588	Xeomin (incobotulinumtoxin A)	**1 unit billing unit**, 50 unit, 100 unit, 200 unit SDV

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GCHP Clinical Guidelines:

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: 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: Refractory disease to first-line chemoimmunotherapy or relapse within 12 months of first-line chemoimmunotherapy; or 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 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. 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 SD infusion bag

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GCHP Clinical Guidelines:

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 1 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 SD infusion bag

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GCHP Clinical Guidelines:

Casgevy *(exagamglogene autotemcel)*

PA Criteria	Criteria Details
Covered Uses (FDA approved indication)	Casgevy is indicated for the treatment of patients aged 12 years and older with: • sickle cell disease (SCD) with recurrent vaso-occlusive crises (VOCs) • transfusion-dependent β-thalassemia (TDT)
Exclusion Criteria	Casgevy is not covered in patients with prior HSCT or prior gene therapy.
Required Medical Information	**FOR SICKLE CELL REQUESTS:** Before the drug is covered, the patient must meet the following requirements: 1. Medical records supporting the request must be provided; AND 2. Patient has a diagnosis of Sickle Cell Disease (SCD) with βS/βS, βS/β0, or βS/β+ genotype confirmed by genetic testing; AND 3. Patient has a history of at least 2 severe vaso-occlusive events per year in the previous 2 years; AND 4. Patient's current weight has been provided; AND 5. Patient has adequate organ function and is eligible for HSCT (stem cell transplant); AND 6. Patient does not have a contraindication to any product or procedure required for successful gene therapy treatment; AND 7. Patient has tried and failed hydroxyurea, or if not tolerated, at least one other SCD treatment such as Endari (L-Glutamine). **FOR BETA THALESSEMIA REQUESTS:** Before the drug is covered, the patient must meet the following requirements: 1. Medical records supporting the request must be provided; AND 2. 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 2 years); AND 3. Must not have a known and available HLA matched donor as determined by the hematologist and/or transplant specialist; AND 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	Patient is at least 12 years of age.

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Prescriber Restrictions	Must be prescribed by or in consultation with a hematologist or other clinically appropriate provider.
Coverage Duration	6 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
J3392	Casgevy (exagamglogene autotemcel)	**Billing unit**: per treatment 3×10^6 CD34+ cells per kg of body weight, which may be composed of multiple vials.

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GCHP Clinical Guidelines:

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	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
J0717	Cimzia (certolizumab pegol) lyophilized powder kit	**Billing unit**: 1 mg 200 mg SDV

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GCHP Clinical Guidelines:

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 - 2. Patient's current weight must be provided - 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: 2 years; reauthorization: 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
J2786	Cinqair (reslizumab)	**Billing unit**: 1 mg 100 mg/10 mL SDV

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GCHP Clinical Guidelines:

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	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
J0598	Cinryze (C-1 esterase inhibitor [human])	**Billing unit**: 10 units 500 unit SDV

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GCHP Clinical Guidelines:

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	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
J3247	Cosentyx IV (secukinumab) 125mg/5 mL vial	**Billing unit**: 1 mg 125mg/ 5mL SDV

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GCHP Clinical Guidelines:

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. LCD - Chemotherapy Drugs and their Adjuncts (L37205)
Age Restriction	None
Prescriber Restrictions	None
Coverage Duration	1 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 20 mg/2 mL, 80 mg/8 mL and 160 mg/16 mL SDV

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GCHP Clinical Guidelines:

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 10 mcg implant

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GCHP Clinical Guidelines:

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: 1. 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 2. 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: 1 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 1.33×10^{14} vector genomes per kilogram (vg/kg) of body weight as a single dose

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GCHP Clinical Guidelines:

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 old.
Prescriber Restrictions	Must be prescribed by or in consultation with a hematologist.
Coverage Duration	Initial 6 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 1,100 mg/22ml (50mg/ml) SDV

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GCHP Clinical Guidelines:

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: 1 year. Reauthorization: 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
J3380	Entyvio IV (vedolizumab) 300mg vial	**Billing unit**: 1 mg 300 mg SDV

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GCHP Clinical Guidelines:

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: 1 year. Reauthorization: 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
J2428	Injection, paliperidone palmitate extended release, 1 mg	**Billing unit**: per 1 mg 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

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GCHP Clinical Guidelines:

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, 105 mg/1.17 mL SD syringe

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GCHP Clinical Guidelines:

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, aged 5 years 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	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
J1305	Evkeeza (evinacumab-dgnb)	**Billing unit**: 5 mg 345 mg/2.3 mL, 1200 mg/8 mL SDV

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GCHP Clinical Guidelines:

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:** **1.** Medical records supporting the request, including documentation of prior therapies and responses to treatment must be provided **2.** Must have an elevated eosinophil level greater than or equal to 150 cells/mcL within 6 weeks (prior to the immediate start of treatment with Fasenra) - OR - greater than or equal to 300 cells/mcL in the previous 12 months 3. Must try and fail 1 ICS/LABA inhaler drug in the past 6 months (fail is defined as an intolerance or inability to improve the condition on required therapy for at least 4 weeks). **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). **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). **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

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Prescriber Restrictions	Prescriber is a specialist or has consulted with a specialist for the condition being treated.
Coverage Duration	Initial: 1 year; reauthorization: 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
J0517	Fasenra (benralizumab) prefilled syringe	**Billing unit**: 1 mg 30 mg/mL SD syringe

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GCHP Clinical Guidelines:

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	1 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 6 mg/0.6 mL prefilled syringe

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GCHP Clinical Guidelines:

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 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
J7326	Gel-One (hyaluronan/ hyaluronic acid) for intra-articular injection	**Billing unit**: per dose 30 mg/3 mL SD syringe

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GCHP Clinical Guidelines:

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 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
J7320	GenVisc 850 (hyaluronan/ hyaluronic acid) for intra-articular injection	**Billing unit**: 1 mg 25 mg/2.5 mL SD syringe

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GCHP Clinical Guidelines:

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 1 month and older with non-myeloid malignancies receiving myelosuppressive anticancer drugs associated with a clinically significant incidence of febrile neutropenia. 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 1 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 300 mcg/0.5 mL, 480 mcg/0.8 mL SD syringe, 300 mcg/mL, 480 mcg/1.6 mL SDV

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GCHP Clinical Guidelines:

Granix *(tbo-filgrastim)*

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GCHP 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: • 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 • Patient has one of the following: o Current use of factor IX prophylaxis therapy; OR o Patient has current or historical life-threatening hemorrhage; OR o Patient has had repeated, serious spontaneous bleeding episodes 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 SD infusion bag

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GCHP 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	1 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 600 mg-10000 unit/5 mL SDV

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GCHP Clinical Guidelines:

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). Herceptin is a HER2/neu receptor antagonist indicated in adults for: The treatment of HER2-overexpressing breast cancer. 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	1 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 150 mg SDV

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GCHP Clinical Guidelines:

Hercessi *(trastuzumab-strf)*

PA Criteria	Criteria Details
Covered Uses (FDA approved indication)	Hercessi is a biosimilar to Herceptin. 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. https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdId=37205&ver=15
Age Restriction	None
Prescriber Restrictions	None
Coverage Duration	1 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 150 mg, 420 mg SDV

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GCHP Clinical Guidelines:

Herzuma *(trastuzumab-pkrb)*

PA Criteria	Criteria Details
Covered Uses (FDA approved indication)	Herzuma is a biosimilar to Herceptin (trastuzumab). 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. https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdId=37205&ver=15
Age Restriction	None
Prescriber Restrictions	None
Coverage Duration	1 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 150 mg, 420 mg SDV

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GCHP Clinical Guidelines:

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 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
J7321	Hyalgan (hyaluronan/ hyaluronic acid) for intra-articular injection	**Billing unit**: per dose 20mg/2 ml SD syringe

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GCHP Clinical Guidelines:

Hyalgan *(hyaluronan/ hyaluronic acid)*

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GCHP Clinical Guidelines:

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 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
J7322	Hymovis (hyaluronan/ hyaluronic acid) for intra-articular injection	**Billing unit**: 1 mg 24 mg/3 mL SD syringe

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GCHP Clinical Guidelines:

Hymovis *(hyaluronan/ hyaluronic acid*

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GCHP Clinical Guidelines:

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:** Medical records supporting the request must be provided and include documentation of the following: 1. Hympavzi is being used for routine prophylaxis to prevent or reduce the frequency of bleeding episodes; 2. Patient has moderate or severe hemophilia A (a clotting factor level <1% or between 1%- 5%) without factors; 3. 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. **For initial requests for Hemophilia B:** Medical records supporting the request must be provided and include documentation of the following: 1. Hympavzi is being used for routine prophylaxis to prevent or reduce the frequency of bleeding episodes; 2. Patient has moderate or severe hemophilia B (a clotting factor level <1% or between 1%- 5%) without factors; 3. Patient has tried with failure (defined as continuing to have spontaneous bleeds) or intolerance, or has a contraindication to factor IX prophylaxis therapy. **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.

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GCHP Clinical Guidelines:

Hympavzi *(marstacimab-hncq)*

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.
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 150 mg/ml SVD

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GCHP Clinical Guidelines:

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 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 75 mcg per each

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GCHP Clinical Guidelines:

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 1 dose with authorization given for 12 weeks; and reauthorization is 1 year. Dose will be approved according to the FDA approved labeling or within accepted standards of medical practice. **For all others (excludes gout):** Initial and Reauthorization 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
J0638	Ilaris (canakinumab)	**Billing unit**: 1 mg 150 mg SDV

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GCHP Clinical Guidelines:

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	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
J3245	Ilumya (tildrakizumab)	**Billing unit**: 1 mg 100 mg SD syringe

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GCHP Clinical Guidelines:

Infugem *(gemcitabine hcl)*

PA Criteria	Criteria Details
Covered Uses (FDA approved indication)	Infugem is a nucleoside metabolic inhibitor indicated for multiple cancers including: 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, 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, c) in combination with cisplatin for the treatment of non-small cell lung cancer, and 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. https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdId=37205&ver=15
Age Restriction	None
Prescriber Restrictions	None
Coverage Duration	Up to 1 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 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,

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			2000 mg/200 mL, 2200 mg/220 mL single dose infusion bag

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GCHP Clinical Guidelines:

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: 1 year. Reauthorization: 2 years. Dose will be approved according to the FDA- approved labeling or within accepted standards of medical practice. 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 2 mg/0.1 mL SDV

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GCHP Clinical Guidelines:

Izervay (avacincaptad pegol sodium/PF)

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GCHP Clinical Guidelines:

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	1 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 150 mg, 420 mg SDV

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GCHP Clinical Guidelines:

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	6 months initial and reauthorization. Dose will be approved according to the FDA- approved labeling or within accepted standards of medical practice. 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 350 mg/20 mL SDV

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GCHP Clinical Guidelines:

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: 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. 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 SD infusion bag

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GCHP Clinical Guidelines:

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. For alpha-mannosidosis, documentation of the diagnosis confirmed by one of the following must also be provided: • biallelic pathogenic variants in MAN2B1 gene OR • 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: 1 year. Dose will be approved according to the FDA approved labeling or within accepted standards of medical practice. 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 10 mg SD Kit

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GCHP Clinical Guidelines:

Lamzede *(velmanase alfa-tycv)*

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GCHP Clinical Guidelines:

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: 1. Medical records supporting the request 2. Diagnosis of type 1 diabetes 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) 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) 5. Lantidra must be taken with concomitant immunosuppressants 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: 1 infusion. Reauthorization: up to 2 additional infusions. 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.

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

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GCHP Clinical Guidelines:

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). https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?ncdid=375&ncdver=1
Age Restriction	None
Prescriber Restrictions	None
Coverage Duration	6 months initial and reauthorization. Dose will be approved according to the FDA- approved labeling or within accepted standards of medical practice. 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 200 mg/2 ml SDV 500 mg/5 ml SDV

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GCHP Clinical Guidelines:

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: 1 year. Reauthorization: 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
J1306	Leqvio (inclisiran)	**Billing unit**: 1 mg 284 mg/1.5 mL prefilled syringe

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GCHP Clinical Guidelines:

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: • Patient's current weight • 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	1 year initial; 2 years reauthorization. Dose will be approved according to the FDA- approved labeling or within accepted standards of medical practice. 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 50 mg SDV

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GCHP Clinical Guidelines:

Lumizyme *(alglucosidase alfa)*

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GCHP Clinical Guidelines:

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: **1.** Patient has a diagnosis of Sickle Cell Disease (SCD) with βS/βS, βS/β0, or βS/β+ genotype confirmed by genetic testing; 2. Patient has a history of at least 4 severe vaso-occlusive events within the previous 2 years; **3.** Patient's current weight has been provided; 4. Patient has adequate organ function and is eligible for HSCT (stem cell transplant); **5.** Patient does not have a contraindication to any product or procedure required for successful gene therapy treatment; 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	6 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 f 3 × 10^6 CD34+ cells/kg of body weight, in one to four infusion bags

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GCHP Clinical Guidelines:

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	1 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 250 mg/10 mL SDV

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GCHP Clinical Guidelines:

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 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
J7327	Monovisc (hyaluronan/ hyaluronic acid) for intra-articular injection	**Billing unit**: per dose 88 mg/4 mL SD syringe

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GCHP Clinical Guidelines:

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	1 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 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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GCHP Clinical Guidelines:

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: 1. Patient's current weight 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	1 year initial; 2 years reauthorization. Dose will be approved according to the FDA- approved labeling or within accepted standards of medical practice. 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 100mg SDV

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GCHP Clinical Guidelines:

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:** 1. Medical records supporting the request, including documentation of prior therapies and responses to treatment must be provided - AND - 2. Must have an elevated eosinophil level greater than or equal to 150 cells/mcL within 6 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 - 3. Must try and fail 1 ICS/LABA inhaler drug in the past 6 months (fail is defined as an intolerance or inability to improve the condition on required therapy for at least 4 weeks). **For reauthorization requests for severe eosinophilic asthma:** 1. Medical records supporting the request, including documentation of prior therapies and responses to treatment must be provided 2. Must have clinical benefit (e.g., decrease in exacerbations, improvement in symptoms, decrease in oral steroid use). **For initial coverage of Hypereosinophilic Syndrome (HES):** 1. Medical records supporting the request, including documentation of prior therapies and responses to treatment must be provided 2. Must have a blood eosinophil count at least 1,000 cells/mcL 3. Must have had HES for at least 6 months 4. Must have had at least 2 flares of HES in the past year defined as symptoms requiring a steroid or increase in current steroid 5. The provider attests that there is NO identifiable non-

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	hematologic secondary cause of HES 6. Must try and fail (defined as an inability to improve symptoms) a generic steroid- sparing drug (e.g., methotrexate, hydroxyurea). **For reauthorization requests for Hypereosinophilic Syndrome (HES):** 1. Medical records supporting the request, including documentation of prior therapies and responses to treatment must be provided 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: 1 year; reauthorization: 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
J2182	Nucala (mepolizumab) Vial	**Billing unit**: 1 mg 100 mg SDV

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GCHP Clinical Guidelines:

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	1 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 250 mg SDV

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GCHP Clinical Guidelines:

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	1 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 300 mcg/0.5mL, 480 mcg/0.8 mL prefilled syringe

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GCHP Clinical Guidelines:

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. For initial requests, medical records supporting the request must be provided and include the following: 1. Diagnosis of moderate-to-severe COPD defined as an FEV1 between 30-70% 2. Trial and failure of dual or triple therapy in the past 6 months that included a LABA/LAMA therapy (e.g., Trelegy Ellipta, Anoro Ellipta, Stiolto Respimat). 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: 1 year. Reauthorization: 2 years. Dose will be approved according to the FDA- approved labeling or within accepted standards of medical practice. 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

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HCPCS	Description	Billing units/How supplied
J7601	Ohtuvayre (ensifentrine)	**Billing unit**: 3 mg 3 mg/2.5mL ampule

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GCHP Clinical Guidelines:

Omvoh *(mirikizumab-mrkz)* IV

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 0, week 4 and week 8) 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 300 mg/15 mL SDV

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GCHP Clinical Guidelines:

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 2. Must provide patient's current weight 3. Must have documentation of a transthyretin (TTR) mutation (e.g., V30M) **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 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	1 year initial and reauthorization. Dose will be approved according to the FDA-approved labeling or within accepted standards of medical practice. **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 10 mg/5 mL SDV

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GCHP Clinical Guidelines:

Ontruzant *(trastuzumab-dttb)*

PA Criteria	Criteria Details
Covered Uses (FDA approved indication)	Ontruzant is a trastuzumab biosimilar. 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: As part of a treatment regimen consisting of doxorubicin, cyclophosphamide, and either paclitaxel or docetaxel As part of a treatment regimen with docetaxel and carboplatin 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. https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdId=37205&ver=15
Age Restriction	None
Prescriber Restrictions	None
Coverage Duration	1 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 150 mg, 420 mg SDV

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GCHP Clinical Guidelines:

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	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
J0129	Orencia IV (abatacept) Vial	**Billing unit**: 10 mg 250 mg SDV

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GCHP Clinical Guidelines:

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	1 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
J7324	Orthovisc (hyaluronan/ hyaluronic acid) for intra-articular injection	**Billing unit**: per dose 30 mg/2 mL SD syringe

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GCHP Clinical Guidelines:

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; 2. Must have a diagnosis of primary hyperoxaluria type 1 (PH1) confirmed by genetic testing of the AGXT mutation or by liver enzyme analysis; 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: 1 year. Reauthorization: 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
J0224	Oxlumo (lumasiran)	**Billing unit**: 0.5 mg 94.5 mg/0.5 mL SDV

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GCHP Clinical Guidelines:

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 0.7 mg implant

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GCHP Clinical Guidelines:

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. https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdid=34771&ver=49&=
Age Restriction	None
Prescriber Restrictions	None
Coverage Duration	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
J1576	Panzyga (immune globulin) intravenous	**Billing unit**: 500 mg 1 gm, 2.5 gm, 5 gm, 10 gm, 20 gm, 30 gm SDV

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GCHP Clinical Guidelines:

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: 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. 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. https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdId=37205&ver=15
Age Restriction	None
Prescriber Restrictions	None
Coverage Duration	1 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 60 mg-60 mg-2000 unit/10 mL, 80 mg-40 mg-2000 unit/15 mL SDV

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GCHP Clinical Guidelines:

PiaSky (crovalimab-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: 1. Diagnosis confirmed by flow cytometry 2. Hemolysis-associated symptoms (thrombosis, organ dysfunction, pain, dyspnea, hemoglobin <10 g/dL etc.) 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**: 1 year. Reauthorization: 2 years. Dose will be approved according to the FDA- approved labeling or within accepted standards of medical practice. **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 340mg/2mL SDV

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GCHP Clinical Guidelines:

Pombiliti *(cipaglucosidase alfa-atga)*

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: 1. Patient's current weight 2. For initial coverage: Confirmation of diagnosis by enzyme assay or genetic testing
Age Restriction	Must be at least 18 years old.
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	1 year initial; 2 years reauthorization. Dose will be approved according to the FDA- approved labeling or within accepted standards of medical practice. 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 105 mg SDV

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GCHP Clinical Guidelines:

Pombiliti *(cipaglucosidase alfa-atga)*

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GCHP Clinical Guidelines:

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 LCD - Bisphosphonate Drug Therapy (L34648)
Age Restriction	None
Prescriber Restrictions	None
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
J0897	Prolia (denosumab)	**Billing unit**: 1 mg 60 mg/mL SD syringe

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GCHP Clinical Guidelines:

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: 1. Documentation confirming the diagnosis; 2. Documentation confirming the superoxide dismutase 1 (SOD1) gene mutation; 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: 1 year. Dose will be approved according to the FDA approved labeling or within accepted standards of medical practice. 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 6 months). 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 100 mg/15 mL (6.7 mg/mL) solution SDV

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GCHP Clinical Guidelines:

Qalsody *(tofersen)*

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GCHP Clinical Guidelines:

Reblozyl (*luspatercept-aamt)*

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:** 1. Use of Reblozyl for the treatment of anemia in an adult with beta thalassemia who requires regular blood transfusions defined as at least 6 red blood cell (RBC) units in the previous 24 weeks (6 months) prior to Reblozyl 2. The patient's current weight. **For Myelodysplastic Syndrome initial coverage, documentation to support the following is also required:** 1. Use of Reblozyl for very low- to intermediate-risk myelodysplastic syndromes as defined by IPSS-R risk score 2. The patient's current weight 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: 1 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

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HCPCS	Description	Billing units/How supplied
J0896	Reblozyl (luspatercept)	**Billing unit**: 0.25 mg 25 mg, 75 mg SDV

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GCHP Clinical Guidelines:

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	1 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 150ml Rectal Suspension

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GCHP Clinical Guidelines:

Releuko *(filgrastim-ayow)*

PA Criteria	Criteria Details
Covered Uses (FDA approved indication)	Releuko is a biosimilar to Neupogen. 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	1 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 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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GCHP Clinical Guidelines:

Remicade *(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	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
J1745	Remicade (infliximab) Generic Infliximab - Janssen only	**Billing unit**: 10 mg 100 mg SDV

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GCHP Clinical Guidelines:

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: 1 year. Reauthorization: 2 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. 2.4 mg/1.5 mL SDV

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GCHP Clinical Guidelines:

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. 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. https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?LCDId=35026
Age Restriction	None
Prescriber Restrictions	None
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
Q5123	Riabni (rituximab-arrx) biosimilar	**Billing unit**: 10 mg 100 mg/10 mL, 500 mg/50 mL SDV

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GCHP Clinical Guidelines:

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). 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. https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?LCDId=35026
Age Restriction	None
Prescriber Restrictions	None
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
J9311	Rituxan Hycela (rituximab/ hyaluronidase)	**Billing unit**: 10 mg 1400 mg-23400 units/11.7 mL, 1600 mg-26800 units/13.4 mL SDV

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GCHP Clinical Guidelines:

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. 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. https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?LCDId=35026
Age Restriction	None
Prescriber Restrictions	None
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
J9312	Rituxan (rituximab)	**Billing unit**: 10 mg 100 mg/10 mL, 500 mg/50 mL SDV

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GCHP Clinical Guidelines:

Rituxan *(rituximab)*

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GCHP Clinical Guidelines:

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; 2. Must have a diagnosis of primary hyperoxaluria type 1 (PH1) confirmed by genetic testing of the AGXT mutation or by liver enzyme analysis; 3. Must have preserved kidney function with an estimated glomerular filtrate rate (eGFR) of 30 mL/min/1.73m^2 or more; 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: 1 year. Reauthorization: 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
J3490*, C9399*	Rivfloza (nedosiran)	Additional information required: National Drug Code (NDC), Strength, Dosage administered, Route of administration. 128 mg/ 0.8 mL and 160 mg/mL prefilled syringe and 80 mg/0.5 mL SDV

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GCHP Clinical Guidelines:

Roctavian *(valoctocogene roxaparvovc-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) – AND - 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: 1. Patient's current weight 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 2 x 10^{13} vector genomes/mL SD infusion bag

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GCHP Clinical Guidelines:

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	1 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 13.2 mg/0.6 mL prefilled syringe

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GCHP Clinical Guidelines:

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 2 to 4 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 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
J2998	Ryplazim (plasminogen, human-tvmh)	**Billing unit**: 1 mg 68.8 mg/12.5 mL SDV

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GCHP Clinical Guidelines:

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:** 1. Baseline Myasthenia Gravis Activities of Daily Living (MG-ADL) of at least 3 2. Confirmed generalized myasthenia gravis that is anti-acetylcholine receptor antibody (AChR-Ab) positive or anti-muscle-specific tyrosine kinase [MuSK] anti-body positive - **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	1 year initial; 2 years reauthorization. Dose will be approved according to the FDA- approved labeling or within accepted standards of medical practice. **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 280mg/2ml (140mg/ml) SDV

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GCHP Clinical Guidelines:

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 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
J2502	Signifor LAR (pasireotide)	**Billing unit**: 1 mg 10 mg, 20 mg, 30 mg, 40 mg, 60 mg SDV

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GCHP Clinical Guidelines:

Simponi Aria *(golimumab)*

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	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
J1602	Simponi Aria (golimumab) IV	**Billing unit**: 1 mg 50 mg/4 mL SDV

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GCHP Clinical Guidelines:

Skyrizi *(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 600mg/10 mL SDV

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GCHP Clinical Guidelines:

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 300 mg/30 mL SDV

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GCHP Clinical Guidelines:

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:** Medical records supporting the request must be provided; 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); 2. Patient is experiencing a GPP flare of moderate-to-severe intensity defined by all the following (a, b, c, and d): a) a Generalized Pustular Psoriasis Physician Global Assessment (GPPPGA) total score of 3 or more; b) New or worsening pustules; c) a GPPPGA pustulation sub-score of 2 or more; and 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 450 mg/7.5 ml SDV

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GCHP Clinical Guidelines:

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	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
J2326	Spinraza (nusinersen sodium)	**Billing unit**: 0.1 mg 12 mg/5 mL SDV

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GCHP Clinical Guidelines:

Spravato *(esketamine)*

PA Criteria	Criteria Details
Covered Uses (FDA approved indication)	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.
Exclusion Criteria	None
Required Medical Information	Medical records supporting the request must be provided; Spravato must be used in combination with an oral antidepressant.
Age Restriction	Must be at least 18 years of age.
Prescriber Restrictions	Must be prescribed by or in consultation with a psychiatrist.
Coverage Duration	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
G2082 - up to 56mg **G2083** - greater than 56mg	Spravato (esketamine)	**Billing unit**: 1 mg 56 mg, 84 mg nasal spray kit (each kit contains 28 mg unit dose)

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GCHP Clinical Guidelines:

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. 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 130 mg/26 mL SDV

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GCHP Clinical Guidelines:

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	1 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 6 mg/0.6 mL prefilled syringe

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GCHP Clinical Guidelines:

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 10 mg/0.1mL SDV

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GCHP Clinical Guidelines:

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: 1 year. Reauthorization: 2 years. Dosing is limited to a frequency of every 60 days. 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 15mg/0.1mL SDV

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GCHP Clinical Guidelines:

Syfovre *(pegcetacoplan)*

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GCHP Clinical Guidelines:

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 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
J7331	Synojoynt (hyaluronan or derivative for intra-articular injection)	**Billing unit**: 1 mg 20 mg/2 mL

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GCHP Clinical Guidelines:

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 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
J7325	Synvisc/Synvisc One (hyaluronan/ hyaluronic acid) for intra-articular injection	**Billing unit**: 1 mg 16 mg/2 mL SD syringe (Synvisc); 48 mg/6 mL SD syringe (Synvisc-One)

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GCHP Clinical Guidelines:

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 Up to $2x10^8$ CAR+ t cells per SD infusion bag

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GCHP Clinical Guidelines:

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 500 mg SDV

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GCHP Clinical Guidelines:

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: 1 year; reauthorization: 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
J2356	Tezspire (tezepelumab-ekko) Pre-filled Autoinjector Pen	**Billing unit**: 1 mg 210 mg/1.91 mL Pen-injector

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GCHP Clinical Guidelines:

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 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
Q5133	Tofidence (tocilizumab-bavi) biosimilar	**Billing unit**: 1 mg 80 mg/4 mL, 200 mg/10 mL, 400 mg/20 mL SDV

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GCHP Clinical Guidelines:

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) 200mg/20ml vial (IV infusion)	**Billing unit**: 1 mg 200mg20 mL SDV

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GCHP Clinical Guidelines:

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 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
J7332	Triluron (hyaluronan/ hyaluronic acid) for intra-articular injection	**Billing unit**: 1 mg 20 mg/2 mL SD syringe

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GCHP Clinical Guidelines:

Triluron *(hyaluronan/hyaluronic acid)*

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GCHP Clinical Guidelines:

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 25 mg/2.5 mL SD syringe

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Approved	N/A	5/15/25	Pharmacy & Therapeutics (P&T) Committee	5/15/25

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GCHP Clinical Guidelines:

Tyenne *(tocilizumab-aazg)*

PA Criteria	Criteria Details
Covered Uses (FDA approved indication)	Tyenne is a biosimilar to Actemra (tocilizumab). 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	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
Q5135	Tyenne IV (tocilizumab-aazg)	**Billing unit**: 1 mg 80 mg/4 mL, 200 mg/10 mL, 400 mg/20 mL SDV

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GCHP 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)**: 1. Medical records supporting the request must be provided, including documentation of prior therapies and responses to treatment 2. Must have confirmation of diagnosis by right heart catheterization **For initial coverage of PH-ILD (WHO Group 3)**: 1. Medical records supporting the request must be provided - AND - 2. Must have confirmation of diagnosis by right heart catheterization 3. Must provide the patient's baseline 6-minute walk test (6MWT) - AND 4. 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**: 2 years initial and reauthorization. **For PH-ILD:** 1 year initial and 2 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 1.74 mg/2.9 mL SD ampule

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GCHP Clinical Guidelines:

Tyvaso *(treprostinil)* inhalation

STATUS	DATE REVISED	REVIEW DATE	APPROVED/REVIEWED BY	EFFECTIVE DATE
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GCHP Clinical Guidelines:

Tzield *(teplizumab-mzww)*

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. For approval, the following must be met: Must have documentation of at least 2 of the following autoantibodies: - Glutamic acid decarboxylase 65 (GAD) autoantibody: - Insulin autoantibody (IAA) - Insulinoma-associated antigen 2 autoantibody (IA-2A) - Zinc transporter 8 autoantibody (ZnT8A) - Islet cell autoantibody (ICA) Must have documentation of dysglycemia defined as meeting one of the following: - A fasting glucose level of 110 to 125 mg/dL – or – - A 2-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

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HCPCS	Description	Billing units/How supplied
J9381	Tzield (teplizumab-mzwv) injection	**Billing unit**: 5 mcg 2mg/2mL SDV

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GCHP Clinical Guidelines:

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	1 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 6 mg/0.6 mL SD syringe

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GCHP Clinical Guidelines:

Ultomiris (ravulizumab-cqvz)

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):** **1.** Patient has anti-aquaporin-4 (AQP4) antibody positive disease; 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; **3.** Ultomiris will not be used in combination with Soliris, Uplizna, Enspryng, or other medications for NMOSD; **4.** Must have an Expanded Disability Status Scale (EDSS) score of ≤7; Medical records supporting the request must be provided; 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. **For myasthenia gravis:** 1. Must have a baseline Myasthenia Gravis Activities of Daily Living (MG-ADL) of 6 or more; **2.** Confirmed diagnosis of generalized myasthenia gravis that is anti-acetylcholine receptor antibody (AChR-Ab) positive; **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

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	is no data to support use in combination with other medications used to treat MG); **4.** Medical records supporting the request must be provided; 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. **For paroxysmal nocturnal hemoglobinuria (PNH):** 1. Must have diagnosis confirmed by flow cytometry; 2. Must have hemolysis-associated symptoms (thrombosis, organ dysfunction, pain); 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); 4. Medical records supporting the request must be provided; 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.
Age Restriction	None
Prescriber Restrictions	For NMSOD: Must be prescribed by or in consultation with a neurologist.
Coverage Duration	1 year (initial); 2 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

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HCPCS	Description	Billing units/How supplied
J1303	Ultomiris (ravulizumab-cwvz)	**Billing unit**: 10 mg 300 mg/3 mL, 1100 mg/11 mL SDV

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GCHP Clinical Guidelines:

Uplizna (*inebilzumab-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 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
J1823	Uplizna (inebilizumab-cdon)	**Billing unit**: 1 mg 100 mg/10 mL SDV

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GCHP Clinical Guidelines:

Vegzelma *(bevacizumab-abcd)*

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: a) metastatic colorectal cancer, in combination with intravenous fluorouracil-based chemotherapy for first- or second-line treatment; 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; c) Unresectable, locally advanced, recurrent or metastatic non-squamous non-small cell lung cancer, in combination with carboplatin and paclitaxel for first-line treatment; d) recurrent glioblastoma in adult; 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 1 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

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	HCPCS	Description	Billing units/How supplied
	Q5129	Injection, bevacizumab-adcd (vegzelma), biosimilar, 10 mg	**Billing unit**: 10 mg 100 mg/4 mL SDV 400 mg/16 mL SDV

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GCHP Clinical Guidelines:

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 8. 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: 1. clinical diagnosis of CHAPLE disease that includes symptoms of the condition (such as diarrhea, vomiting, abdominal pain, etc.) and a low serum albumin; 2. confirmation of CD55 loss-of function mutation by genetic testing; 3. baseline serum albumin; and 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: 1 year; Reauthorization: 2 years. Dose will be approved according to the FDA- approved labeling or within accepted standards of medical practice. 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 400 mg/2 mL SDV

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GCHP Clinical Guidelines:

Veopoz *(pozelimab-bbfg)*

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GCHP Clinical Guidelines:

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	1 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	Injection, bendamustine hydrochloride (vivimusta), 1 mg	**Billing unit**: 1 mg 100mg/ 4 ml MDV

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GCHP Clinical Guidelines:

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: 1. Patient has levodopa-responsive advanced PD with clearly defined "on" periods; 2. Patient is receiving optimal carbidopa/levodopa therapy; 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. 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: 1 year. Reauthorization: 2 years. Dose will be approved according to the FDA- approved labeling or within accepted standards of medical practice. 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**: per 5.25 mg 120 mg/2,400 mg per 10 mL SDV

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GCHP Clinical Guidelines:

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:** (1) Medical records supporting the request must be provided; (2) Patient must be evaluated for and determined not to have medication overuse headache (MOH);
Age Restriction	None
Prescriber Restrictions	None
Coverage Duration	6 months initial coverage; 2 years reauthorization. Dose will be approved according to the FDA approved labeling or within accepted standards of medical practice. 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 100 mg/mL SDV

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GCHP Clinical Guidelines:

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:** Medical records supporting the request must be provided. 1. Baseline Myasthenia Gravis Activities of Daily Living (MG-ADL) of at least 5 2. Confirmed diagnosis of generalized myasthenia gravis that is anti-acetylcholine receptor antibody (AChR-Ab) positive **For reauthorization:** 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	1 year initial; 2 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 400mg/20ml SDV

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GCHP Clinical Guidelines:

Vyvgart *(efgartigimod alfa-fcab)*

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GCHP Clinical Guidelines:

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: **1.** Must have a confirmed diagnosis of Pulmonary Arterial Hypertension (PAH), World Health Organization Group 1, by right heart catheterization; **2.** Must have WHO functional class II or III symptoms; 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: 1 year; Reauthorization: 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
J3590*, C9399*	Winrevair (sotatercept-csrk)	Additional information required: National Drug Code (NDC), Strength, Dosage administered, Route of administration. 45mg, 60mg SDV

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GCHP Clinical Guidelines:

Winrevair *(sotatercept)*

STATUS	DATE REVISED	REVIEW DATE	APPROVED/REVIEWED BY	EFFECTIVE DATE
Created	3/26/25	3/26/25	Dawn Shojai, PharmD, Senior Pharmacy Benefit Consultant (PSG)	N/A
Approved	N/A	8/21/25	Pharmacy & Therapeutics (P&T) Committee	8/21/25

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GCHP Clinical Guidelines:

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. For initial coverage, must also provide the following: 1. Documentation of a diagnosis of acid sphingomyelinase deficiency (ASMD) Type A/B or Type B 2. Confirmation of ASMD by enzyme assay demonstrating low ASM enzyme activity (<10% of controls) 3. Clinical symptoms of ASMD including low diffusion capacity of the lungs for carbon monoxide (DLCO) and splenomegaly 4. Baseline DLCO 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: 1 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

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HCPCS	Description	Billing units/How supplied
J0218	Xenpozyme (olipudase alfa-rpcp)	**Billing unit**: 1 mg 20mg SDV

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GCHP Clinical Guidelines:

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 2 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 120 mg/1.7 mL SDV

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GCHP Clinical Guidelines:

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 40 mg/mL SDV

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GCHP Clinical Guidelines:

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:** 1. Medical records supporting the request must be provided, including documentation of prior therapies and responses to treatment must be provided 2. Must have tried and failed 1 ICS/LABA inhaler in combination with 1 other asthma controller drug in the past 6 months (failed is defined as an intolerance or inability to improve the condition on required therapy for at least 4 weeks); 3. Must provide patient's current weight and baseline IgE level 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) 5. A baseline (defined above) positive skin test or in vitro reactivity to a perennial aeroallergen. **For reauthorization requests for asthma:** 1. Medical records supporting the request must be provided, including documentation of prior therapies and responses to treatment must be provided 2. Must provide patient's current weight and baseline IgE level 3. (2) Must have documented clinical benefit (e.g., decrease in exacerbations, improvement in symptoms)

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For initial coverage of chronic urticaria:

1. Medical records supporting the request must be provided, including documentation of prior therapies and responses to treatment must be provided
2. Patient has a confirmed diagnosis of chronic urticaria defined as urticaria occurring for more than 6 weeks
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 1 of the following: H2 antihistamine (e.g., famotidine), oral steroid, or leukotriene modifier.

For reauthorization requests for chronic urticaria:

1. Medical records supporting the request must be provided, including documentation of prior therapies and responses to treatment must be provided
2. Must have documented clinical benefit (e.g. decrease in exacerbations, improvement in symptoms, decrease in steroid use).

For initial coverage of nasal polyps:

1. Medical records supporting the request must be provided, including documentation of prior therapies and responses to treatment must be provided
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)
3. Must try and fail (defined as an inability to improve symptoms for least 4 weeks) intranasal steroids
4. Must be used in combination with an intranasal steroid
5. Must provide patient's current weight and baseline IgE level.

For reauthorization requests for nasal polyps:

1. Medical records supporting the request must be provided, including documentation of prior therapies and responses to

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	treatment must be provided 2. Must have documented clinical benefit (e.g. decrease in exacerbations, improvement in symptoms, decrease in steroid use) 3. Must provide patient's current weight and baseline IgE level 4. Must continue to be used in combination with an intranasal steroid **For initial coverage of food allergy:** 1. Medical records supporting the request must be provided 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 3. Patient has a clinical history of a significant allergic reaction to the specified foods 4. Patient has a baseline IgE level of at least 30 IU/mL 5. Xolair must be used in conjunction with a food allergen-avoidant diet 6. Patient's current weight and baseline IgE level have been provided 7. Patient is at least 1 year of age. **For reauthorization requests for food allergy:** 1. Medical records supporting the request must be provided 2. Xolair must continue to be used in conjunction with a food allergen-avoidant diet 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	1 year initial and reauthorization for food allergy; 1 year initial and 2 years reauthorization for all others. 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

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HCPCS	Description	Billing units/How supplied
J2357	Xolair (omalizumab) Vial/Prefilled syringe	**Billing unit**: 5 mg 150 mg SDV,; 75 mg, 150 mg SD syringe

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GCHP Clinical Guidelines:

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: • Adult patients with large B-cell lymphoma that is refractory to first-line chemoimmunotherapy or that relapses within 12 months of first-line chemoimmunotherapy. • 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. 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 Up to 2 x 10^8 CAR+ T-cells per SD infusion bag

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GCHP Clinical Guidelines:

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 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
J7677	Yupelri (revefenacin)	**Billing unit**: 1 mcg 175 mcg/3 mL SDV

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GCHP Clinical Guidelines:

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. 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 0.18 mg implant

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GCHP Clinical Guidelines:

Ziextenzo *(pegfilgrastim-bmez)*

PA Criteria	Criteria Details
Covered Uses (FDA approved indication)	Ziextenzo 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. • Increase survival in patients acutely exposed to myelosuppressive doses of radiation (Hematopoietic Subsyndrome of Acute Radiation Syndrome) 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	1 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 6 mg/0.6 mL SD syringe

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GCHP Clinical Guidelines:

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:** 1. Medical records supporting the request must be provided. 2. Confirmed generalized myasthenia gravis that is anti-acetylcholine receptor antibody (AChR-Ab) positive 3. Baseline Myasthenia Gravis Activities of Daily Living (MG-ADL) of 6 or more 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	12 weeks (initial); 1 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. 16.6 mg/0.416 mL, 23 mg/0.574 mL, and 32.4 mg/0.81 mL prefilled syringes

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GCHP Clinical Guidelines:

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 5.5 mL or 8.3 mL SDV (each kit will provide sufficient number of vials based on patient weight)

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GCHP Clinical Guidelines:

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; 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	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
J1748	Zymfentra (infliximab-dyyb)	**Billing unit**: 10 mg 120 mg/mL prefilled syringe and prefilled pen

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GCHP Clinical Guidelines:

Zynteglo *(onasemnogene abeparvovec)*

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; 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 2 years OR at least 8 transfusions of pRBCs per year in the previous 2 years; 3. Must not have a known and available HLA matched donor as determined by the hematologist and/or transplant specialist; 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

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HCPCS	Description	Billing units/How supplied
J3393	Zynteglo (betibeglogene autotemcel)	**Billing unit**: per dose 20 mL infusion bag

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