

| PA Criteria | Criteria Details | | | | | | | | | | | | | | |
|---|--|---|----------------|--------------|-------------------------------------|---|---|-------|-----------------------------------|----------------------|-------------|-------|--|-------|--|
| Description | IMAAVY™ is a neonatal Fc receptor (FcRn) blocker; it is a human IgG1 monoclonal antibody that binds to FcRn resulting in the reduction of circulating IgG levels. | | | | | | | | | | | | | | |
| Covered Uses (FDA approved indication) | IMAAVY is indicated for the treatment of generalized myasthenia gravis (gMG) in adults and pediatric patients ≥ 12 years of age who are anti-acetylcholine receptor (AChR) or anti-muscle-specific tyrosine kinase (MuSK) antibody positive. | | | | | | | | | | | | | | |
| Dosing and Administration | <table border="1"> <thead> <tr> <th>Indication</th> <th>Dosing Regimen</th> <th>Maximum Dose</th> </tr> </thead> <tbody> <tr> <td>Generalized Myasthenia Gravis (gMG)</td> <td>Initial Dose: 30 mg/kg IV infusion over 30 min Maintenance Dose: 15 mg/kg IV infusion over minimum 15 min; administered two weeks after initial dose; continue every two weeks thereafter.</td> <td>Initial Dose: 30 mg/kg Maintenance: 15 mg/kg</td> </tr> </tbody> </table> | Indication | Dosing Regimen | Maximum Dose | Generalized Myasthenia Gravis (gMG) | Initial Dose: 30 mg/kg IV infusion over 30 min Maintenance Dose: 15 mg/kg IV infusion over minimum 15 min; administered two weeks after initial dose; continue every two weeks thereafter. | Initial Dose: 30 mg/kg Maintenance: 15 mg/kg | | | | | | | | |
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| Billing and Coding Information | <table border="1"> <thead> <tr> <th>10-digit NDC</th> <th>11-digit NDC</th> </tr> </thead> <tbody> <tr> <td>57894-801-01</td> <td>57894-0801-01</td> </tr> </tbody> </table> <table border="1"> <thead> <tr> <th>HCPCS Code</th> <th>Description</th> </tr> </thead> <tbody> <tr> <td>C9305</td> <td>Injection, nipocalimab-aahu, 3 mg</td> </tr> </tbody> </table> <table border="1"> <thead> <tr> <th>CPT Procedural Codes</th> <th>Description</th> </tr> </thead> <tbody> <tr> <td>96365</td> <td>IV infusion, for therapy, prophylaxis, or diagnosis; initial, up to one hour</td> </tr> <tr> <td>96413</td> <td>Chemotherapy administration, IV infusion; up to one hour</td> </tr> </tbody> </table> <p>NOTE: an infusion of 15 minutes or less is considered an IV push.</p> | 10-digit NDC | 11-digit NDC | 57894-801-01 | 57894-0801-01 | HCPCS Code | Description | C9305 | Injection, nipocalimab-aahu, 3 mg | CPT Procedural Codes | Description | 96365 | IV infusion, for therapy, prophylaxis, or diagnosis; initial, up to one hour | 96413 | Chemotherapy administration, IV infusion; up to one hour |
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| Product Availability | <p><i>Single-dose vial:</i> 1200 mg/6.5 mL (185 mg/mL)</p> <p>**300 mg/1.62 mL vial anticipated to be commercially available in 2026**</p> | | | | | | | | | | | | | | |
| Contraindications | Patients with a history of serious hypersensitivity reactions (including anaphylaxis and angioedema) to nipocalimab or any of the excipients in IMAAVY™. | | | | | | | | | | | | | | |

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| <p>Recommended Medical Monitoring</p> | <p>IMAAVY has been associated with:</p> <ul style="list-style-type: none"> • Infections • Hypersensitivity reactions (angioedema, anaphylaxis, rash, urticaria, and eczema) • Infusion-related reactions <p>Patients should be monitored for any of these reactions. IMAAVY dose may be delayed, reduced or permanently discontinued based on the severity of adverse reactions.</p> <p>Immunizations:</p> <ul style="list-style-type: none"> • The safety of immunization with LIVE vaccines and the immune response to vaccination during treatment with IMAAVY are unknown. • Because IMAAVY causes a reduction in IgG levels, vaccination with LIVE vaccines is not recommended during treatment with IMAAVY (<i>see Appendix</i>). <p>Drug-Drug Interactions:</p> <ul style="list-style-type: none"> • Concomitant use with medications that bind to the human neonatal Fc receptor (FcRn) may lower systemic exposures and reduce effectiveness of said medications (<i>see Appendix</i>). • Closely monitor patients for reduced effectiveness of medications that bind to FcRn |
| <p>Approval Criteria</p> | <ul style="list-style-type: none"> a. Physician administered IV infusion; in-office or HOPD <ul style="list-style-type: none"> i. Cannot be self-administered b. Generalized Myasthenia Gravis (must meet all): <ul style="list-style-type: none"> i. Diagnosis of Generalized Myasthenia Gravis <ul style="list-style-type: none"> 1. Myasthenia Gravis Foundation of America classification of II – IV; AND 2. Myasthenia Gravis Activities of Daily Living (MG-ADL) score \geq 6 ii. Prescribed by or in consultation with a neurologist iii. Patient age \geq 12 years of age iv. Patient meets ONE of the following: <ul style="list-style-type: none"> 1. Confirmed anti-acetylcholine receptor antibody positive; OR 2. Confirmed anti-muscle-specific tyrosine kinase antibody positive v. Patient on stable dose of standard of care gMG therapy (<i>see Appendix</i>) vi. Patient has evidence of unresolved symptoms of gMG (<i>see Appendix</i>) vii. Initial dose does not exceed 30 mg/kg as a single dose viii. Maintenance dose does not exceed 15 mg/kg every two weeks |
| <p>Age Restriction</p> | <p>Age \geq 12 years.</p> |
| <p>Coverage Duration</p> | <p>Initial: six months. Reauthorization: 12 months.</p> <p>Dose will be approved according to the FDA approved labeling or within accepted standards of medical practice.</p> |

| Appendix | Examples of drugs that bind to FcRn Receptors | Examples of standard of care treatments for gMG | Examples of unresolved symptoms of gMG |
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| | <ul style="list-style-type: none"> a. Monoclonal Antibodies b. Immunoglobulin products c. Antibody derivatives containing the human Fc domain <ul style="list-style-type: none"> • Abrocitinib • Antithymocyte Globulin • Baricitinib • Brincidofovir • Brivudine • Certolizumab • Delgocitinib • Denosumab • Deucravacitinib • Etanercept • Etrasimod • Filgotinib • Inebilizumab • Infliximab • Leflunomide • Natalizumab • Ocrelizumab • Ofatumumab • Omalizumab • Pimecrolimus • Ritlecitinib • Tofacitinib • Trastuzumab • Ublituximab • Upadacitinib | <ul style="list-style-type: none"> a. Any combination of the following: <ul style="list-style-type: none"> i. Anticholinesterase <ul style="list-style-type: none"> • Pyridostigmine • Neostigmine ii. Corticosteroid <ul style="list-style-type: none"> • Prednisone iii. Immunosuppressant <ul style="list-style-type: none"> • Azathioprine • Cyclophosphamide • Cyclosporine • Eculizumab • Efgartigimod alfa • Methotrexate • Mycophenolate mofetil • Ravulizumab • Rituximab • Rozanolixizumab • Tacrolimus • Zulicoplan | <ul style="list-style-type: none"> a. Any functional disability resulting in discontinuation of physical activity b. Changes in facial expressions c. Decrease in respiratory function d. Diplopia e. Fatigue f. Problems chewing g. Problems swallowing h. Problems talking i. Ptosis j. Trouble walking k. Weakness in hands, fingers, feet, legs or neck |
| | | List of Live Vaccinations | |
| | | <ul style="list-style-type: none"> • Adenovirus vaccine • Bacille Calmette-Guérin (BCG) • Dengue tetravalent live vaccine • Live attenuated influenza vaccine (intranasal) • Live attenuated oral poliovirus vaccine • Measles, mumps, and rubella vaccine • Measles, mumps, rubella, and varicella vaccine • Measles vaccine • Mumps vaccine • Oral typhoid vaccine • Rotavirus vaccine (oral) • Rubella vaccine • Smallpox vaccine • Varicella vaccine • Yellow fever vaccine • Zoster vaccine live | |



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