

**Medicare Part B
Step Therapy Program**

Questions about Step Therapy?

**Cigna Healthcare has
the answers.**



What is Step Therapy?

Step Therapy is a required process that applies to certain Part B prescription drugs.

How does Step Therapy work?

Step Therapy requires customers to first try a preferred medication over non-preferred medications that treat the same condition.

What if the preferred medication is ineffective?

If the preferred medication is proven ineffective or causes negative side-effects, then a non-preferred medication may be covered.

What if the preferred drug has been tried in the past?

If the preferred medication was tried in the past 365 days, a non-preferred medication may be covered. If the preferred medication hasn't been tried in the past 365 days, Step Therapy is required.

How do I find out what drugs require Part B Step Therapy?

The Step Therapy chart applies to all Cigna HealthcareSM Medicare markets.



| Step Therapy drug class | Preferred* medications | Non-preferred medications |
|--|--|---|
| Antiemetic - Serotonin Receptor Antagonists (Injectable) for Oncology | <ul style="list-style-type: none"> • Aloxi • Granisetron • Ondansetron | Sustol |
| Antiemetic - Substance P/Neurokinin-1 Receptor Antagonists (Injectable) for Oncology | Emend | <ul style="list-style-type: none"> • Akynzeo • Cinvanti |
| Bevacizumab (Oncology) | <ul style="list-style-type: none"> • Mvasi • Zirabev | <ul style="list-style-type: none"> • Alymsys • Avastin • Vegzelma |
| Botulinum Toxins | <ul style="list-style-type: none"> • Botox • Daxxify • Dysport • Xeomin | Myobloc |
| Colony Stimulating Factors Short-Acting | <ul style="list-style-type: none"> • Nivestym • Zarxio | <ul style="list-style-type: none"> • Granix • Neupogen • Releuko |
| Colony Stimulating Factors Long-Acting | <ul style="list-style-type: none"> • Neulasta/Neulasta Onpro • Nyvepria • Udenyca | <ul style="list-style-type: none"> • Fulphila • Fylnetra • Rolvedon • Stimufend • Zixtenzo |
| Immune Globulins IV | <ul style="list-style-type: none"> • Flebogamma DIF • Gammagard Liquid • Gammagard S/D • Gammaked • Gammaplex • Gamunex-C • Octagam • Privigen | <ul style="list-style-type: none"> • Alyglo • Asceniv • Bivigam • Panzyga |
| Immune Globulins SC | <ul style="list-style-type: none"> • Cutaquig • Gammagard Liquid • Gammaked • Gamunex-C • Hizentra • Xembify | <ul style="list-style-type: none"> • Cuvitru • HyQvia |
| Immunomodulators | <ul style="list-style-type: none"> • Avsola • Inflectra • Renflexis | Remicade, infliximab (authorized generic) |
| Intravenous Iron | Venofer | <ul style="list-style-type: none"> • Feraheme • Injectafer • Monoferric |
| Ophthalmic Disorders Intravitreal Vascular Endothelial Growth Factor (VEGF) Inhibitors | Avastin | <ul style="list-style-type: none"> • Beovu • Byooviz • Cimerli • Eylea • Eylea HD • Lucentis • Vabysmo |

*Preferred medications may require prior authorization.

| Step Therapy drug class | Preferred* medications | Non-preferred medications | |
|---|--|--|--|
| Paclitaxel Medications | Paclitaxel | <ul style="list-style-type: none"> • Abraxane • Paclitaxel protein-bound | |
| Rituximab | <ul style="list-style-type: none"> • Riabni • Ruxience • Truxima | <ul style="list-style-type: none"> • Rituxan Hycela • Rituxan IV | |
| Somatostatin Analogs Long-Acting | <ul style="list-style-type: none"> • Somatuline Depot (J1930) • Lanreotide (J1930) | <ul style="list-style-type: none"> • Lanreotide (J1932) • Sandostatin LAR | |
| Systemic Lupus Erythematosus (SLE) [Lupus] | Benlysta IV | Saphnelo | |
| Testosterone Injectable | <ul style="list-style-type: none"> • Depo-Testosterone (testosterone cypionate) • Delatestryl (testosterone enanthate) | <ul style="list-style-type: none"> • Aveed • Testopel • Xyoster | |
| Trastuzumab | <ul style="list-style-type: none"> • Kanjinti • Ogvri • Trazimera | <ul style="list-style-type: none"> • Herceptin • Hylecta • Herceptin IV | <ul style="list-style-type: none"> • Herzuma • Ontruzant |
| Viscosupplements | <ul style="list-style-type: none"> • Monovisc • Orthovisc • Synvisc • Synvisc One | <ul style="list-style-type: none"> • Durolane • Euflexxa • Gel-One • Gelsyn-3 • GenVisc 850 • Hyalgan • Hymovis | <ul style="list-style-type: none"> • Sodium Hyaluronate 1% • Supartz FX • Synojoont • Triluron • TriVisc • Visco-3 |

For the following classes, preferred medications may be covered under the Part D (pharmacy) benefit:

| Step Therapy drug class | Preferred* medications | Non-preferred medications |
|---|--|---------------------------|
| Calcitonin Gene-Related Peptide Inhibitors** | Preferred Part D medications (reference Part D Drug List and Part D UM requirements) | Vyepti |
| Proprotein Convertase Subtilisin/Kexin Type 9 (PSEN9) Inhibitors** | Preferred Part D medications (reference Part D Drug List and Part D UM requirements) | Leqvio |

*Preferred medications may require prior authorization.

**Applies to MAPD plans only.

Coverage criteria

Antiemetic - Serotonin Receptor Antagonists (injectable) for oncology

| Preferred* medications | Non-preferred medications |
|---|---------------------------|
| <ul style="list-style-type: none">AloxiGranisetronOndansetron | Sustol |

Non-preferred medication Step Therapy criteria

Applicable MAC regions: CGS JI5, FCSO JN, NGS J6, NGS JK, Noridian JE, Noridian JF, Novitas JH, Novitas JL, Palmetto JJ, Palmetto JM, WPS J5, WPS J8.

Sustol may be covered for chemotherapy-induced nausea and vomiting prevention when the criteria listed below is satisfied:

- History of use (brand or generic) of one injectable preferred medication **or**
- Continuation of prior therapy or use within the past 365 days.

Antiemetic – Substance P/Neurokinin-1 Receptor Antagonists (injectable) for oncology

| Preferred* medications | Non-preferred medications |
|------------------------|--|
| Emend | <ul style="list-style-type: none">AkynzeoCinvanti |

Non-preferred medication Step Therapy criteria

Applicable MAC regions: CGS JI5, FCSO JN, NGS J6, NGS JK, Noridian JE, Noridian JF, Novitas JH, Novitas JL, Palmetto JJ, Palmetto JM, WPS J5, WPS J8.

Akynzeo or Cinvanti may be covered for chemotherapy-induced nausea and vomiting prevention when the criteria listed below is satisfied:

- History of use of intravenous preferred medication (brand or generic) **or**
- Continuation of prior therapy or use within the past 365 days.

Bevacizumab (Oncology)

| Preferred* medications | Non-preferred medications |
|---|--|
| <ul style="list-style-type: none">MvasiZirabev | <ul style="list-style-type: none">AlymsysAvastinVegzelma |

Non-preferred medication Step Therapy criteria

Applicable MAC regions: CGS JI5, FCSO JN, NGS J6, NGS JK, Noridian JE, Noridian JF, Novitas JH, Novitas JL, Palmetto JJ, Palmetto JM, WPS J5, WPS J8.

Alymsys, Avastin or Vegzelma may be covered for oncology indications when the criteria listed below is satisfied:

- History of use of one preferred medication **and**
- Cannot continue to use the preferred medication due to a formulation difference in the inactive ingredient(s) which, according to the prescriber, would result in a significant allergy or serious adverse reaction **or**
- Continuation of prior therapy or use within the past 365 days.

Botulinum Toxins

| Preferred* medications | Non-preferred medications |
|--|---------------------------|
| <ul style="list-style-type: none">• Botox• Daxxify• Dysport• Xeomin | Myobloc |

Non-preferred medication Step Therapy criteria

Applicable MAC regions: CGS JI5, NGS J6, NGS JK.

Myobloc may be covered when the criteria listed below is satisfied:

- Myobloc is being prescribed to treat one of the following conditions:
 - > Chronic Sialorrhea or
 - > Urinary Incontinence Associated with a Neurological Condition or
 - > Primary Axillary Hyperhidrosis or
- History of use of one preferred medication **or**
- Continuation of prior therapy or use within the past 365 days.

Non-preferred medication Step Therapy criteria

Applicable MAC regions: FCSO JN, Noridian JE, Noridian JF, Novitas JH, Novitas JL.

Myobloc may be covered when the criteria listed below is satisfied:

- History of use of one preferred medication **or**
- Continuation of prior therapy or use within the past 365 days.

Non-preferred medication Step Therapy criteria

Applicable MAC regions: Palmetto JJ, Palmetto JM.

Myobloc may be covered when the criteria listed below is satisfied:

- Myobloc is being prescribed to treat one of the following conditions:
 - > Overactive Bladder with Symptoms of Urge Urinary Incontinence, Urgency, and Frequency or
 - > Urinary Incontinence Associated with a Neurological Condition or
 - > Primary Axillary Hyperhidrosis or
- History of use of one preferred medication **or**
- Continuation of prior therapy or use within the past 365 days.

Non-preferred medication Step Therapy criteria

Applicable MAC regions: WPS J5, WPS J8.

Myobloc may be covered when the criteria listed below is satisfied:

- Myobloc is being prescribed to treat one of the following conditions:
 - > Palmar Hyperhidrosis or
 - > Primary Axillary Hyperhidrosis or
- History of use of one preferred medication **or**
- Continuation of prior therapy or use within the past 365 days.

Colony Stimulating Factors Short-Acting

| Preferred* medications | Non-preferred medications |
|---|---|
| <ul style="list-style-type: none">NivestymZarxio | <ul style="list-style-type: none">GranixNeupogenReleuko |

Non-preferred medication Step Therapy criteria

Applicable MAC regions: CGS JI5, FCSO JN, NGS J6, NGS JK, Noridian JE, Noridian JF, Novitas JH, Novitas JL, Palmetto JJ, Palmetto JM, WPS J5, WPS J8.

Granix, Neupogen or Releuko may be covered when the criteria listed below is satisfied:

- History of use of one preferred medication **and**
- Cannot continue to use the preferred medication due to a formulation difference in the inactive ingredient(s) which, according to the prescriber, would result in a significant allergy or serious adverse reaction **or**
- Continuation of prior therapy or use within the past 365 days.

Colony Stimulating Factors Long-Acting

| Preferred* medications | Non-preferred medications |
|--|--|
| <ul style="list-style-type: none">Neulasta/Neulasta OnproNyvepriaUdenyca | <ul style="list-style-type: none">FulphilaFylnetraRolvedon <ul style="list-style-type: none">StimufendZiextenzo |

Non-preferred medication Step Therapy criteria

Applicable MAC regions: CGS JI5, FCSO JN, NGS J6, NGS JK, Noridian JE, Noridian JF, Novitas JH, Novitas JL, Palmetto JJ, Palmetto JM, WPS J5, WPS J8.

Fulphila, Fylnetra, Stimufend or Ziextenzo may be covered when the criteria listed below is satisfied:

- History of use of one preferred medication **and**
- Cannot continue to use the preferred medication due to a formulation difference in the inactive ingredient(s) which, according to the prescriber, would result in a significant allergy or serious adverse reaction **or**
- Continuation of prior therapy or use within the past 365 days.

Rolvedon may be covered when criteria listed below is satisfied:

- History of use of one pegfilgrastim medication **or**
- Continuation of prior therapy or use within the past 365 days.

Immune Globulins IV

| Preferred* medications | Non-preferred medications |
|---|--|
| <ul style="list-style-type: none">Flebogamma DIFGammagard LiquidGammagard S/DGammaked <ul style="list-style-type: none">GammaplexGamunex-COctagamPrivigen | <ul style="list-style-type: none">AlygloAsceniv <ul style="list-style-type: none">BivigamPanzyga |

Non-preferred medication Step Therapy criteria

Applicable MAC regions: CGS JI5. Additional MAC regions are listed below.

Alyglo, may be covered when the criteria listed below are satisfied:

- A product with minimal content of coagulation factor XIa is needed based on a comorbidity of the patient, per prescriber, **or**

- Alyglo is being prescribed to treat one of the following conditions:
 - > Immune Thrombocytopenia (ITP), or
 - > Human Immunodeficiency Virus (HIV)-Infected Infants and Children to Prevent Recurrent Infections, or
 - > Guillain Barre Syndrome, or
 - > Multiple Sclerosis (MS), Acute Severe Exacerbation or Relapses, or
 - > Autoimmune Mucocutaneous Blistering Diseases (Pemphigus Vulgaris, Pemphigus Foliaceus, Bullous Pemphigoid, Mucous Membrane Pemphigoid [Cicatricial Pemphigoid], and Epidermolysis Bullosa Acquisita), or
 - > Chronic Inflammatory Demyelinating Polyneuropathy (CIDP) or Polyradiculoneuropathy, or
 - > Multifocal Motor Neuropathy (MMN), or
 - > Dermatomyositis or Polymyositis, or
 - > Myasthenia Gravis, or
 - > Lambert-Eaton Myasthenic Syndrome (LEMS), or
 - > Autoimmune Hemolytic Anemia, or
 - > Stiff-Person Syndrome (Moersch-Woltman Syndrome), or
- History of use of two preferred medications, **or**
- Continuation of prior therapy or use within the past 365 days.

Asceniv, may be covered when the criteria listed below are satisfied:

- Patient requires an immune globulin with elevated levels of respiratory syncytial virus (RSV) antibodies, per prescriber (such as a patient requiring elevated levels of RSV antibodies for repeated RSV infections despite adequate immune globulin dosing in a compliant patient), or
- Asceniv is being prescribed to treat one of the following conditions:
 - > Immune Thrombocytopenia (ITP), or
 - > Human Immunodeficiency Virus (HIV)-Infected Infants and Children to Prevent Recurrent Infections, or
 - > Guillain Barre Syndrome, or
 - > Multiple Sclerosis (MS), Acute Severe Exacerbation or Relapses, or
 - > Autoimmune Mucocutaneous Blistering Diseases (Pemphigus Vulgaris, Pemphigus Foliaceus, Bullous Pemphigoid, Mucous Membrane Pemphigoid [Cicatricial Pemphigoid], and Epidermolysis Bullosa Acquisita), or
 - > Chronic Inflammatory Demyelinating Polyneuropathy (CIDP) or Polyradiculoneuropathy, or
 - > Multifocal Motor Neuropathy (MMN), or
 - > Dermatomyositis or Polymyositis, or
 - > Myasthenia Gravis, or
 - > Lambert-Eaton Myasthenic Syndrome (LEMS), or
 - > Autoimmune Hemolytic Anemia, or
 - > Stiff-Person Syndrome (Moersch-Woltman Syndrome), or
- History of use of two preferred medications, **or**
- Continuation of prior therapy or use within the past 365 days.

Bivigam or Panzyga, may be covered when the criteria listed below are satisfied:

- Bivigam or Panzyga is being prescribed to treat one of the following conditions:
 - > Immune Thrombocytopenia (ITP), or
 - > Human Immunodeficiency Virus (HIV)-Infected Infants and Children to Prevent Recurrent Infections, or
 - > Guillain Barre Syndrome, or
 - > Multiple Sclerosis (MS), Acute Severe Exacerbation or Relapses, or
 - > Autoimmune Mucocutaneous Blistering Diseases (Pemphigus Vulgaris, Pemphigus Foliaceus, Bullous Pemphigoid, Mucous Membrane Pemphigoid [Cicatricial Pemphigoid], and Epidermolysis Bullosa Acquisita), or
 - > Chronic Inflammatory Demyelinating Polyneuropathy (CIDP) or Polyradiculoneuropathy, or
 - > Multifocal Motor Neuropathy (MMN), or
 - > Dermatomyositis or Polymyositis, or
 - > Myasthenia Gravis, or
 - > Lambert-Eaton Myasthenic Syndrome (LEMS), or
 - > Autoimmune Hemolytic Anemia, or
 - > Stiff-Person Syndrome (Moersch-Woltman Syndrome), or
- History of use of two preferred medications, **or**
- Continuation of prior therapy or use within the past 365 days.

Non-preferred medication Step Therapy criteria

Applicable MAC regions: FCSO JN, Novitas JH, Novitas JL. Additional MAC regions are listed below.

Alyglo, may be covered when the criteria listed below are satisfied:

- A product with minimal content of coagulation factor XIa is needed based on a comorbidity of the patient, per prescriber, **or**
- Alyglo is being prescribed to treat one of the following conditions:
 - > Autoimmune Mucocutaneous Blistering Diseases (Pemphigus Vulgaris, Pemphigus Foliaceus, Bullous Pemphigoid, Mucous Membrane Pemphigoid [Cicatricial Pemphigoid], and Epidermolysis Bullosa Acquisita), or
 - > Autoimmune Hemolytic Anemia, or
 - > Lambert-Eaton Myasthenic Syndrome (LEMS), or
 - > Neuromyelitis Optica (Devia Syndrome), or
 - > Treatment of Autoimmune Encephalitis, or
 - > Dermatomyositis or Polymyositis, or
 - > Inclusion Body Myositis, or
 - > Immune-Mediated Necrotizing Myopathy, or
 - > Overlap Syndrome with Myositis (Including Anti-Synthetase Syndrome), or
 - > Systemic Lupus Erythematosus, or
 - > Thyroid Eye Disease (Grave's Disease), or
- History of use of two preferred medications, **or**
- Continuation of prior therapy or use within the past 365 days.

Asceniv, may be covered when the criteria listed below are satisfied:

- Patient requires an immune globulin with elevated levels of respiratory syncytial virus (RSV) antibodies, per prescriber (such as a patient requiring elevated levels of RSV antibodies for repeated RSV infections despite adequate immune globulin dosing in a compliant patient), **or**
- Asceniv is being prescribed to treat one of the following conditions:
 - > Autoimmune Mucocutaneous Blistering Diseases (Pemphigus Vulgaris, Pemphigus Foliaceus, Bullous Pemphigoid, Mucous Membrane Pemphigoid [Cicatricial Pemphigoid], and Epidermolysis Bullosa Acquisita), or
 - > Autoimmune Hemolytic Anemia, or
 - > Lambert-Eaton Myasthenic Syndrome (LEMS), or
 - > Neuromyelitis Optica (Devia Syndrome), or
 - > Treatment of Autoimmune Encephalitis, or
 - > Dermatomyositis or Polymyositis, or
 - > Inclusion Body Myositis, or
 - > Immune-Mediated Necrotizing Myopathy, or
 - > Overlap Syndrome with Myositis (Including Anti-Synthetase Syndrome), or
 - > Systemic Lupus Erythematosus, or
 - > Thyroid Eye Disease (Grave's Disease), or
- History of use of two preferred medications, **or**
- Continuation of prior therapy or use within the past 365 days.

Bivigam or Panzyga, may be covered when the criteria listed below are satisfied:

- Bivigam or Panzyga is being prescribed to treat one of the following conditions:
 - > Autoimmune Mucocutaneous Blistering Diseases (Pemphigus Vulgaris, Pemphigus Foliaceus, Bullous Pemphigoid, Mucous Membrane Pemphigoid [Cicatricial Pemphigoid], and Epidermolysis Bullosa Acquisita), or
 - > Autoimmune Hemolytic Anemia, or
 - > Lambert-Eaton Myasthenic Syndrome (LEMS), or
 - > Neuromyelitis Optica (Devia Syndrome), or
 - > Treatment of Autoimmune Encephalitis, or
 - > Dermatomyositis or Polymyositis, or
 - > Inclusion Body Myositis, or
 - > Immune-Mediated Necrotizing Myopathy, or
 - > Overlap Syndrome with Myositis (Including Anti-Synthetase Syndrome), or
 - > Systemic Lupus Erythematosus, or

- > Thyroid Eye Disease (Grave's Disease), or
- History of use of two preferred medications, **or**
- Continuation of prior therapy or use within the past 365 days.

Non-preferred medication Step Therapy criteria

Applicable MAC regions: NGS J6, NGS JK. Additional MAC regions are listed below.

Alyglo, may be covered when the criteria listed below are satisfied:

- A product with minimal content of coagulation factor XIa is needed based on a comorbidity of the patient, per prescriber, **or**
- Alyglo is being prescribed to treat one of the following conditions:
 - > Autoimmune Mucocutaneous Blistering Diseases (Pemphigus Vulgaris, Pemphigus Foliaceus, Bullous Pemphigoid, Mucous Membrane Pemphigoid [Cicatricial Pemphigoid], and Epidermolysis Bullosa Acquisita), or
 - > Stiff-Person Syndrome (Moersch-Woltman Syndrome), or
 - > Autoimmune Retinopathy, or
 - > Systemic Lupus Erythematosus, or
- History of use of two preferred medications, **or**
- Continuation of prior therapy or use within the past 365 days.

Asceniv, may be covered when the criteria listed below are satisfied:

- Patient requires an immune globulin with elevated levels of respiratory syncytial virus (RSV) antibodies, per prescriber (such as a patient requiring elevated levels of RSV antibodies for repeated RSV infections despite adequate immune globulin dosing in a compliant patient), **or**
- Asceniv is being prescribed to treat one of the following conditions:
 - > Autoimmune Mucocutaneous Blistering Diseases (Pemphigus Vulgaris, Pemphigus Foliaceus, Bullous Pemphigoid, Mucous Membrane Pemphigoid [Cicatricial Pemphigoid], and Epidermolysis Bullosa Acquisita), or
 - > Stiff-Person Syndrome (Moersch-Woltman Syndrome), or
 - > Autoimmune Retinopathy, or
 - > Systemic Lupus Erythematosus, or
- History of use of two preferred medications, **or**
- Continuation of prior therapy or use within the past 365 days.

Bivigam or Panzyga, may be covered when the criteria listed below are satisfied:

- Bivigam or Panzyga is being prescribed to treat one of the following conditions:
 - > Autoimmune Mucocutaneous Blistering Diseases (Pemphigus Vulgaris, Pemphigus Foliaceus, Bullous Pemphigoid, Mucous Membrane Pemphigoid [Cicatricial Pemphigoid], and Epidermolysis Bullosa Acquisita), or
 - > Stiff-Person Syndrome (Moersch-Woltman Syndrome), or
 - > Autoimmune Retinopathy, or
 - > Systemic Lupus Erythematosus, or
- History of use of two preferred medications, **or**
- Continuation of prior therapy or use within the past 365 days.

Non-preferred medication Step Therapy criteria

Applicable MAC regions: Noridian JE, Noridian JF. Additional MAC regions are listed below.

Alyglo, may be covered when the criteria listed below are satisfied:

- A product with minimal content of coagulation factor XIa is needed based on a comorbidity of the patient, per prescriber, **or**
- Alyglo is being prescribed to treat one of the following conditions:
 - > Autoimmune Mucocutaneous Blistering Diseases (Pemphigus Vulgaris, Pemphigus Foliaceus, Bullous Pemphigoid, Mucous Membrane Pemphigoid [Cicatricial Pemphigoid], and Epidermolysis Bullosa Acquisita), or
 - > Immune Thrombocytopenia (ITP), or
 - > Dermatomyositis or Polymyositis, or
 - > Guillain Barre Syndrome, or
 - > Myasthenia Gravis, or
 - > Chronic Inflammatory Demyelinating Polyneuropathy (CIDP) or Polyradiculoneuropathy, or

- > Multiple Sclerosis (MS), Acute Severe Exacerbation or Relapses, or
- > Multifocal Motor Neuropathy (MMN), or
- History of use of two preferred medications, **or**
- Continuation of prior therapy or use within the past 365 days.

Asceniv, may be covered when the criteria listed below are satisfied:

- Patient requires an immune globulin with elevated levels of respiratory syncytial virus (RSV) antibodies, per prescriber (such as a patient requiring elevated levels of RSV antibodies for repeated RSV infections despite adequate immune globulin dosing in a compliant patient), **or**
- Asceniv is being prescribed to treat one of the following conditions:
 - > Autoimmune Mucocutaneous Blistering Diseases (Pemphigus Vulgaris, Pemphigus Foliaceus, Bullous Pemphigoid, Mucous Membrane Pemphigoid [Cicatricial Pemphigoid], and Epidermolysis Bullosa Acquisita), or
 - > Immune Thrombocytopenia (ITP), or
 - > Dermatomyositis or Polymyositis, or
 - > Guillain Barre Syndrome, or
 - > Myasthenia Gravis, or
 - > Chronic Inflammatory Demyelinating Polyneuropathy (CIDP) or Polyradiculoneuropathy, or
 - > Multiple Sclerosis (MS), Acute Severe Exacerbation or Relapses, or
 - > Multifocal Motor Neuropathy (MMN), or
- History of use of two preferred medications, **or**
- Continuation of prior therapy or use within the past 365 days.

Bivigam or Panzyga, may be covered when the criteria listed below are satisfied:

- Bivigam or Panzyga is being prescribed to treat one of the following conditions:
 - > Autoimmune Mucocutaneous Blistering Diseases (Pemphigus Vulgaris, Pemphigus Foliaceus, Bullous Pemphigoid, Mucous Membrane Pemphigoid [Cicatricial Pemphigoid], and Epidermolysis Bullosa Acquisita), or
 - > Immune Thrombocytopenia (ITP), or
 - > Dermatomyositis or Polymyositis, or
 - > Guillain Barre Syndrome, or
 - > Myasthenia Gravis, or
 - > Chronic Inflammatory Demyelinating Polyneuropathy (CIDP) or Polyradiculoneuropathy, or
 - > Multiple Sclerosis (MS), Acute Severe Exacerbation or Relapses, or
 - > Multifocal Motor Neuropathy (MMN), or
- History of use of two preferred medications, **or**
- Continuation of prior therapy or use within the past 365 days.

Non-preferred medication Step Therapy criteria

Applicable MAC regions: Palmetto JJ, Palmetto JM. Additional MAC regions are listed below.

Alyglo, may be covered when the criteria listed below are satisfied:

- A product with minimal content of coagulation factor XIa is needed based on a comorbidity of the patient, per prescriber, **or**
- Alyglo is being prescribed to treat one of the following conditions:
 - > Autoimmune Mucocutaneous Blistering Diseases (Pemphigus Vulgaris, Pemphigus Foliaceus, Bullous Pemphigoid, Mucous Membrane Pemphigoid [Cicatricial Pemphigoid], and Epidermolysis Bullosa Acquisita), **or**
 - > Myasthenia Gravis, or
- History of use of two preferred medications, **or**
- Continuation of prior therapy or use within the past 365 days.

Asceniv, may be covered when the criteria listed below are satisfied:

- Patient requires an immune globulin with elevated levels of respiratory syncytial virus (RSV) antibodies, per prescriber (such as a patient requiring elevated levels of RSV antibodies for repeated RSV infections despite adequate immune globulin dosing in a compliant patient), **or**
- Asceniv is being prescribed to treat one of the following conditions:
 - > Autoimmune Mucocutaneous Blistering Diseases (Pemphigus Vulgaris, Pemphigus Foliaceus, Bullous Pemphigoid, Mucous Membrane Pemphigoid [Cicatricial Pemphigoid], and Epidermolysis Bullosa Acquisita), or

- > Myasthenia Gravis, or
- History of use of two preferred medications, **or**
- Continuation of prior therapy or use within the past 365 days.

Bivigam or Panzyga, may be covered when the criteria listed below are satisfied:

- Bivigam or Panzyga is being prescribed to treat one of the following conditions:
 - > Autoimmune Mucocutaneous Blistering Diseases (Pemphigus Vulgaris, Pemphigus Foliaceus, Bullous Pemphigoid, Mucous Membrane Pemphigoid [Cicatricial Pemphigoid], and Epidermolysis Bullosa Acquisita), or
 - > Myasthenia Gravis, or
- History of use of two preferred medications, **or**
- Continuation of prior therapy or use within the past 365 days.

Non-preferred medication Step Therapy criteria

Applicable MAC regions: WPS J5, WPS J8.

Alyglo, may be covered when the criteria listed below are satisfied:

- A product with minimal content of coagulation factor Xia is needed based on a comorbidity of the patient, per prescriber, **or**
- Alyglo is being prescribed to treat one of the following conditions:
 - > Autoimmune Mucocutaneous Blistering Diseases (Pemphigus Vulgaris, Pemphigus Foliaceus, Bullous Pemphigoid, Mucous Membrane Pemphigoid [Cicatricial Pemphigoid], and Epidermolysis Bullosa Acquisita), or
 - > Severe Vasculitic Syndromes, Systemic (Polyarteritis nodusa), Churg-Strauss Vasculitis, and Livedoid Vasculitis (Atrophie Blanche), or
 - > Pyoderma Gangrenosum, or
 - > Immune-Mediated Neutropenia, or
 - > Stevens-Johnson Syndrome and/or Toxic Epidermal Necrolysis, or
 - > Systemic Lupus Erythematosus, or
 - > Autoimmune Hemolytic Anemia, or
 - > Thrombocytopenia, Feto-neonatal Alloimmune, or
 - > Myasthenia Gravis, or
 - > Dermatomyositis or Polymyositis, or
 - > Immune Thrombocytopenia (ITP), or
 - > Stiff-Person Syndrome (Moersch-Woltman Syndrome), or
- History of use of two preferred medications, **or**
- Continuation of prior therapy or use within the past 365 days.

Asceniv, may be covered when the criteria listed below are satisfied:

- Patient requires an immune globulin with elevated levels of respiratory syncytial virus (RSV) antibodies, per prescriber (such as a patient requiring elevated levels of RSV antibodies for repeated RSV infections despite adequate immune globulin dosing in a compliant patient), or
- Asceniv is being prescribed to treat one of the following conditions:
 - > Autoimmune Mucocutaneous Blistering Diseases (Pemphigus Vulgaris, Pemphigus Foliaceus, Bullous Pemphigoid, Mucous Membrane Pemphigoid [Cicatricial Pemphigoid], and Epidermolysis Bullosa Acquisita), or
 - > Severe Vasculitic Syndromes, Systemic (Polyarteritis nodusa), Churg-Strauss Vasculitis, and Livedoid Vasculitis (Atrophie Blanche), or
 - > Pyoderma Gangrenosum, or
 - > Immune-Mediated Neutropenia, or
 - > Stevens-Johnson Syndrome and/or Toxic Epidermal Necrolysis, or
 - > Systemic Lupus Erythematosus, or
 - > Autoimmune Hemolytic Anemia, or
 - > Thrombocytopenia, Feto-neonatal Alloimmune, or
 - > Myasthenia Gravis, or
 - > Dermatomyositis or Polymyositis, or
 - > Immune Thrombocytopenia (ITP), or
 - > Stiff-Person Syndrome (Moersch-Woltman Syndrome), or

- History of use of two preferred medications, or
- Continuation of prior therapy or use within the past 365 days.

Bivigam or Panzyga, may be covered when the criteria listed below are satisfied:

- Bivigam or Panzyga is being prescribed to treat one of the following conditions:
 - > Autoimmune Mucocutaneous Blistering Diseases (Pemphigus Vulgaris, Pemphigus Foliaceus, Bullous Pemphigoid, Mucous Membrane Pemphigoid [Cicatricial Pemphigoid], and Epidermolysis Bullosa Acquisita), or
 - > Severe Vasculitic Syndromes, Systemic (Polyarteritis nodosa), Churg-Strauss Vasculitis, and Livedoid Vasculitis (Atrophie Blanche), or
 - > Pyoderma Gangrenosum, or
 - > Immune-Mediated Neutropenia, or
 - > Stevens-Johnson Syndrome and/or Toxic Epidermal Necrolysis, or
 - > Systemic Lupus Erythematosus, or
 - > Autoimmune Hemolytic Anemia, or
 - > Thrombocytopenia, Feto-neonatal Alloimmune, or
 - > Myasthenia Gravis, or
 - > Dermatomyositis or Polymyositis, or
 - > Immune Thrombocytopenia (ITP), or
 - > Stiff-Person Syndrome (Moersch-Woltman Syndrome), or
- History of use of two preferred medications, **or**
- Continuation of prior therapy or use within the past 365 days.

Immune Globulins SC

| Preferred* medications | Non-preferred medications |
|--|--|
| <ul style="list-style-type: none"> • Cutaquig • Gammagard Liquid • Gammaked | <ul style="list-style-type: none"> • Gamunex-C • Hizentra • Xembify |

Non-preferred medication Step Therapy criteria

Applicable MAC regions: CGS JI5, FCSO JN, NGS J6, NGS JK, Noridian JE, Noridian JF, Novitas JH, Novitas JL, Palmetto JJ, Palmetto JM, WPS J5, WPS J8.

Cuvitru may be covered when the criteria listed below are satisfied:

- Patient with hyperprolinemia, the patient has tried Xembify, **or**
- Patient with a hypersensitivity to polysorbate 80, **or**
- History of use of two preferred medications, **or**
- Continuation of prior therapy or use within the past 365 days.

HyQvia may be covered when the criteria listed below are satisfied:

- Patient is being treated for chronic inflammatory demyelinating polyneuropathy, the patient has tried Hizentra, **or**
- History of use of two preferred medications, **or**
- Continuation of prior therapy or use within the past 365 days.

Immunomodulators

| Preferred* medications | Non-preferred medications |
|--|---|
| <ul style="list-style-type: none"> • Avsola • Inflectra • Renflexis | Remicade, including Infliximab (authorized generic) |

Non-preferred medication Step Therapy criteria

Applicable MAC regions: NGS J6, NGS JK. Additional MAC regions listed below.

Remicade, including Infliximab (authorized generic) may be covered when the criteria listed below is satisfied:

- Infliximab is being prescribed to treat one of the following conditions:
 - > Behcet's Disease
 - > Sarcoidosis
 - > Microscopic Colitis, Refractory, **or**
- History of use of one preferred medication **and**
- Cannot continue to use the preferred medication due to a formulation difference in the inactive ingredient(s) which, according to the prescriber, would result in a significant allergy or serious adverse reaction **or**
- Continuation of prior therapy or use within the past 365 days.

Non-preferred medication Step Therapy criteria

Applicable MAC regions: Palmetto JJ, Palmetto JM. Additional MAC regions listed below.

Remicade, including Infliximab (authorized generic) may be covered when criteria listed below is satisfied:

- Infliximab is being prescribed to treat one of the following conditions:
 - > Crohn's Disease
 - > Plaque Psoriasis
 - > Ulcerative Colitis
 - > Behcet's Disease (Behcet's Syndrome)
 - > Hidradenitis Suppurativa
 - > Sarcoidosis
 - > Spondyloarthritis (SpA), other subtypes **or**
- History of use of one preferred medication **and**
- Cannot continue to use the preferred medication due to a formulation difference in the inactive ingredient(s) which, according to the prescriber, would result in a significant allergy or serious adverse reaction **or**
- Continuation of prior therapy or use within the past 365 days.

Non-preferred medication Step Therapy criteria

Applicable MAC regions: CGS JI5, FCSO JN, Noridian JE, Noridian JF, Novitas JH, Novitas JL, WPS J5, WPS J8.

Remicade, including Infliximab (authorized generic) may be covered when criteria listed below is satisfied:

- History of use of one preferred medication **and**
- Cannot continue to use the preferred medication due to a formulation difference in the inactive ingredient(s) which, according to the prescriber, would result in a significant allergy or serious adverse reaction **or**
- Continuation of prior therapy or use within the past 365 days.

Intravenous Iron

| Preferred* medications | Non-preferred medications |
|-------------------------------|--|
| Venofer | <ul style="list-style-type: none">• Feraheme• Injectafer• Monoferric |

Non-preferred medication Step Therapy criteria

Applicable MAC regions: CGS JI5, FCSO JN, NGS J6, NGS JK, Noridian JE, Noridian JF, Novitas JH, Novitas JL, Palmetto JJ, Palmetto JM, WPS J5, WPS J8.

Feraheme, Injectafer or Monoferric may be covered when the criteria listed below is satisfied:

- Used for iron deficiency anemia in a patient with chronic kidney disease who is on dialysis **or**
- For other conditions:
 - History of use of the preferred medication **or**
 - Continuation of prior therapy or use within the past 365 days.

Ophthalmic Disorders Intravitreal Vascular Endothelial Growth Factor (VEGF) Inhibitors

| Preferred* medications | Non-preferred medications |
|------------------------|--|
| Avastin | <ul style="list-style-type: none">• Beovu• Byooviz• Cimerli• Eyle• Eylea HD• Lucentis• Vabysmo |

Non-preferred medication Step Therapy criteria

Applicable MAC regions: CGS JI5, FCSO JN, NGS J6, NGS JK, Noridian JE, Noridian JF, Novitas JH, Novitas JL, Palmetto JJ, Palmetto JM, WPS J5, WPS J8.

Beovu or Vabysmo may be covered when the criteria listed below is satisfied:

- History of use of the preferred ophthalmic medication **and**
- Inadequate efficacy or intolerance was demonstrated **or**
- Safety of using the repackaged ophthalmic Avastin injection is of significant concern, in the prescriber's professional opinion **or**
- The supplier of the repackaged ophthalmic Avastin injection is of significant concern, in the prescriber's professional opinion **or**
- Continuation of prior therapy or use within the past 365 days.

Eylea or Eylea HD may be covered when criteria listed below is satisfied:

- History of use of the preferred ophthalmic medication **and**
- Inadequate efficacy or intolerance was demonstrated **or**
- Has diabetic macular edema and a baseline visual acuity worse than 20/40 according to the prescriber **or**
- Has diabetic macular edema with significant retinal thickening according to the prescriber **or**
- Has diabetic retinopathy (without diabetic macular edema) **or**
- Safety of using the repackaged ophthalmic Avastin injection is of significant concern, in the prescriber's professional opinion **or**
- The supplier of the repackaged ophthalmic Avastin injection is of significant concern, in the prescriber's professional opinion **or**
- Continuation of prior therapy or use within the past 365 days.

Byooviz, Cimerli or Lucentis may be covered when criteria listed below is satisfied:

- History of use of the preferred ophthalmic medication **and**
- Inadequate efficacy or intolerance was demonstrated **or**
- Has diabetic retinopathy (without diabetic macular edema) **or**
- Safety of using the repackaged ophthalmic Avastin injection is of significant concern, in the prescriber's professional opinion **or**
- The supplier of the repackaged ophthalmic Avastin injection is of significant concern, in the prescriber's professional opinion **or**
- Continuation of prior therapy or use within the past 365 days.

Paclitaxel Medications

| Preferred* medications | Non-preferred medications |
|------------------------|---|
| Paclitaxel | <ul style="list-style-type: none">• Abraxane• Paclitaxel protein-bound |

Non-preferred medication Step Therapy criteria

Applicable MAC regions: CGS JI5, FCSO JN, NGS J6, NGS JK, Noridian JE, Noridian JF, Novitas JH, Novitas JL, Palmetto JJ, Palmetto JM, WPS J5, WPS J8.

Abraxane or Paclitaxel protein-bound may be covered when the criteria listed below is satisfied:

- For non-small cell lung cancer:
 - > Hypersensitivity reaction to Paclitaxel intravenous infusion or Docetaxel intravenous infusion or
 - > Contraindication to the standard pre-medications or
 - > Used as subsequent therapy with advanced or metastatic disease or
 - > Continuation of prior therapy or use within the past 365 days
- For breast cancer, cervical cancer, endometrial cancer, melanoma, ovarian cancer:
 - > Hypersensitivity reaction to Paclitaxel intravenous infusion or Docetaxel intravenous infusion or
 - > Contraindication to the standard pre-medications or
 - > Continuation of prior therapy or use within the past 365 days

Rituximab

| Preferred* medications | Non-preferred medications |
|---|---|
| <ul style="list-style-type: none">• Riabni• Ruxience• Truxima | <ul style="list-style-type: none">• Rituxan Hycela• Rituxan IV |

Non-preferred medication Step Therapy criteria

Applicable MAC regions: CGS JI5. Additional MAC regions listed below.

Rituxan intravenous may be covered when the criteria listed below is satisfied:

- History of use of one preferred medication **and**
- Cannot continue to use the preferred medication due to a formulation difference in the inactive ingredient(s) which, according to the prescriber, would result in a significant allergy or serious adverse reaction **or**
- Continuation of prior therapy within the past 365 days **or**
- Rituxan intravenous is being prescribed to treat one of the following conditions:
 - > Graft Versus Host Disease (GVHD) or
 - > Immune Thrombocytopenia (ITP) or
 - > Multiple Sclerosis or
 - > Neuromyelitis Optica (NMO) Spectrum Disorder or
 - > Systemic Lupus Erythematosus (SLE) [Lupus] or
 - > Thrombotic Thrombocytopenic Purpura (Acquired) or
 - > Evans Syndrome or
 - > Bullous Pemphigoid or
 - > Immunotherapy-Related Encephalitis or
 - > Immune-Mediated Myopathy/Idiopathic Inflammatory Myopathy or
 - > Immunoglobulin G4-Related Disease (IgG4-RD) or
 - > Myasthenia Gravis or
 - > Minimal Change Disease or
 - > Antibody-Mediated Rejection (AMR).

Rituxan Hycela may be covered when the criteria listed below is satisfied:

- History of use of one preferred medication, but according to prescriber cannot continue to use the medication **or**
- Inability to obtain or maintain intravenous access **or**
- Continuation of prior therapy or use within the past 365 days.

Non-preferred medication Step Therapy criteria

Applicable MAC regions: NGS J6, NGS JK. Additional MAC regions listed below.

Rituxan intravenous may be covered when criteria listed below is satisfied:

- History of use of one preferred medication **and**
- Cannot continue to use the preferred medication due to a formulation difference in the inactive ingredient(s) which, according to the prescriber, would result in a significant allergy or serious adverse reaction **or**
- Continuation of prior therapy within the past 365 days **or**
- Rituxan intravenous is being prescribed to treat one of the following conditions:
 - > Immune Thrombocytopenia (ITP) or
 - > Multiple Sclerosis or
 - > Antibody-Mediated Rejection (AMR) or
 - > Immune-Mediated Myopathy/Idiopathic Inflammatory Myopathy or
 - > Hemophilia (Acquired) or
 - > Thrombotic Thrombocytopenic Purpura (Acquired) or
 - > Immunoglobulin G4-Related Disease (IgG4-RD) or
 - > Minimal Change Disease or
 - > Chronic Inflammatory Demyelinating Polyneuropathy (CIDP) or
 - > Sjogren's Syndrome and Systemic Sclerosis.

Rituxan Hycela may be covered when criteria listed below is satisfied:

- History of use of one preferred medication, but according to prescriber cannot continue to use the medication **or**
- Inability to obtain or maintain intravenous access **or**
- Continuation of prior therapy or use within the past 365 days.

Non-preferred medication Step Therapy criteria

Applicable MAC regions: Palmetto JJ, Palmetto JM. Additional MAC regions listed below.

Rituxan intravenous may be covered when criteria listed below is satisfied:

- History of use of one preferred medication **and**
- Cannot continue to use the preferred medication due to a formulation difference in the inactive ingredient(s) which, according to the prescriber, would result in a significant allergy or serious adverse reaction **or**
- Continuation of prior therapy within the past 365 days **or**
- Rituxan intravenous is being prescribed to treat one of the following conditions:
 - > Rheumatoid Arthritis (RA) or
 - > Graft Versus Host Disease (GVHD) or
 - > Multiple Sclerosis or
 - > Autoimmune Hemolytic Anemia or
 - > Multifocal Motor Neuropathy (MMN) or
 - > Polymyositis or
 - > Prior to Autologous Stem Cell Rescue for Progressive or Relapsed Disease.

Rituxan Hycela may be covered when criteria listed below is satisfied:

- History of use of one preferred medication, but according to prescriber cannot continue to use the medication **or**
- Inability to obtain or maintain intravenous access **or**
- Continuation of prior therapy or use within the past 365 days.

Non-preferred medication Step Therapy criteria

Applicable MAC regions: FCSO JN, Noridian JE, Noridian JF, Novitas JH, Novitas JL, WPS J5, WPS J8.

Rituxan intravenous may be covered when criteria listed below is satisfied:

- History of use of one preferred medication **and**
- Cannot continue to use the preferred medication due to a formulation difference in the inactive ingredient(s) which, according to the prescriber, would result in a significant allergy or serious adverse reaction **or**
- Continuation of prior therapy or use within the past 365 days.

Rituxan Hycela may be covered when criteria listed below is satisfied:

- History of use of one preferred medication, but according to prescriber cannot continue to use the medication **or**
- Inability to obtain or maintain intravenous access **or**
- Continuation of prior therapy or use within the past 365 days.

Somatostatin Analogs Long-Acting

| Preferred* medications | Non-preferred medications |
|--|--|
| Somatuline Depot (JI930) Lanreotide (JI930) | <ul style="list-style-type: none">• Lanreotide (JI932)• Sandostatin LAR |

Non-preferred medication Step Therapy criteria

Applicable MAC regions: CGS JI5, FCSO JN, NGS J6, NGS JK, Noridian JE, Noridian JF, Novitas JH, Novitas JL, Palmetto JJ, Palmetto JM, WPS J5, WPS J8.

Lanreotide (JI932) may be covered when the criteria listed below is satisfied:

For Acromegaly:

- History of use of one preferred medication **and**
- Cannot continue to use the preferred medication due to a formulation difference in the inactive ingredient(s) which, according to the prescriber, would result in a significant allergy or serious adverse reaction **or**
- Continuation of prior therapy or use within the past 365 days.

For Neuroendocrine Tumor(s) [NETs] of the Gastrointestinal Tract, Lung, Thymus (Carcinoid Tumors), and Pancreas (including glucagonomas, gastrinomas, vasoactive intestinal peptides-secreting tumors [VIPomas], insulinomas):

- History of use of one preferred medication **and**
- Cannot continue to use the preferred medication due to a formulation difference in the inactive ingredient(s) which, according to the prescriber, would result in a significant allergy or serious adverse reaction **or**
- Continuation of prior therapy or use within the past 365 days.

Sandostatin LAR may be covered when the criteria listed below is satisfied:

For Acromegaly:

- History of use of one preferred medication **or**
- Continuation of prior therapy or use within the past 365 days.

For Neuroendocrine Tumor(s) [NETs] of the Gastrointestinal Tract, Lung, Thymus (Carcinoid Tumors), and Pancreas (including glucagonomas, gastrinomas, vasoactive intestinal peptides-secreting tumors [VIPomas], insulinomas):

- History of use of one preferred medication **or**
- Continuation of prior therapy or use within the past 365 days.

For Pheochromocytoma and Paraganglioma:

- History of use of one preferred medication **or**
- Continuation of prior therapy or use within the past 365 days.

Systemic Lupus Erythematosus (SLE) Lupus

| Preferred* medications | Non-preferred medications |
|------------------------|---------------------------|
| Benlysta IV | Saphnelo |

Non-preferred medication Step Therapy criteria

Applicable MAC regions: CGS JI5, FCSO JN, NGS J6, NGS JK, Noridian JE, Noridian JF, Novitas JH, Novitas JL, Palmetto JJ, Palmetto JM, WPS J5, WPS J8.

Saphnelo may be covered when the criteria listed below is satisfied:

- History of Benlysta use **or**
- History of depression or suicidality, according to prescriber **or**
- Continuation of prior therapy or use within the past 365 days.

Testosterone Injectable

| Preferred* medications | Non-preferred medications |
|---|---|
| <ul style="list-style-type: none">• Depo-Testosterone (testosterone cypionate)• Delatestryl (testosterone enanthate) | <ul style="list-style-type: none">• Aveed• Testopel• Xyosterd |

Non-preferred medication Step Therapy criteria

Applicable MAC regions: CGS JI5, FCSO JN, NGS J6, NGS JK, Noridian JE, Noridian JF, Novitas JH, Novitas JL, Palmetto JJ, Palmetto JM, WPS J5, WPS J8.

Aveed, Testopel or Xyosterd may be covered when the criteria listed below is satisfied:

- History of use of one preferred medication **or**
- Continuation of prior therapy or use within the past 365 days.

Trastuzumab

| Preferred* medications | Non-preferred medications |
|--|--|
| <ul style="list-style-type: none">• Kanjinti• Ogvir• Trazimera | <ul style="list-style-type: none">• Herceptin Hylecta• Herceptin IV <ul style="list-style-type: none">• Herzuma• Ontruzant |

Non-preferred medication Step Therapy criteria

Applicable MAC regions: CGS JI5, FCSO JN, NGS J6, NGS JK, Noridian JE, Noridian JF, Novitas JH, Novitas JL, Palmetto JJ, Palmetto JM, WPS J5, WPS J8.

Herceptin intravenous, Herzuma or Ontruzant may be covered when the criteria listed below is satisfied:

- History of use of one preferred medication **and**
- Cannot continue to use the preferred medication due to a formulation difference in the inactive ingredient(s) which, according to the prescriber, would result in a significant allergy or serious adverse reaction **or**
- Continuation of prior therapy or use within the past 365 days.

Herceptin Hylecta may be covered when criteria listed below is satisfied:

- History of use of one preferred medication, but according to prescriber cannot continue to use the medication **or**
- Inability to obtain or maintain intravenous access **or**
- Continuation of prior therapy or use within the past 365 days.

Viscosupplements

| Preferred* medications | Non-preferred medications |
|--|---|
| <ul style="list-style-type: none">• Monovisc• Orthovisc• Synvisc• Synvisc One | <ul style="list-style-type: none">• Durolane• Eufllexxa• Gel-One• Gelsyn-3• GenVisc 850• Hyalgan• Hymovis <ul style="list-style-type: none">• Sodium Hyaluronate 1%• Supartz FX• Synojoont• Triluron• TriVisc• Visco-3 |

Non-preferred medication Step Therapy criteria

Applicable MAC regions: CGS JI5, FCSO JN, NGS J6, NGS JK, Noridian JE, Noridian JF, Novitas JH, Novitas JL. Does not apply to all other MAC regions not listed.

Durolane, Eufllexxa, Gel-One, Gelsyn-3, GenVisc 850, Hyalgan, Hymovis, Sodium Hyaluronate 1%, Supartz FX, Synojoont, Triluron, TriVisc or Visco-3 may be covered when the criteria listed below is satisfied:

- History of two different preferred medication therapy courses **or**
- Continuation of prior therapy or use within the past 365 days.

For the following classes, preferred medications may be covered under the Part D (pharmacy) benefit:

Calcitonin Gene-Related Peptide Inhibitors**

| Preferred* medications | Non-preferred medications |
|--|---------------------------|
| Preferred Part D medication (reference Part D Drug List and Part D UM requirements) | Vyepti |

Non-preferred medication Step Therapy criteria

Applicable MAC regions: CGS JI5, FCSO JN, NGS J6, NGS JK, Noridian JE, Noridian JF, Novitas JH, Novitas JL, Palmetto JJ, Palmetto JM, WPS J5, WPS J8.

Vyepti may be covered when the criteria listed below is satisfied:

- History of use of one preferred Part D subcutaneous calcitonin gene-related peptide inhibitor for migraine prophylaxis **or**
- Continuation of prior therapy or use within the past 365 days.

Proprotein Convertase Subtilisin/Kexin Type 9 (PCSK9) Inhibitors**

| Preferred* medications | Non-preferred medications |
|--|---------------------------|
| Preferred Part D medication (reference Part D Drug List and Part D UM requirements) | Leqvio |

Non-preferred medication Step Therapy criteria

Applicable MAC regions: CGS JI5, FCSO JN, NGS J6, NGS JK, Noridian JE, Noridian JF, Novitas JH, Novitas JL, Palmetto JJ, Palmetto JM, WPS J5, WPS J8.

Leqvio may be covered when the criteria listed below is satisfied:

- History of use of one preferred Part D proprotein convertase subtilisin kexin type 9 (PCSK9) inhibitor **and**
- Inadequate efficacy or significant intolerance, according to prescriber **or**
- Continuation of prior therapy or use within the past 365 days.

Applicable codes

Antiemetic - Serotonin Receptor Antagonists (injectable) for oncology

| HCPCS code | Description |
|---------------|--|
| Preferred | |
| JI626 | Injection, granisetron hydrochloride, 100 mcg |
| J2405 | Injection, ondansetron hydrochloride, per 1 mg |
| J2469 | Injection, palonosetron HCl, 25 mcg |
| Non-preferred | |
| JI627 | Injection, granisetron, extended-release, 0.1 mg |

Antiemetic - Substance P/Neurokinin-1 Receptor Antagonists (injectable) for oncology

| HCPCS code | Description |
|---------------|--|
| Preferred | |
| JI453 | Injection, fosaprepitant, 1 mg |
| Non-preferred | |
| JOI85 | Injection, aprepitant, 1 mg |
| JI454 | Injection, fosnetupitant 235 mg and palonosetron 0.25 mg |

Bevacizumab (oncology)

| HCPCS code | Description |
|---------------|---|
| Preferred | |
| Q5I07 | Injection, bevacizumab-awwb, biosimilar, (Mvasi), 10 mg |
| Q5I18 | Injection, bevacizumab-bvzr, biosimilar, (Zirabev), 10 mg |
| Non-preferred | |
| J9035 | Injection, bevacizumab, 10 mg |

| HCPCS code | Description |
|------------|---|
| Q5I26 | Injection, bevacizumab-maly, biosimilar, (Alymsys), 10 mg |
| Q5I29 | Injection, bevacizumab-adcd (Vegzelma), biosimilar, 10 mg |

Botulinum Toxins

| HCPCS code | Description |
|---------------|---|
| Preferred | |
| J0585 | Injection, onabotulinumtoxinA, 1 unit |
| J0589 | Injection, daxibotulinumtoxinA-lanm, 1 unit |
| J0586 | Injection, abobotulinumtoxinA, 5 units |
| J0588 | Injection, incobotulinumtoxinA, 1 unit |
| Non-preferred | |
| J0587 | Injection, rimabotulinumtoxinB, 100 units |

Colony Stimulating Factors Short-Acting

| HCPCS code | Description |
|---------------|---|
| Preferred | |
| Q5I01 | Injection, filgrastim-sndz, biosimilar, (Zarxio) 1 mcg |
| Q5I10 | Injection, filgrastim-aafi, biosimilar, (Nivestym), 1 mcg |
| Non-preferred | |
| J1442 | Injection, filgrastim (G-CSF), (Neupogen) excludes biosimilars, 1 mcg |
| J1447 | Injection, tbo-filgrastim, (Granix) 1 mcg |
| Q5I25 | Injection, filgrastim-ayow, biosimilar, (Releuko), 1 mcg |

Colony Stimulating Factors Long-Acting

| HCPCS code | Description |
|---------------|--|
| Preferred | |
| J2506 | Injection, pegfilgrastim, excludes biosimilar, 0.5 mg |
| Q5I11 | Injection, pegfilgrastim-cbqv (Udenyca), biosimilar, 0.5 mg |
| Q5I22 | Injection, pegfilgrastim-apgf (Nyvepria), biosimilar, 0.5 mg |
| Non-preferred | |

| HCPCS code | Description |
|------------|--|
| JI449 | Injection, eflapegrastim-xnst, 0.1 mg |
| Q5108 | Injection, pegfilgrastim-jmdb (Fulphila), biosimilar, 0.5 mg |
| Q5120 | Injection, pegfilgrastim-bmez, (Ziextenzo), biosimilar, 0.5 mg |
| Q5127 | Injection, pegfilgrastim-fpgk (Stimufend), biosimilar, 0.5 mg |
| Q5130 | Injection, pegfilgrastim-pbbk (Fylnetra), biosimilar, 0.5 mg |

Immune Globulins IV

| HCPCS code | Description |
|---------------|---|
| Preferred | |
| JI572 | Injection, Immune globulin (Flebogamma), 500 mg |
| JI569 | Injection, Immune globulin (Gammagard liquid), 500 mg |
| JI566 | Injection, Immune globulin (powder), 500 mg |
| JI561 | Injection, Immune globulin (Gamunex-C/Gammaked), 500 mg |
| JI557 | Injection, Immune globulin (Gammaplex), 500 mg |
| JI568 | Injection, Immune globulin (Octagam), 500 mg |
| JI459 | Injection, immune globulin (Privigen), 500 mg |
| Non-preferred | |
| JI599 | Injection, Immune globulin, (liquid), 500 mg |
| JI554 | Injection, Immune globulin (Asceniv), 500 mg |
| JI556 | Injection, Immune globulin (Bivigam), 500 mg |
| JI576 | Injection, Immune globulin (Panzyga), 500 mg |

Immune Globulins SC

| HCPCS code | Description |
|------------|---|
| Preferred | |
| JI551 | Injection, Immune globulin (Cutaquig), 100 mg |
| JI569 | Injection, Immune globulin (Gammagard liquid), 500 mg |
| JI561 | Injection, Immune globulin (Gamunex-C/Gammaked), 500 mg |
| JI559 | Injection, Immune globulin (Hizentra), 100 mg |
| JI558 | Injection, immune globulin (Xembify), 100 mg |

| HCPCS code | Description |
|---------------|--|
| Non-preferred | |
| J1555 | Injection, Immune globulin (Cuvitru), 100 mg |
| J1575 | Injection, Immune globulin (Hyqvia), 100 mg |

Immunomodulators

| HCPCS code | Description |
|---------------|--|
| Preferred | |
| Q5I03 | Injection, infliximab-dyyb, biosimilar, (Inflectra), 10 mg |
| Q5I04 | Injection, infliximab-abda, biosimilar, (Renflexis), 10 mg |
| Q5I21 | Injection, infliximab-axxq, biosimilar, (Avsola), 10 mg |
| Non-preferred | |
| J1745 | Injection, infliximab, excludes biosimilar, 10 mg |

Intravenous Iron

| HCPCS code | Description |
|---------------|---|
| Preferred | |
| J1756 | Injection, iron sucrose, 1 mg |
| Non-preferred | |
| J1437 | Injection, ferric derisomaltose, 10 mg |
| J1439 | Injection, ferric carboxymaltose, 1 mg |
| Q0I38 | Injection, ferumoxytol, for treatment of iron deficiency anemia, 1 mg |

Ophthalmic Disorders

Intravitreal Vascular Endothelial Growth Factor (VEGF) Inhibitors

| HCPCS code | Description |
|---------------|---|
| Preferred | |
| C9257 | Injection, bevacizumab (Avastin), 0.25 mg |
| J7999 | Compounded drug, not otherwise classified |
| J9035 | Injection, bevacizumab (Avastin), 10 mg |
| Non-preferred | |
| JOI78 | Injection, afibercept, 1 mg |
| JOI79 | Injection, brolucizumab-dbll, 1 mg |

| HCPCS code | Description |
|------------|--|
| J0I77 | Injection, aflibercept hd, Img |
| J2777 | Injection, faricimab-svoa, 0.1 mg |
| J2778 | Injection, ranibizumab, 0.1 mg |
| Q5I24 | Injection, ranibizumab-nuna, biosimilar, (Byooviz), 0.1 mg |
| Q5I28 | Injection, ranibizumab-eqrn (Cimerli), biosimilar, 0.1 mg |

Paclitaxel Medications

| HCPCS code | Description |
|---------------|---|
| Preferred | |
| J9267 | Injection, paclitaxel, I mg |
| Non-preferred | |
| J9259 | Injection, paclitaxel protein-bound particles (American Regent) not therapeutically equivalent to J9264, I mg |
| J9264 | Injection, paclitaxel protein-bound particles, I mg |

Rituximab

| HCPCS code | Description |
|---------------|--|
| Preferred | |
| Q5I15 | Injection, rituximab-abbs, biosimilar, (Truxima), 10 mg |
| Q5I19 | Injection, rituximab-pvvr, biosimilar, (Ruxience), 10 mg |
| Q5I23 | Injection, rituximab-arrx, biosimilar, (Riabni), 10 mg |
| Non-preferred | |
| J9311 | Injection, rituximab 10 mg and hyaluronidase |
| J9312 | Injection, rituximab, 10 mg |

Somatostatin Analogs Long-Acting

| HCPCS code | Description |
|---------------|--------------------------------------|
| Preferred | |
| J1930 | Injection, lanreotide, I mg |
| Non-preferred | |
| J1932 | Injection, lanreotide, (cipla), I mg |

| HCPCS code | Description |
|------------|-----------------------------------|
| J2353 | Injection, octreotide depot, I mg |

Systemic Lupus Erythematosus (SLE) Lupus

| HCPCS code | Description |
|---------------|-----------------------------------|
| Preferred | |
| JO490 | Injection, belimumab, IO mg |
| Non-preferred | |
| JO491 | Injection, anifrolumab-fnia, I mg |

Testosterone Injectable

| HCPCS code | Description |
|---------------|---|
| Preferred | |
| JI071 | Injection, testosterone cypionate, I mg |
| J3I2I | Injection, testosterone enanthate, I mg |
| Non-preferred | |
| J3I45 | Injection, testosterone undecanoate, I mg |
| J3490 | Unclassified drugs, Testopel |
| J3490 | Unclassified drugs, Xyosterd |

Trastuzumab

| HCPCS code | Description |
|---------------|---|
| Preferred | |
| Q5II4 | Injection, Trastuzumab-dkst, biosimilar, (Ogivri), IO mg |
| Q5II6 | Injection, trastuzumab-qyyp, biosimilar, (Trazimera), IO mg |
| Q5II7 | Injection, trastuzumab-anns, biosimilar, (Kanjinti), IO mg |
| Non-preferred | |
| J9355 | Injection, trastuzumab, excludes biosimilar, IO mg |
| J9356 | Injection, trastuzumab, IO mg and hyaluronidase-oysk |
| Q5II2 | Injection, trastuzumab-dttb, biosimilar, (Ontruzant), IO mg |
| Q5II3 | Injection, trastuzumab-pkrb, biosimilar, (Herzuma), IO mg |

Viscosupplements

| HCPCS code | Description |
|---------------|--|
| Preferred | |
| J7324 | Hyaluronan or derivative, Orthovisc, for intra-articular injection, per dose |
| J7325 | Hyaluronan or derivative, Synvisc or Synvisc-One, for intra-articular injection, 1 mg |
| J7327 | Hyaluronan or derivative, Monovisc, for intra-articular injection, per dose |
| Non-preferred | |
| J7318 | Hyaluronan or derivative, Durolane, for intra-articular injection, 1 mg |
| J7320 | Hyaluronan or derivative, GenVisc 850, for intra-articular injection, 1 mg |
| J7321 | Hyaluronan or derivative, Hyalgan, Supartz or Visco-3, for intra-articular injection, per dose |
| J7322 | Hyaluronan or derivative, Hymovis, for intra-articular injection, 1 mg |
| J7323 | Hyaluronan or derivative, Euflexxa, for intra-articular injection, per dose |
| J7326 | Hyaluronan or derivative, Gel-One, for intra-articular injection, per dose |
| J7328 | Hyaluronan or derivative, Gel-Syn, for intra-articular injection, 0.1 mg |
| J7329 | Hyaluronan or derivative, TriVisc, for intra-articular injection, 1 mg |
| J7331 | Hyaluronan or derivative, Synjoptynt, for intra-articular injection, 1 mg |
| J7332 | Hyaluronan or derivative, Triluron, for intra-articular injection, 1 mg |

For the following classes, preferred medications may be covered under the Part D (pharmacy) benefit:

Calcitonin Gene-Related Peptide Inhibitors**

| HCPCS code | Description |
|---------------|---|
| Preferred | |
| N/A | Preferred Part D medication (reference Part D Drug List and Part D UM requirements) |
| Non-preferred | |
| J3032 | Injection, eptinezumab-jjmr, 1 mg |

Proprotein Convertase Subtilisin/Kexin Type 9 (PCSK9) Inhibitors**

| HCPCS code | Description |
|---------------|---|
| Preferred | |
| N/A | Preferred Part D medication (reference Part D Drug List and Part D UM requirements) |
| Non-preferred | |
| J1306 | Injection, inclisiran, 1 mg |

References

1. Centers for Medicare and Medicaid Services, National Government Services, Inc, National Coverage Determinations (NCD), Local Coverage Determinations (LCD), and Local Coverage Articles (LCA) applicable coverage policies. Available at <https://www.cms.gov/medicare-coverage-database/search.aspx>
2. NCCN Clinical Practice Guidelines in Oncology® (NCCN Guidelines®). Available at www.nccn.org

Antiemetic - Serotonin Receptor Antagonists (Injectable) for Oncology

1. Aloxi® intravenous injection [prescribing information]. Iselin, NJ: Helsinn; April 2020.
2. Ondansetron intramuscular injection or intravenous infusion [prescribing information]. Lake Zurich, IL: Fresenius Kabi; March 2020.
3. Granisetron intravenous infusion [prescribing information]. Rockford, IL: Fresenius Kabi; December 2019.
4. Sustol® extended-release subcutaneous injection [prescribing information]. Redwood City, CA: Heron; June 2023.
5. Hesketh PJ, Kris MG, Basch E, et al. Antiemetics: American Society of Clinical Oncology Clinical Practice Guideline Update. *J Clin Oncol.* 2020 Aug 20; 38(24):2782-2797.
6. Gan T, Belani K, Bergese S, et al. Fourth consensus guidelines for the management of postoperative nausea and vomiting. *Anesth Analg.* 2020; 131:411-448.

Antiemetic – Substance P/Neurokinin-1 Receptor Antagonists (Injectable) for Oncology

1. Cinvanti™ intravenous infusion [prescribing information]. San Diego, CA: Heron; September 2023.
2. Emend® intravenous infusion [prescribing information]. Whitehouse Station, NJ: Merck; May 2022.
3. Akynezo® intravenous infusion [prescribing information]. Iselin, NJ: Helsinn; February 2023.

Bevacizumab (Oncology)

1. Avastin® intravenous infusion [prescribing information]. South San Francisco, CA: Genentech; December 2020.
2. Mvasi® intravenous infusion [prescribing information]. Thousand Oaks, CA: Amgen; November 2021.
3. Zirabev™ intravenous infusion [prescribing information]. New York, NY: Pfizer; February 2021.
4. Alymsys® intravenous infusion [prescribing information]. Bridgewater, NJ: Amneal; April 2022.
5. Vezzelma™ intravenous infusion [prescribing information]. Incheon, Republic of Korea: Celltrion; September 2022.
6. Escudier B, Pluzanska A, Koralewski P, et al; AVOREN Trial investigators. Bevacizumab plus interferon alfa-2a for treatment of metastatic renal cell carcinoma: a randomised, double-blind phase III trial. *Lancet.* 2007;370:2103-2111.
7. Rini BI, Halabi S, Rosenberg JE, et al. Phase III trial of bevacizumab plus interferon alfa versus interferon alfa monotherapy in patients with metastatic renal cell carcinoma: final results of CALGB 90206. *J Clin Oncol.* 2010;28:2137-2143.
8. Ray-Coquard IL, Domont J, Tresch-Brunel E, et al. Paclitaxel given once per week with or without bevacizumab in patients with advanced angiosarcoma: A randomized Phase II trial. *J Clin Oncol.* 2015;33:2797-2802.
9. Agulnik M, Yarber JL, Okuno SH, et al. An open-label, multicenter, phase II study of bevacizumab for the treatment of angiosarcoma and epithelioid hemangioendotheliomas. *Ann Oncol.* 2013;24:257-263.
10. Park MS, Patel SR, Ludwig JA, et al. Activity of temozolamide and bevacizumab in the treatment of locally advanced, recurrent, and metastatic hemangiopericytoma and malignant solitary fibrous tumor. *Cancer.* 2011;117:4939-4947.
- II. Grill J, Massimino M, Bouffet E, et al. Phase II, open-label, randomized, multicenter trial (HERBY) of bevacizumab in pediatric patients with newly diagnosed high-grade glioma. *J Clin Oncol.* 2018;36:951-958.
12. Gulhati P, Raghav K, Schroff RT, et al. Bevacizumab combined with capecitabine and oxaliplatin in patients with advanced adenocarcinoma of the small bowel or Ampulla of Vater: A single-center, open-label, phase 2 study. *Cancer.* 2017;123:1011-1017.
13. Raghav K, Liu S, Overman MJ, et al. Efficacy, safety, and biomarker analysis of combined PD-L1 (atezolizumab) and VEGF (bevacizumab) blockage in advanced malignant peritoneal mesothelioma. *Cancer Discov.* 2021;11:2738-2747.
14. Ceresoli GL, Zucali PA, Mencoboni M, et al. Phase II study of pemetrexed and carboplatin plus bevacizumab as first-line therapy in malignant pleural mesothelioma. *Br J Cancer.* 2013;109:552-558.
15. Aghajanian C, Sill MW, Darcy KM, et al. Phase II trial of bevacizumab in recurrent or persistent endometrial cancer: A Gynecologic Oncology Group Study. *J Clin Oncol.* 2011;29:2259-2265.
16. Rubinstein M, Dickinson S, Narayan P, et al. Bevacizumab in advanced endometrial cancer. *Gynecol Oncol.* 2021;161:720-726.

Botulinum Toxins

1. Botox® injection [prescribing information]. Madison, NJ: Allergan; August 2022.
2. Daxxify® injection [prescribing information]. Newark, CA: Revance; August 2023.
3. Dysport® injection [prescribing information]. Cambridge, MA and Fort Worth, TX: Ipsen/Galderma; July 2020.
4. Myobloc® injection [prescribing information]. San Francisco, CA: Solstice Neurosciences; September 2020.
5. Xeomin® injection [prescribing information]. Raleigh, NC: Merz; August 2021.
6. Micromedex®. IBM Corporation. Available at: <http://www.micromedexsolutions.com> Accessed on January 9, 2023. Search terms: Botox.
7. Micromedex®. IBM Corporation. Available at: <http://www.micromedexsolutions.com> Accessed on October 9, 2023. Search terms: Dysport.
8. Bhidayasiri R, Truong DD. Expanding use of botulinum toxin. *J Neurol Sci.* 2005;235(I-2):I-9.
9. American Headache Society. The American Headache Society position statement on integrating new migraine treatments into clinical practice. *Headache.* 2019;59:I-18.
10. Vaezi MF, Pandolfino JE, Yadlapati RH, et al. ACG Clinical Guidelines: diagnosis and management of achalasia. *Am J Gastroenterol.* 2020 Sep;115(9):1393-1411.
- II. Wald A, Bharucha AE, Limketkai B, et al. ACG Clinical Guidelines: Management of Benign Anorectal Disorders. *Am J Gastroenterol.* 2021 Oct 1;116(10):1987-2008.
12. Lang AM. Botulinum toxin type A therapy in chronic pain disorders. *Arch Phys Med Rehabil.* 2003;84(3 Suppl 1):S69-73.
13. von Lindern JJ, Niederhagen B, Berge S, Appel T. Type A botulinum toxin in the treatment of chronic facial pain associated with masticatory hyperactivity. *J Oral Maxillofac Surg.* 2003;61(7):774-778.
14. Borodic GE, Acquadro MA. The use of botulinum toxin for the treatment of chronic facial pain. *J Pain.* 2002;3(I)21-27.

15. Freund B, Schwartz M, Symington JM. Botulinum toxin: new treatment for temporomandibular disorders. *Br J Oral Maxillofac Surg*. 2000;38(5):466-471.
16. Foster L, Clapp L, Erickson M, Jabbari B. Botulinum toxin A and chronic low back pain: a randomized, double-blind study. *Neurology*. 2001;56:1290-1293.
17. Jabbari B, Ney J, Sichani A, et al. Treatment of refractory, chronic low back pain with botulinum neurotoxin A: an open-label, pi
18. Simpson DM, Blitzer A, Brashear A, et al. Assessment: botulinum neurotoxin for the treatment of movement disorders (an evidence-based review): Report of the Therapeutics and Technology Assessment Subcommittee of the American Academy of Neurology. *Neurology*. 2008;70:1699-1706.
19. Stachler RJ, Francis DO, Schwartz SR, et al. Clinical practice guideline: hoarseness (dysphonia). *Otolaryngology – Head and Neck Surgery*. 2018;Supplement:I-42.
20. Zesiewicz TA, Elble R, Louis ED, et al. Evidence-based guideline update: Treatment of essential tremor: Report of the Quality Standards Subcommittee of the American Academy of Neurology. *Neurology*. 2011;77:1752-1755.
21. International Hyperhidrosis Society. Primary focal craniofacial and gustatory hyperhidrosis (Frey's Syndrome). Updated January 15, 2012. Available at: <https://sweathelp.org/treatments-hcp/clinical-guidelines/primary-focal-hyperhidrosis/primary-focal-facial-and-gustatory.html>. Accessed on January 9, 2023.
22. Naumann M, So Y, Argoff CE, et al. Assessment: botulinum neurotoxin in the treatment of autonomic disorders and pain (an evidence-based review) [RETIRED]. Report of the therapeutics and technology assessment subcommittee of the American Academy of Neurology. *Neurology*. 2008;70(19):I707-I714.
23. Cheng CM, Chen JS, Patel RP. Unlabeled uses of botulinum toxins: A review, part I. *Am J Health Syst Pharm*. 2006;63(2): I45-I52.
24. Lowe N, Campanati A, Bodokh I, et al. The place of botulinum toxin type A in the treatment of focal hyperhidrosis. *Br J Dermatol*. 2004;151(6):II15-II22.
25. Porta M, Maggioni G. Botulinum toxin (BoNT) and back pain. *J Neurol*. 2004;251(Suppl I):I/I5-I/I8.
26. Porta M. A comparative trial of botulinum toxin type A and methylprednisolone for the treatment of myofascial pain syndrome and pain from chronic muscle spasm. *Pain*. 2000;85:101-105.
27. Qerama E, Fuglsang-Frederiksen, Kasch H, et al. A double-blind, controlled study of botulinum toxin A in chronic myofascial pain. *Neurology*. 2006;67(2):241-245.
28. Ruiz MF, Moreno M, Sanchez-Garrido CM, et al. Botulinum treatment of infantile esotropia with abduction nystagmus. *J Ped Ophthalm Strabismus*. 2000;37:196-205.
29. Repka MX, Savino PJ, Reinecke RD. Treatment of acquired nystagmus with botulinum neurotoxin A. *Arch Ophthalmol*. 1994;112(10):I320-I324.
30. Leigh RJ, Tomsak RL, Grant MP, et al. Effectiveness of botulinum toxin administered to abolish acquired nystagmus. *Ann Neurol*. 1992;32(5):633-642.
31. Kao LY, Chao AN. Subtenon injection of botulinum toxin for treatment of traumatic sixth nerve palsy. *J Pediatr Ophthalmol Strabismus*. 2003;40(I):27-30.
32. Hung HL, Kao LY, Sun MH. Botulinum toxin treatment for acute traumatic complete sixth nerve palsy. *Eye*. 2005;19(3):337-341. 30. Elizondo-Rodriguez J, Araujo-Lopez Y, Moreno-Gonzalez JA, et al. A comparison of botulinum toxin A and intralesional steroids for the treatment of plantar fasciitis: a randomized, double-blinded study. *Foot Ankle Int*. 2013;34(I):8-14.
33. Thomas JL, Christensen JC, Kravitz SR, et al. The diagnosis and treatment of heel pain: a clinical practice guideline – revision 2010. *J Foot Ankle Surg*. 2010;49:S1-S19.
34. Lakraj AA, Moghimi N, Jabbari B. Sialorrhea: anatomy, pathophysiology and treatment with emphasis on the role of botulinum toxin. *Toxins*. 2013;5:I010-I031.
35. Simpson DM, Hallett M, Ashman EJ, et al. Practice guideline update summary: botulinum neurotoxin for the treatment of blepharospasm, cervical dystonia, adult spasticity, and headache. Report of the Guideline Development Subcommittee of the American Academy of Neurology. *Neurology*. 2016;86:I818-I826.
36. Clinical Pharmacology [database online]. Tampa, FL: Elsevier, Inc.; 2022. Available at: <https://www.clinicalkey.com/pharmacology/>. Accessed on January 9, 2023. Search terms: Botox.
37. Walker TJ, Dayan SH. Comparison and overview of currently available neurotoxins. *J Clin Aesthet Dermatol*. 2014;7(2):31-39.
38. Scaglione F. Conversion ratio between Botox®, Dysport®, and Xeomin® in clinical practice. *Toxins (Basel)*. 2016;8(3):65.
39. Camilleri M, Parkman HP, Shafi MA, et al. Clinical guideline: management of gastroparesis. *Am J Gastroenterol*. 2013;108(I):I8-38.
40. Ailani J, Burch RC, Robbins MS, on behalf of the Board of Directors of the American Headache Society. The American Headache Society Consensus Statement: Update on integrating new migraine treatments into clinical practice. *Headache*. 2021;O0:I-I9. 41. Micromedex. Merative LP. Available at: <https://www.micromedexsolutions.com/>. Accessed on August 7, 2023. Search terms: lisinopril, verapamil. 42. Clinical Pharmacology. ClinicalKey. Available at: <https://www.clinicalkey.com/pharmacology/>. Accessed on August 7, 2023. Search terms: lisinopril, verapamil.
41. Brisinda G, Bentivoglio AR, Maria G, et al. Treatment with botulinum neurotoxin of gastrointestinal smooth muscles and sphincters spasms. *Mov Disord*. 2004;19(Suppl 8):S146-S156.
42. Friedenberg F, Gollamudi S, Parkman HP. The use of botulinum toxin for the treatment of gastrointestinal motility disorders. *Dig Dis Sci*. 2004;49(2):I65-I75.
43. Bansal C, Omlin KJ, Hayes CM, et al. Novel cutaneous uses for botulinum toxin type A. *J Cosmet Dermatol*. 2006;5(3):268-272.
44. Truong D, Comella C, Fernandez HH, et al; Dysport Benign Essential Blepharospasm Study Group. Efficacy and safety of purified botulinum toxin type A (Dysport) for the treatment of benign essential blepharospasm: a randomized, placebo-controlled, phase II trial. *Parkinsonism Relat Disord*. 2008;14(5):407-414.
45. Kollewe K, Mohammadi B, Köhler S, et al. Blepharospasm: long-term treatment with either Botox®, Xeomin® or Dysport®. *J Neural Transm*. 2015;122(3):427-431.
46. Tan EK. Botulinum toxin treatment of sialorrhea: comparing different therapeutic preparations. *Eur J Neurol*. 2006;13 (Suppl I):60-64.
47. Sheffield JK, Jakovic J. Botulinum toxin in the treatment of tremors, dystonias, sialorrhea and other symptoms associated with Parkinson's disease. *Expert Rev Neurotherapeutics*. 2007;7(6):637-647.

48. Clinical Pharmacology [database online]. Tampa, FL: Elsevier, Inc.; 2022. Available at: <https://www.clinicalkey.com/pharmacology/>. Accessed on October 9, 2023. Search terms: Dysport.

Colony Stimulating Factors Short-Acting

- I. Neupogen® intravenous or subcutaneous injection [prescribing information]. Thousand Oaks, CA: Amgen; April 2021.
2. Zarxio™ intravenous or subcutaneous injection [prescribing information]. Princeton, NJ: Sandoz; March 2021.
3. Nivestym™ intravenous or subcutaneous injection [prescribing information]. Lake Forest, IL: Hospira/Pfizer; August 2023.
4. Releuko® subcutaneous or intravenous injection [prescribing information]. Bridgewater, NJ: Amneal; April 2022.
5. Granix® subcutaneous injection [prescribing information]. North Wales, PA: Teva; April 2020.
6. Smith TJ, Bohlke K, Lyman GH, Carson KR, et al. Recommendations for the use of WBC growth factors: American Society of Clinical Oncology Clinical Practice Guideline Update. *J Clin Oncol.* 2015;33(28):3199-3212.
7. Kuritzkes DR, Parenti D, Ward DJ, et al, and the G-CSF 930101 study group. Filgrastim prevents severe neutropenia and reduces infective morbidity in patients with advanced HIV infection: Results of a randomized, multicenter controlled trial. *AIDS.* 1998;12:65-71.
8. Hermans P, Rozenbaum W, Joy A, et al, and the G-CSF 92105 Study Group. Filgrastim to treat neutropenia and support myelosuppressive medication dosing in HIV infection. *AIDS.* 1996;10:1627-1633.
9. Kuritzkes DR. Neutropenia, neutrophil dysfunction, and bacterial infection in patients with human immunodeficiency virus disease: The role of granulocyte colony-stimulating factor. *Clin Infect Dis.* 2000;30:256-260.
- IO. Mitsuyasu R. Prevention of bacterial infections in patients with advanced HIV infection. *AIDS.* 1999;13(Suppl 2):S19-S23.
- II. Tesfa D, Keisu M, Palblad J. Idiosyncratic drug-induced agranulocytosis: Possible mechanism and management. *Am J Hematol.* 2009;84:428-434.
12. Andersohn F, Konzen C, Garbe E. Systematic review: Agranulocytosis
13. Beaushesne MF, Shalansky SJ. Nonchemotherapy drug-induced agranulocytosis: A review of 118 patients treated with colony-stimulating factors. *Pharmacother.* 1999;19(3):299-305.
14. Bhatt V, Saleem A. Review: Drug-induced neutropenia-pathophysiology, clinical features, and management. *Ann Clin Lab Sci.* 2004;34(2):I31-I36.
15. Curtis BR. Drug-induced immune neutropenia/agranulocytosis. *Immunohematology.* 2014;30(2):95-101.
16. Andres E, Mourot-Cottet R. Non-chemotherapy drug-induced neutropenia – an update. *Expert Opin Drug Saf.* 2017;16(II):I235-I242.
17. Andres E, Mourot-Cottet R, Maloisel F, et al. Idiosyncratic drug-induced neutropenia and agranulocytosis. *QJM.* 2017 May;110(5):299-305.

Colony Stimulating Factors Long-Acting

- I. Neulasta® subcutaneous injection [prescribing information]. Thousand Oaks, CA: Amgen; March 2021.
2. Fulphila® subcutaneous injection [prescribing information]. Rockford, IL: Mylan; July 2023.
3. Udenycat™ subcutaneous injection [prescribing information]. Redwood City, CA: Coherus; March 2023.
4. Zixtenzo™ subcutaneous injection [prescribing information]. Princeton, NJ: Sandoz; Decemeber 2022.
5. Nyvepria™ subcutaneous injection [prescribing information]. New York, NY: Pfizer; June 2023.
6. Fylnetra® subcutaneous injection [prescribing information]. Bridgewater, NJ: Amneal; May 2022.
7. Stimufend® subcutaneous injection [prescribing information]. Lake Zurich, IL: Fresenius Kabi; September 2022.
8. Rolvedon™ subcutaneous injection [prescribing information]. Irvine, CA: Spectrum; June 2023.
9. Smith TJ, Bohlke K, Lyman GH, Carson KR, et al. Recommendations for the use of WBC growth factors: American Society of Clinical Oncology Clinical Practice Guideline Update. *J Clin Oncol.* 2015;33(28):3199-3212.
- IO. IJakob A, Hirsch FW, Engelhardt M. Successful treatment of a patient with myelodysplastic syndrome (RAEB) with darbepoetin alfa in combination with pegfilgrastim. *Ann Hematol.* 2005;84(10):694-695.

Immune Globulins IV

- I. Bivigam® 10% intravenous solution [prescribing information]. Boca Raton, FL: ADMA Biologics; December 2022.
2. Flebogamma® 5% DIF intravenous solution [prescribing information]. Los Angeles, CA: Grifols; September 2019.
3. Flebogamma DIF 10% intravenous solution [prescribing information]. Los Angeles, CA: Grifols; September 2019.
4. Gammagard® Liquid 10% solution [prescribing information]. Lexington, MA: Takeda; January 2024.
5. Gammagard® S/D IgA < 1 mcg/mL in a 5% intravenous solution [prescribing information]. Lexington, MA: Takeda; March 2023.
6. Gammakded™ 10% solution [prescribing information]. Fort Lee, NJ: Kedrion; January 2020.
7. Gammoplex® 5% intravenous solution [prescribing information]. Durham, NC: BPL; November 2021.
8. Gammoplex 10% intravenous solution [prescribing information]. Durham, NC: BPL; November 2021.
9. Gamunex®-C 10% solution [prescribing information]. Los Angeles, CA: Grifols; January 2020.
10. Octagam® 5% intravenous solution [prescribing information]. Paramus, NJ: Octapharma; April 2022.
- II. Octagam® 10% intravenous solution [prescribing information]. Paramus, NJ: Octapharma; April 2022.
12. Privigen® 10% intravenous solution [prescribing information]. Kankakee, IL: CSL Behring; March 2022.
13. Panzyga 10% intravenous solution [prescribing information]. New York; NY: Pfizer; February 2021.
14. Asceniv 10% intravenous solution [prescribing information]. Boca Raton, FL. ADMA Biologics; April 2019.
15. Alyglo™ 10% intravenous solution [prescribing information]. Teaneck, NJ: GC Biopharma; December 2023.
16. Perez EE, Orange JS, Bonilla F, et al. Update on the use of immunoglobulin in human disease: A review of evidence. *J Allergy Clin Immunol.* 2017;139(3S):S1-S46

Immune Globulins SC

- I. Gammagard® Liquid 10% [prescribing information]. Lexington, MA: Takeda; January 2024.
2. Gammakded™ 10% solution [prescribing information]. Fort Lee, NJ: Kedrion; January 2020.
3. Gamunex®-C 10% solution [prescribing information]. Research Triangle Park, NC: Grifols; January 2020.
4. Hizentra® 20% subcutaneous solution [prescribing information]. Kankakee, IL: CSL Behring; April 2023.
5. HyQvia® 10% subcutaneous solution with recombinant human hyaluronidase [prescribing information]. Lexington, MA: Takeda; January 2024.

6. McLean HQ, Fiebelkorn AP, Temte JL, Wallace GS; Centers for Disease Control and Prevention. Prevention of measles, rubella, congenital rubella syndrome, and mumps, 2013: summary recommendations of the Advisory Committee on Immunization Practices (ACIP). *MMWR Recomm Rep.* 2013;62:1-34.
7. Xembify® 20% subcutaneous solution [prescribing information]. Research Triangle Park, NC: Grifols; August 2020.
8. Cuvitru™ 20% subcutaneous solution [prescribing information]. Lexington, MA: Takeda; March 2023.
9. Cutaquig® 16.5% subcutaneous solution [prescribing information]. New York, NY: Pfizer; November 2021.
10. Perez EE, Orange JS, Bonilla F, et al. Update on the use of immunoglobulin in human disease: A review of evidence. *J Allergy Clin Immunol.* 2017;139(3S):S1-S46.
- II. Bonilla FA, Khan DA, Ballas ZK, et al. Practice parameter for the diagnosis and management of primary immunodeficiency. *J Allergy Clin Immunol.* 2015;136:II86-II205.

Immunomodulators

- I. Remicade® injection [prescribing information]. Horsham, PA: Janssen Biotech; June 2018.
2. Inflectra™ injection for IV use [prescribing information]. Lake Forest, IL: Hospira/Pfizer; April 2016.
3. Renflexis injection for IV use [prescribing information]. Whitehouse Station, NJ: Samsung Bioepis/Merck; April 2017.
4. Avsola [prescribing information]. Thousand Oaks, CA: Amgen; December 2019.
5. Lichtenstein GR, Loftus EV, Isaacs KL, et al. ACG Clinical Guideline: Management of Crohn's Disease in Adults. *Am J Gastroenterol.* 2018;113(4):48I-51I.
6. Feuerstein JD, Ho EY, Shmidt E, et al. AGA clinical practice guidelines on the medical management of moderate to severe luminal and perianal fistulizing Crohn's disease. *Gastroenterology.* 2021;160(7):2496-2508.
7. Menter A, Strober BE, Kaplan DH, et al. Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with biologics. *J Am Acad Dermatol.* 2019;80(4):I029-I072.
8. Singh JA, Guyatt G, Oggie A, et al. 2018 American College of Rheumatology/National Psoriasis Foundation Guideline for the treatment of psoriatic arthritis. *Arthritis Care Res (Hoboken).* 2019;71(I):2-29.
9. Fraenkel L, Bathon JM, England BR, et al. 2021 American College of Rheumatology guideline for the treatment of rheumatoid arthritis. *Arthritis Rheumatol.* 2021;73(7):II08-II23.
10. Ward MM, Deodhar A, Gensler LS, et al. 2019 update of the American College of Rheumatology/Spondylitis Association of America/Spondyloarthritis Research and Treatment Network recommendations for the treatment of ankylosing spondylitis and nonradiographic axial spondyloarthritis. *Arthritis Rheumatol.* 2019;110:1599-1613.
- II. Rubin DT, Ananthakrishnan AN, Siegel CA, et al. ACG clinical guideline: ulcerative colitis in adults. *Am J Gastroenterol.* 2019;114(3):384-413.
12. Pardi DS, D'Haens G, Shen B, et al. Clinical guidelines for the management of pouchitis. *Inflamm Bowel Dis.* 2009;15(9):I424-I431.
13. Feuerstein JD, Isaac s KL, Schneider Y, et al. AGA clinical practice guidelines on the management of moderate to severe ulcerative colitis. *Gastroenterology.* 2020;158:1450-1461.
14. Hatemi G, Christensen R, Bang D, et al. 2018 update of the EULAR recommendations for the management of Behcet's syndrome. *Ann Rheum Dis.* 2018;77(6):808-818.
15. Levy-Clarke G, Jabs DA, Read RW, et al. Expert panel recommendations for the use of anti-tumor necrosis factor biologic agents in patients with ocular inflammatory disorders. *Ophthalmology.* 2014;121(3):785-796.
16. Grant A, Gonzalez T, Montgomery MO, et al. Infliximab therapy for patients with moderate to severe hidradenitis suppurativa: a randomized, double-blind, placebo-controlled crossover trial. *J Am Acad Dermatol.* 2010;62(2):205-217.
17. Sullivan TP, Welsh E, Kerdell FA, et al. Infliximab for hidradenitis suppurativa. *Br J Dermatol.* 2003;149:I046-I049.
18. Fardet L, Dupuy A, Kerob D, et al. Infliximab for severe hidradenitis suppurativa: transient clinical efficacy in 7 consecutive patients. *J Am Acad Dermatol.* 2007;56:624-628.
19. Haslund P, Lee RA, Jemec GB. Treatment of hidradenitis suppurativa with tumour necrosis factor-alpha inhibitors. *Acta Derm Venereol.* 2009;89(6):595-600.
20. Papadakis KA, Treyzon L, Abreu MT, et al. Infliximab in the treatment of medically refractory indeterminate colitis. *Aliment Pharmacol Ther.* 2003;18:74I-747.
21. Gornet JM, Couve S, Hassani Z, et al. Infliximab for refractory ulcerative colitis or indeterminate colitis: an open-label multicentre study. *Aliment Pharmacol Ther.* 2003;18:I75-I8I.
22. Ringold S, Angeles-Han ST, Beukelman T, et al. 2019 American College of Rheumatology/Arthritis Foundation guideline for the treatment of juvenile idiopathic arthritis: therapeutic approaches for non-systemic polyarthritis, sacroiliitis, and enthesitis. *Arthritis Rheumatol.* 2019;71(6):846-863.
23. Ringold S, Weiss PF, Beukelman T, et al. 2013 update of the 2011 American College of Rheumatology recommendations for the treatment of juvenile idiopathic arthritis: recommendations for the medical therapy of children with systemic juvenile idiopathic arthritis and tuberculosis screening among children receiving biologic medications. *Arthritis Rheum.* 2013;65(10):2499-2512.
24. Dabade TS, Davis MD. Diagnosis and treatment of the neutrophilic dermatoses (pyoderma gangrenosum, Sweet's syndrome). *Dermatol Ther.* 2011;24(2):273-284.
25. Baughman RP, Valeyre D, Korsten P, et al. ERS clinical practice guidelines on treatment of sarcoidosis. *Eur Respir J.* 2021;58(6):2004079.
26. Riera E, Olivé A, Narváez J, et al. Adult onset Still's disease: review of 41 cases. *Clin Exp Rheumatol.* 2011;29(2):33I-336.
27. Pouchot J, Arlet JB. Biological treatment in adult-onset Still's disease. *Best Pract Res Clin Rheumatol.* 2012;26(4):477-487.
28. Kontzias A, Efthimiou P. Adult-onset Still's disease: pathogenesis, clinical manifestations and therapeutic advances. *Drugs.* 2008;68:319-337.
29. Dastmalchi, M, Grundtman, C, Alexanderson, H, et al. A high incidence of disease flares in an open pilot study of infliximab in patients with refractory inflammatory myopathies. *Ann Rheum Dis.* 2008;67:I670-I677.
30. Hellmich B, Agueda A, Monti S, et al. 2018 Update of the EULAR recommendations for the management of large vessel vasculitis. *Ann Rheum Dis.* 2020;79(I):I9-30.
31. Onel KB, Horton DB, Lovell DJ, et al. 2021 American College of Rheumatology guideline for the treatment of juvenile idiopathic

arthritis: therapeutic approaches for oligoarthritis, temporomandibular joint arthritis, and systemic juvenile idiopathic arthritis. *Arthritis Rheumatol.* 2022 Apr;74(4):553-569.

Intravenous Iron

- I. Injectafer® intravenous infusion or injection [prescribing information]. Shirley, NY: American Regent; May 2023.
2. Venofer® intravenous infusion or injection [prescribing information]. Shirley, NY: American Regent; July 2022.
3. Feraheme® intravenous infusion [prescribing information]. Waltham, MA: AMAG Pharmaceuticals; June 2022.
4. Monoferic® intravenous infusion [prescribing information]. Morristown, NJ: Pharmacosmos Therapeutics; August 2022.
5. Kidney Disease: Improving Global Outcomes (KDIGO) Anemia Work Group. KDIGO Clinical Practice Guideline for Anemia in Chronic Kidney Disease. *Kidney Int.* 2012;2(Suppl):279-335.
6. Yancy CW, Jessup M, Bozkurt B, et al. 2017 ACC/AHA/HFSA focused update of the 2013 ACCF/AHA guideline for the management of heart failure. *J Am Coll Cardiol.* 2017;70(6):776-803

Ophthalmic Disorders Intravitreal Vascular Endothelial Growth Factor (VEGF) Inhibitors

- I. Beovu® intravitreal injection [prescribing information]. Hanover, NJ: Novartis; December 2022.
2. Eylea® intravitreal injection [prescribing information]. Tarrytown, NY: Regeneron; February 2023.
3. Lucentis® intravitreal injection [prescribing information]. South San Francisco, CA: Genentech; October 2020.
4. Byooviz™ intravitreal injection [prescribing information]. Cambridge, MA: Biogen; June 2023.
5. Vabysmo™ intravitreal injection [prescribing information]. South San Francisco, CA: Genentech; January 2023.
6. Cimerli™ intravitreal injection [prescribing information]. Redwood City, CA: Coherus; November 2022.
7. Eylea™ HD intravitreal injection [prescribing information]. Tarrytown, NY: Regeneron; August 2023.
8. American Academy of Ophthalmology Retina/Vitreous Panel. Preferred Practice Pattern® Guidelines. Age-related macular degeneration. San Francisco, CA: American Academy of Ophthalmology; 2019. Available at: <https://www.aao.org/preferred-practice-pattern/age-related-macular-degeneration-ppp>. Accessed on July 21, 2023.
9. American Academy of Ophthalmology Retina/Vitreous Panel. Preferred Practice Pattern® Guidelines. Diabetic retinopathy. San Francisco, CA: American Academy of Ophthalmology; 2019. Available at: <https://www.aao.org/preferred-practice-pattern/diabetic-retinopathy-ppp>. Accessed on July 21, 2023.
- IO. Barakat MR, Kaiser PK. VEGF inhibitors for the treatment of neovascular age-related macular degeneration. *Expert Opin Investig Drugs.* 2009;18(5):637-646.
- II. Tolentino M. Systemic and ocular safety of intravitreal anti-VEGF therapies for ocular neovascular disease. *Surv Ophthalmol.* 2011;56(2):95-113.
12. Kinnunen K, Ylä-Herttuala S. Vascular endothelial growth factors in retinal and choroidal neovascular diseases. *Ann Med.* 2012;44(1):1-17.
13. Horsley MB, Kahook MY. Anti-VEGF therapy for glaucoma. *Curr Opin Ophthalmol.* 2010;21(2):112-117.

Paclitaxel Medications

- I. Paclitaxel intravenous infusion [prescribing information]. Lake Forest, IL: Hospira; April 2021.
2. Abraxane® intravenous infusion [prescribing information]. Summit, NJ: Celgene; August 2020.
3. Shroff RT, Javle MM, Xiao L, et al. Gemcitabine, cisplatin, and nab-paclitaxel for the treatment of advanced biliary tract cancers. A phase 2 clinical trial. *JAMA Oncol.* 2019;5:824-830.
4. Sahai V, Catalano PJ, Zalupski MM, et al. Nab-paclitaxel and gemcitabine as first-line treatment of advanced or metastatic cholangiocarcinoma. A Phase 2 clinical trial. *JAMA Oncol.* 2018;4:I707-I712.
5. Alberts DS, Blessing JA, Landrum LM, et al. Phase II trial of nab-paclitaxel in the treatment of recurrent or persistent advanced cervical cancer: A gynecologic oncology group study. *Gynecol Oncol.* 2012;127:451-455.

Rituximab

- I. Rituxan [prescribing information]. South San Francisco, CA: Genentech; December 2021.
2. Ruxience [prescribing information]. New York, NY: Pfizer; November 2021.
3. Truxima [prescribing information]. North Wales, PA: Teva/Celtrion; April 2023.
4. Rituxan Hycela™ injection for SC use [prescribing information]. South San Francisco, CA: Biogen and Genentech/Roche; June 2021.
5. Riabni [prescribing information]. Thousand Oaks, CA: Amgen; June 2022.
6. Chung SA, Langford CA, Maz M, et al. 2021 American College of Rheumatology/Vasculitis Foundation guideline for the management of antineutrophil cytoplasmic antibody-associated vasculitis. *Arthritis Rheumatol.* 2021 Jul 8 [online ahead of print].
7. Tieu J, Smith R, Basu N, et al. Rituximab for maintenance of remission in ANCA-associated vasculitis: expert consensus guidelines. *Rheumatology (Oxford).* 2020;59(4):e24-e32.
8. Fraenkel L, Bathon JM, England BR, et al. 2021 American College of Rheumatology guideline for the treatment of rheumatoid arthritis. *Arthritis Rheumatol.* 2021;73(7):II08-II23.
9. Neunert C, Terrell DR, Arnold DM, et al. American Society of Hematology 2019 guidelines for immune thrombocytopenia. *Blood Adv.* 2019;3(23):3829-3866.
- IO. A Consensus Paper by the Multiple Sclerosis Coalition. The use of disease-modifying therapies in multiple sclerosis. Updated June 2019. Available at: http://ms-coalition.org/wp-content/uploads/2019/06/MSC_DMTPaper_062019.pdf. Accessed on July 18, 2023.
- II. Rae-Grant A, Day GS, Marrie RA, et al. Practice guideline recommendations summary: disease-modifying therapies for adults with multiple sclerosis. Report of the Guideline Development, Dissemination, and Implementation Subcommittee of the American Academy of Neurology. *Neurology.* 2018;90:777-788. 20. Siegel Rare Neuroimmune Association. Neuromyelitis Optica Spectrum Disorders. Available at: About_NMOSD_2018.pdf (wearesrna.org). Accessed on July 18, 2023.
12. Fanouriakis A, Kostopoulou M, Alunno A, et al. 2019 update of the EULAR recommendations for the management of systemic lupus erythematosus. *Ann Rheum Dis.* 2019;78(6):736-745.
13. Harman KE, Brown D, Exton LS, et al. British Association of Dermatologists' guidelines for the management of pemphigus vulgaris 2017. *Br J Dermatol.* 2017;177(5):II70-II201.

14. Clinical Pharmacology [database online]. Tampa, FL: Elsevier, Inc.; 2022. Available at: <https://www.clinicalkey.com/pharmacology/>. Accessed on October 10, 2022. Search terms: Rituximab. 31. Micromedex®. IBM Corporation. Available at: <http://www.micromedexsolutions.com> Accessed on October 10, 2021. Search terms: Rituximab.
15. Kasperkiewicz M, Shimanovich I, Ludwig RJ, Rose C, Zillikens D, Schmidt E. RITUXIMAB for treatment-refractory pemphigus and pemphigoid: a case series of 17 patients. *J Am Acad Dermatol.* 2011;65(3):552-558.
16. Lourari S, Herve C, Doffoel-Hantz V, et al. Bullous and mucous membrane pemphigoid show a mixed response to RITUXIMAB: experience in seven patients. *J Eur Acad Dermatol Venereol.* 2011;25(10):1238-1240.
17. Levine TD. RITUXIMAB in the treatment of dermatomyositis: an open-label pilot study. *Arthritis Rheum.* 2005;52(2):601-607.
18. Unger L, Kampf S, Luthke K, Aringer M. RITUXIMAB therapy in patients with refractory dermatomyositis or polymyositis: differential effects in a real-life population. *Rheumatology (Oxford).* 2014;53(9):1630-1638.
19. de Souza FHC, Mirossi R, de Moraes JCB, Bonfa E, Shinjo SK. Favorable RITUXIMAB response in patients with refractory idiopathic inflammatory myopathies. *Adv Rheumatol.* 2018;58(1):31.
20. Barsotti S, Cioffi E, Tripoli A, et al. The use of RITUXIMAB in idiopathic inflammatory myopathies: description of a monocentric cohort and review of the literature. *Reumatismo.* 2018;70(2):78-84.
21. Ebbo M, Grados A, Samson M, et al. Long-term efficacy and safety of RITUXIMAB in IgG4-related disease: Data from a French nationwide study of thirty-three patients. *PLoS One.* 2017;12(9):e0183844.
22. Khosroshahi A, Carruthers MN, Deshpande V, Unizony S, Bloch DB, Stone JH. RITUXIMAB for the treatment of IgG4-related disease: lessons from 10 consecutive patients. *Medicine (Baltimore).* 2012;91(1):57-66.
23. Colvin MM, Cook JL, Chang P, et al. Antibody-mediated rejection in cardiac transplantation: emerging knowledge in diagnosis and management: a scientific statement from the American Heart Association. *Circulation.* 2015;131(18):1608-1639.
24. Vo AA, Lukovsky M, Toyoda M, et al. RITUXIMAB and intravenous immune globulin for desensitization during renal transplantation. *N Engl J Med.* 2008;359(3):242-251.
25. Zwicker JI, Muia J, Dolatshahi L, et al. Adjuvant low-dose rituximab and plasma exchange for acquired TTP. *Blood.* 2019;134(13):106-1109.
26. Remuzzi G, Chiarchiu C, Abbate M, et al. Rituximab for idiopathic membranous nephropathy. *Lancet.* 2002;360(9337):923-4.
27. KDIGO 2021 Clinical Practice Guideline for the Management of Glomerular Diseases. *Kidney Int.* 2021 Oct;100(4S):S1-S276.
28. Schneider B, Naidoo J, Santomasso B, et al. Management of Immune-Related Adverse Events in Patients Treated With Immune Checkpoint Inhibitor Therapy: ASCO Guideline Update. *J Clin Oncol.* 2021;39(36):4073-4126.

Somatostatin Analogs Long-Acting

1. Somatuline® Depot injection [prescribing information]. Basking Ridge, NJ: Ipsen; February 2023.
2. Lanreotide subcutaneous injection [prescribing information]. Warren, NJ: Cipla; December 2021.
3. Sandostatin® LAR Depot intramuscular injection [prescribing information]. East Hanover, NJ: Novartis; July 2023.
4. Strosberg JR, Halfdanarson TR, Bellizi AR, et al. The North American Neuroendocrine Tumor Society consensus guidelines for surveillance and medical management of midgut neuroendocrine tumors. *Pancreas.* 2017;46(6):707-714.

Systemic Lupus Erythematosus (SLE) Lupus

1. Benlysta® injection [prescribing information]. Rockville, MD: Human Genome Sciences/GlaxoSmithKline; February 2023.
2. Saphnelo® injection [prescribing information]. Wilmington, DE: AstraZeneca; September 2022.
3. Hahn BH, McMahon MA, Wilkinson A, et al. American College of Rheumatology guidelines for screening, treatment, and management of lupus nephritis. *Arthritis Care Res (Hoboken).* 2012;64(6):797-808.
4. Rovin BH, Adler SG, Barratt J, et al. Executive summary of the KDIGO 2021 guideline for the management of glomerular diseases. *Kidney Int.* 2021;100(4):753-779.
5. Fanouriakis A, Kostopoulou M, Alunno A, et al. 2019 update of the EULAR recommendations for the management of systemic lupus erythematosus. *Ann Rheum Dis.* 2019;78(6):736-745.
6. Stohl W, Merrill JT, McKay JD, et al. Efficacy and safety of belimumab in patients with rheumatoid arthritis: a phase II, randomized, double-blind, placebo-controlled, dose-ranging study. *J Rheumatol.* 2013;40(5):579-589.

Testosterone Injectable

1. Depo®-Testosterone [prescribing information]. New York, NY: Pfizer; August 2018.
2. Testosterone enanthate injection [prescribing information]. Berkeley Heights, NJ: Hikma; January 2021.
3. Testopel® [prescribing information]. Malvern, PA: Endo; August 2018.
4. Aveed™ [prescribing information]. Malvern, PA: Endo; August 2021.
5. Xyosteal [prescribing information]. Ewing, NJ: Antares; November 2019.
6. Lee M. Erectile Dysfunction. Urologic Disorders. In: Dípilo JT, Talbert RL, Yee GC, et al, eds. *Pharmacotherapy: A pathophysiologic approach.* 8th ed. New York: McGraw Hill Medical; 2008:1437-1454.
7. Mulhall JP, Trost LW, Brannigan RE, et al. Evaluation and Management of Testosterone Deficiency. American Urological Association. 2018. Available at: [Testosterone Deficiency Guideline - American Urological Association \(auanet.org\)](https://www.auanet.org/-/media/assets/guidelines/testosterone-deficiency). Accessed on September 1, 2023.
8. Bhagat S, Brito JP, Cunningham GR, et al. Testosterone therapy in men with hypogonadism: an Endocrine Society clinical practice guideline. *J Clin Endocrinol Metab.* 2018;103(5):1715-1744.
9. Hembree WC, Cohen-Kettenis P, Gooren L, et al. Endocrine treatment of gender-dysphoric/gender-incongruent persons: an Endocrine Society clinical practice guideline. *J Clin Endocrinol Metab.* 2017;102(11):3869-3903.

Trastuzumab

1. Herceptin® intravenous infusion [prescribing information]. South San Francisco, CA: Genentech; February 2021.
2. Herzuma® intravenous infusion [prescribing information]. North Wales, PA: Teva; May 2019.
3. Kanjinti® intravenous infusion [prescribing information]. Thousand Oaks, CA: Amgen; October 2022.
4. Ogvir® intravenous infusion [prescribing information]. Steinhausen, Switzerland: Mylan; July 2023.
5. Trazimera™ intravenous infusion [prescribing information]. New York, NY: Pfizer; November 2020.

6. Herceptin Hylecta™ subcutaneous injection [prescribing information]. South San Francisco, CA: Genentech; February 2019.
7. Ontruzant® intravenous infusion [prescribing information]. Whitehouse Station, NJ: Merck; March 2020.

Viscosupplements

1. Durolane® intraarticular injection [prescribing information]. Durham, NC: Bioventus; not dated.
2. Euflexxa® intraarticular injection [prescribing information]. Parsippany, NJ: Ferring; July 2016.
3. Gel-One® intraarticular injection [prescribing information]. Warsaw, IN: Zimmer; May 2011.
4. Gelsyn-3® intraarticular injection [prescribing information]. Durham, NC: Bioventus; 2016.
5. GenVisc® 850 intraarticular injection [prescribing information]. Doylestown, PA: OrthogenRx; not dated.
6. Hyalgan® intraarticular injection [prescribing information]. Parsippany, NJ: Fidia Pharma; May 2014.
7. Hymovis® intraarticular injection [prescribing information]. Parsippany, NJ: Fidia Pharma; October 2015/2021.
8. Monovisc® intraarticular injection [prescribing information]. Bedford, MA: DePuy Synthes; not dated.
9. Orthovisc® intraarticular injection [prescribing information]. Raynham, MA: DePuy Synthes; September 2014.
10. Sodium hyaluronate 1% intraarticular injection [prescribing information]. North Wales, PA: Teva; March 2019.
- II. Supartz® FX™ intraarticular injection [prescribing information]. Durham, NC: Bioventus; April 2015.
12. Synvisc® intraarticular injection [prescribing information]. Ridgefield, NJ: Genzyme; September 2014.
13. Synvisc-One® intraarticular injection [prescribing information]. Ridgefield, NJ: Genzyme; September 2014.
14. Triluron intraarticular injection [prescribing information]. Florham Park, NJ: Fidia Pharma; March 2019.
15. Trivisc intraarticular injection [prescribing information]. Doylestown, PA: OrthogenRx; not dated.
16. Visco-3 intraarticular injection [prescribing information]. Durhan, NC: Bioventus; not dated.
17. SynoJoynt™ injection [prescribing information]. Naples, FL: Arthrex; 2022.
18. Kolasinski SH, Neogi T, Hochberg MC, et al. 2019 American College of Rheumatology/Arthritis Foundation Guideline for the management of osteoarthritis of the hand, hip, and knee. *Arthritis Care Res.* 2019;72(2):149-162.
19. American Academy of Orthopaedic Surgeons Management of Osteoarthritis of the Knee (Non-Arthroplasty) Evidence-Based Clinical Practice Guideline. Published August 31, 2021. Available at: Osteoarthritis of the Knee - Clinical Practice Guideline (CPG) | American Academy of Orthopaedic Surgeons (aaos.org). Accessed on September 21, 2023.
20. Bannuru RR, Osani MC, Vaysbrot EE, et al. OARSI guidelines for the non-surgical management of knee, hip, and polyarticular osteoarthritis. *Osteoarthritis Cartilage.* 2019;27(11):1578-1589.
21. Petrella RJ, Petrella MJ, Cogliano A. Periarticular hyaluronic acid in acute ankle sprain. *Clin J Sport Med.* 2007;17(4):251-257.
22. Petrella MJ, Cogliano A, Petrella RJ. Original research: long-term efficacy and safety of periarticular hyaluronic acid in acute ankle sprain. *Phys Sportsmed.* 2009;37(1):64-70.
23. Izquierdo R, Voloshin I, Edwards S, et al. Treatment of glenohumeral osteoarthritis. *J Am Acad Orthop Surg.* 2010;18(6):375-382.
24. Sun SF, Chou YJ, Hsu CW, et al. Efficacy of intra-articular hyaluronic acid in patients with osteoarthritis of the ankle: a prospective study. *Osteoarthritis Cartilage.* 2006;14(9):867-874.
25. Salk RS, Chang TJ, D'Costa WF, et al. Sodium hyaluronate in the treatment of osteoarthritis of the ankle: a controlled, randomized, double-blind, pilot study. *J Bone Joint Surg Am.* 2006;88(2):295-302.
26. Karatosun V, Unver B, Ozden A, et al. Intra-articular hyaluronic acid compared to exercise therapy in osteoarthritis of the ankle. A prospective randomized trial with long-term follow-up. *Clin Exp Rheumatol.* 2008;26(2):288-294.
27. Sun SF, Chou YJ, Hsu CW, Chen WL. Hyaluronic acid as a treatment for ankle osteoarthritis. *Curr Rev Musculoskelet Med.* 2009;2(2):78-82.
28. Cohen MM, Altman RD, Hollstrom R, et al. Safety and efficacy of intra-articular sodium hyaluronate (Hyalgan) in a randomized, double-blind study for osteoarthritis of the ankle. *Foot Ankle Int.* 2008;29(7):657-663.
29. Abate M, Pulcini D, Di Iorio A, Schiavone C. Viscosupplementation with intra-articular hyaluronic acid for treatment of osteoarthritis in the elderly. *Curr Pharm Des.* 2010;16(6):631-640.
30. DeGroot H 3rd, Uzunishvili S, Weir R, et al. Intra-articular injection of hyaluronic acid is not superior to saline solution injection for ankle arthritis: a randomized, double-blind, placebo-controlled study. *J Bone Joint Surg Am.* 2012;94(1):2-8.
31. Sun SF, Hsu CW, Sun HP, et al. The effect of three weekly intra-articular injections of hyaluronate on pain, function, and balance in patients with unilateral ankle arthritis. *J Bone Joint Surg Am.* 2011;93(18):1720-1726.
32. Tikiz C, Unlu Z, Sener A, et al. Comparison of the efficacy of lower and higher molecular weight viscosupplementation in the treatment of hip osteoarthritis. *Clin Rheumatol.* 2005;24:244-250.
33. Migliore A, Tormenta S, Severino L, et al. The symptomatic effects of intra-articular administration of hylan G-F 20 on osteoarthritis of the hip: clinical data of 6 months follow-up. *Clin Rheumatol.* 2006;25(3):389-393.
34. Qvistgaard E, Christensen R, Torp-Pedersen S, Bliddal H. Intra-articular treatment of hip osteoarthritis: a randomized trial of hyaluronic acid, corticosteroid, and isotonic saline. *Osteoarthritis Cartilage.* 2006;14(2):163-170.
35. Caglar-Yagci H, Unsal S, Yagci I, et al. Safety and efficacy of ultra-sound guided intra-articular hylan G-F 20 injection in osteoarthritis of the hip: a pilot study. *Rheumatol Int.* 2005;25(5):341-344.
36. Conrozier T, Vignon E. Is there evidence to support the inclusion of viscosupplementation in the treatment paradigm for patients with hip osteoarthritis? *Clin Exp Rheumatol.* 2005;23(5):711-716.
37. Van Den Bekerom MPJ. Viscosupplementation in symptomatic severe hip osteoarthritis: a review of the literature and report on 60 patients. *Acta Orthop Belg.* 2006;72:560-568.
38. Fernandez Lopez JC, Ruano-Ravina A. Efficacy and safety of intraarticular hyaluronic acid in the treatment of hip osteoarthritis: a systematic review. *Osteoarthritis Cartilage.* 2006;14(12):I306-I311.
39. Richette P, Ravaud P, Conrozier T, et al. Effect of hyaluronic acid in symptomatic hip osteoarthritis: a multicenter, randomized, placebo-controlled trial. *Arthritis Rheum.* 2009;60(3):824-830.
40. Hsieh LF, Hsu WC, Lin YJ, et al. Addition of intra-articular hyaluronate injection to physical therapy program produces no extra benefits in patients with adhesive capsulitis of the shoulder: a randomized controlled trial. *Arch Phys Med Rehabil.* 2012;93(6):957-964.
41. Penning LI, de Bie RA, Walenkamp GH. The effectiveness of injections of hyaluronic acid or corticosteroid in patients with

- subacromial impingement: a three-arm randomised controlled trial. *J Bone Joint Surg Br.* 2012;94(9):I246-I252.
42. Tang X, Pei FX, Zhou ZK, et al. A randomized, single-blind comparison of the efficacy and tolerability of hyaluronate acid and meloxicam in adult patients with Kashin-Beck disease of the knee. *Clin Rheumatol.* 2012;31(7):I079-I086.
 43. Chau JY, Chan WL, Woo SB, et al. Hyaluronic acid instillation following arthroscopic anterior cruciate ligament reconstruction: a double-blinded, randomised controlled study. *J Orthop Surg (Hong Kong).* 2012;20(2):I62-I65.

Calcitonin Gene-Related Peptide Inhibitors**

- I. Vyepti® intravenous infusion [prescribing information]. Bothell, WA: Lundbeck; October 2022.
2. Aimovig® injection for subcutaneous use [prescribing information]. Thousand Oaks, CA: Amgen; May 2023.
3. Ajovy® injection for subcutaneous use [prescribing information]. North Wales, PA: Teva; October 2022.
4. Emgality® injection for subcutaneous use [prescribing information]. Indianapolis, IN: Lilly; May 2022
5. Headache Classification Subcommittee of the International Headache Society. The International Classification of Headache Disorders: 3rd edition. *Cephalgia.* 2018;38:I-2II.
6. MacGregor EA. In the clinic. Migraine. *Ann Intern Med.* 2017;I66(7):ITC49-ITC64.
7. Lipton RB, Silberstein SD. Episodic and chronic migraine headache: breaking down barriers to optimal treatment and prevention. *Headache.* 2015;52:I03-I22.
8. American Headache Society. The American Headache Society position statement on integrating new migraine treatments into clinical practice. *Headache.* 2019;59:I-I8.
9. Ailani J, Burch RC, Robbins MS, on behalf of the Board of Directors of the American Headache Society. The American Headache Society Consensus Statement: Update on integrating new migraine treatments into clinical practice. *Headache.* 2021;OO:I-I9.
10. Ashina M, Saper J, Cady R, et al. Eptinezumab in episodic migraine: a randomized, double-blind, placebo-controlled study (PROMISE-I). *Cephalgia.* 2020;40(3):24I-254.
- II. Data on file. Eptinezumab-jjmr Pre-Approval Dossier, version I.7. Lundbeck, Inc.; Deerfield, IL; received on March 2, 2020.
12. Qulipta® tablets [prescribing information]. Madison, NJ: AbbVie; April 2023.
13. Nurtec® ODT [prescribing information]. New Haven, CT: Biohaven; April 2022.
14. Micromedex. Merative LP. Available at: <https://www.micromedexsolutions.com/>. Accessed on August 7, 2023. Search terms: lisinopril, verapamil.
15. Clinical Pharmacology. ClinicalKey. Available at: <https://www.clinicalkey.com/pharmacology/> Accessed on August 7, 2023. Search terms: lisinopril, verapamil.

Proprotein Convertase Subtilisin/Kexin Type 9 (PCSK9) Inhibitors**

- I. Praluent® subcutaneous injection [prescribing information]. Tarrytown, NY: Regeneron; April 2021.
2. Repatha® subcutaneous injection [prescribing information]. Thousand Oaks, CA: Amgen; September 2021.
3. Leqvio® subcutaneous injection [prescribing information]. East Hanover, NJ: Novartis; July 2023.
4. Lloyd-Jones DM, Morris PB, Ballantyne CM, et al. 2022 ACC Expert Consensus Decision Pathway on the Role of Non-Statin Therapies for LDL-Cholesterol Lowering in the Management of Atherosclerotic Cardiovascular Disease Risk. *J Am Coll Cardiol.* 2022;80(14):I366-I4I8.
5. Stone NJ, Robinson J, Lichtenstein AH, et al. 2013 ACC/AHA guideline on the treatment of blood cholesterol to reduce atherosclerotic cardiovascular risk in adults: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines. *Circulation.* 2014;129(25 Suppl 2):SI-S45.
6. Grundy SM, Stone NJ, Bailey AL, et al. AHA/ACC/AACVPR/AAPA/ABC/ACPM/ADA/AGS/APhA/ASPC/NLA/PCNA guideline on the management of blood cholesterol. A report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines. *Circulation.* 2019;I39:eI082-eI43.
7. Newman CB, Blaha MJ, Boord JB, et al. Lipid management in patients with endocrine disorders: an Endocrine Society clinical practice guideline. *J Clin Endocrinol Metab.* 2020;I05(I2):36I3-3682.
8. Jacobson TA, Ito MK, Maki KC, et al. National Lipid Association recommendations for patient-centered management of dyslipidemia: Part I-full report. *J Clin Lipidol.* 2015;9:I29-I69.
9. Goldberg AC, Hopkins PN, Toth PP, et al. Familial hypercholesterolemia: screening, diagnosis and management of pediatric and adult patients. *J Clin Lipidol.* 2011;5:SI-S8.
10. Gidding SS, Champagne MA, de Ferranti SD, et al. The agenda for familial hypercholesterolemia. A scientific statement from the American Heart Association. *Circulation.* 2015;I32(22):2I67-2I92.
- II. Haase A, Goldberg AC. Identification of people with heterozygous familial hypercholesterolemia. *Curr Opin Lipidol.* 2012;23:282-289.
12. Virani SS, Newby LK, Arnold SV, et al. 2023 AHA/ACC/ACCP/ASPC/NLA/PCNA guideline for the management of patients with chronic coronary disease: a report of the American Heart Association/American College of Cardiology Joint Committee on Clinical Practice Guidelines. *J Am Coll Cardiol.* 2023 July 14. [Online ahead of print].

Revision history

| Date | Summary of changes |
|----------|---|
| 1/1/2025 | Coverage criteria <ul style="list-style-type: none">No updates |



Cigna Healthcare products and services are provided exclusively by or through operating subsidiaries of The Cigna Group. The Cigna names, logos, and marks, including THE CIGNA GROUP and CIGNA HEALTHCARE are owned by Cigna Intellectual Property, Inc.