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 Healthcare® Medicare markets.

cigna healthcare

Effective 10/01/2025
Y0036_26_1705528524_C

Step therapy drug class	Preferred* medications	Non-preferred medications
Antiemetic - serotonin receptor antagonists (injectable) for oncology	• Granisetron • Ondansetron • Palonosetron	Sustol
Antiemetic - substance p/neurokinin-1 receptor antagonists (injectable) for oncology	Emend	• Akynzeo • Cinvanti
Bevacizumab (oncology)	• Alymsys • Mvasi • Zirabev	• Avastin • Avzivi • Vegzelma
Botulinum toxins	• Botox • Daxxify • Dysport • Xeomin	Myobloc
Colony stimulating factors Short acting	• Nivestym • Zarxio	• Granix • Neupogen • Nypozi • Releuko
Colony stimulating factors Long acting	• Neulasta/Neulasta Onpro • Nyvepria • Udenyca	• Fulphila • Fylnetra • Rolvedon • Ryzneuta • Stimufend • Ziextenzo
Immune globulins IV	• Flebogamma DIF • Gammagard Liquid • Gammagard S/D • Gammaked • Gammaplex • Gamunex-C • Octagam • Privigen	• Alyglo • Asceniv • Bivigam • Panzyga • Yimmugo
Immune globulins SC	• Cutaquig • Gammagard liquid • Gammaked • Gamunex-C • Hizentra • Xembify	• Cuvitru • HyQvia
Immunomodulators	• Avsola • Inflectra • Renflexis	Remicade, infliximab (authorized generic)
Intravenous iron	Venofer	• Feraheme • Injectafer • Monoferric
Ophthalmic disorders Intravitreal vascular endothelial growth factor (VEGF) inhibitors	Avastin	• Beovu • Byooviz • Cimerli • Eylea • Eylea HD • Lucentis • Pavblu • Vabysmo

*Preferred medications may require prior authorization.

Step therapy drug class	Preferred* medications	Non-preferred medications
Paclitaxel medications	Paclitaxel	• Abraxane • Paclitaxel protein-bound
Rituximab	• Riabni • Ruxience • Truxima	• Rituxan hycela • Rituxan IV
Somatostatin analogs Long acting	• Lanreotide (JI930 & JI932) • Somatuline depot (JI930)	Sandostatin LAR
Systemic lupus erythematosus (SLE; Lupus)	Benlysta IV	Saphnelo
Testosterone Injectable	• Delatestryl (testosterone enanthate) • Depo-testosterone (testosterone cypionate)	• Aveed • Azmiro • Testopel • Xyosted
Tocilizumab	• Tyenne	• Actemra • Tofidence
Trastuzumab	• Kanjinti • Ogivri • Trazimera	• Herceptin hylecta • Herceptin IV • Hercessi • Herzuma • Ontruzant
Viscosupplements	• Monovisc • Orthovisc • Synvisc • Synvisc one	• Durolane • Euflexxa • Gel-One • Gelsyn-3 • GenVisc 850 • Hyalgan • Hymovis • Sodium hyaluronate I% • Supartz FX • Synojoynt • 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 utilization management [UM] requirements)	Vyepti
Proprotein convertase subtilisin/kexin type 9 (PSCK9) 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
• Granisetron • Ondansetron • Palonosetron	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 are 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-I receptor antagonists (injectable) for oncology

Preferred* medication	Non-preferred medications
Emend	• Akynzeo • Cinvanti

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 are 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
• Alymsys • Mvasi • Zirabev	• Avastin • Avzivi • Vegzelma

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

Avastin, Avzivi or Vegzelma may be covered for oncology indications when the criteria listed below are 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 medication
• 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 are 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 are 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 are 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 are 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	
• Nivestym • Zarxio	• Granix • Neupogen	• Nypozi • Releuko

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 Nypozi, or Releuko may be covered when the criteria listed below are 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
• Neulasta/Neulasta Onpro • Nyvepria • Udenyca/Autoinjector/Onbody	• Fulphila • Fylnetra • Rolvedon • Ryzneuta • Stimufend • Ziextenzo

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 are 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 or Ryzneuta may be covered when criteria listed below are 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
• Flebogamma DIF • Gammagard Liquid • Gammagard S/D • Gammaked • Gammaplex • Gamunex-C • Octagam • Privigen	• Alyglo • Asceniv • Bivigam • Panzyga • Yimmugo

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

- Bivigam, Panzyga or Yimmugo 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 barré 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 (graves' disease), or
  - Immune thrombocytopenia (ITP), or
  - Multiple sclerosis (MS), acute severe exacerbation or relapses, or
  - Myasthenia gravis, 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
  - 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 (graves' disease), or
  - Immune thrombocytopenia (ITP), or
  - Multiple sclerosis (MS), acute severe exacerbation or relapses, or
  - Myasthenia gravis, 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, Panzyga or Yimmugo may be covered when the criteria listed below are satisfied:

- Bivigam, Panzyga or Yimmugo 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 pptica (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 (graves' disease), or
  - Immune thrombocytopenia (ITP), or
  - Multiple sclerosis (MS), acute severe exacerbation or relapses, or
  - Myasthenia gravis, 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: 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
  - Dermatomyositis or polymyositis, or
  - Immune thrombocytopenia (ITP). or
  - Immune-mediated necrotizing myopathy, 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
  - Dermatomyositis or polymyositis. or
  - Immune thrombocytopenia (ITP). or
  - Immune-mediated necrotizing myopathy, or
- History of use of two preferred medications, **or**
- Continuation of prior therapy or use within the past 365 days

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

- Bivigam, Panzyga or Yimmugo 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
  - Dermatomyositis or polymyositis, or
  - Immune thrombocytopenia (ITP), or

  - Immune-mediated necrotizing mMyopathy. 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 barré 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
  - Lambert-eaton myasthenic syndrome (LEMS), 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 barré 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
  - Lambert-eaton myasthenic syndrome (LEMS), or
- History of use of two preferred medications,**or**
- Continuation of prior therapy or use within the past 365 days

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

- Bivigam, Panzyga or Yimmugo 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 barré 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
  - Lambert-eaton myasthenic syndrome (LEMS), 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
  - Dermatomyositis or polymyositis, or
  - Immune thrombocytopenia (ITP), or
  - Lambert-eaton myasthenic syndrome (LEMS), or
  - Multiple sclerosis (MS), acute severe exacerbation or relapses, or
  - Pure red cell aplasia (PRCA), immunologic subtype. 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
  - Myasthenia gravis, or
  - Dermatomyositis or polymyositis, or
  - Immune thrombocytopenia (ITP), or
  - Lambert-eaton myasthenic syndrome (LEMS), or
  - Multiple sclerosis (MS), acute severe exacerbation or relapses, or
  - Pure red cell aplasia (PRCA), immunologic subtype, 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, Panzyga or Yimmugo may be covered when the criteria listed below are satisfied:

- Bivigam, Panzyga or Yimmugo 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
  - Dermatomyositis or polymyositis, or
  - Immune thrombocytopenia (ITP), or
  - Lambert-eaton myasthenic syndrome (LEMS), or
  - Multiple sclerosis (MS), acute severe exacerbation or relapses, or
  - Pure red cell aplasia (PRCA), immunologic subtype, 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: 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
  - Lambert-eaton myasthenic syndrome (LEMS), or
  - Pure red cell aplasia (PRCA), immunologic subtype, 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
  - Lambert-eaton myasthenic syndrome (LEMS), or
  - Pure red cell aplasia (PRCA), immunologic subtype, or
- History of use of two preferred medications,**or**
- Continuation of prior therapy or use within the past 365 days.

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

- Bivigam, Panzyga or Yimmugo 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
  - Lambert-eaton myasthenic syndrome (LEMS), or
  - Pure red cell aplasia (PRCA), immunologic subtype, 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
• Cutaquig • Gammagard Liquid • Gammaked	• Gamunex-C • Hizentra • Xembify	• Cuvitru • HyQvia

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 medication
• 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 are 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 are satisfied:

- Infliximab is being prescribed to treat one of the following conditions:
  - Crohn's disease
  - Plaque psoriasis
  - Ulcerative colitis
  - Behcet's disease
  - 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 are 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* medication	Non-preferred medications
Venofer	• 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 are 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* medication	Non-preferred medications	
Avastin	• Beovu • Byooviz • Cimerli • Eylea	• Eylea HD • Lucentis • Pavblu • 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 may be covered when the criteria listed below are satisfied:

- History of use of the preferred ophthalmic medication**and**
- Inadequate efficacy or intolerability 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, Eylea HD or Pavblu may be covered when criteria listed below are satisfied:

- History of use of the preferred ophthalmic medication**and**
- Inadequate efficacy or intolerability was demonstrated**or**
- Has diabetic macular edema and a baseline Early Treatment Diabetic Retinopathy Study (ETDRS) best-corrected visual acuity (BCVA) of 20/50 or worse (< 69 ETDRS letters) 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 are satisfied:

- History of use of the preferred ophthalmic medication**and**
- Inadequate efficacy or intolerability 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

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

- History of use of the preferred ophthalmic medication,**and**
- Inadequate efficacy or intolerability was demonstrated**or**
- Has diabetic macular edema and a baseline Early Treatment Diabetic Retinopathy Study (ETDRS) best-corrected visual acuity (BCVA) of 20/50 or worse (< 69 ETDRS letters) according to the prescriber**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* medication	Non-preferred medications
Paclitaxel	• 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 are satisfied:

- For non-small cell lung cancer:
  - Hypersensitivity reaction to Paclitaxel intravenous infusion or Docetaxel intravenous infusion **or**
  - Contraindication to the standard premedications **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 premedications **or**
  - Continuation of prior therapy or use within the past 365 days

Rituximab

Preferred* medications	Non-preferred medications
• Riabni • Ruxience • Truxima	• Rituxan Hycela • Rituxan IV

Non-preferred medication step therapy criteria

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

Rituxan IV may be covered when the criteria listed below are 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 (MS) **or**
  - Neuromyelitis optica (NMO) spectrum disorder **or**
  - Systemic lupus erythematous (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 are 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 are 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 (MS) **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 are 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 are 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 (MS) **or**
  - Autoimmune Hemolytic Anemia **or**
  - Multifocal Motor Neuropathy (MMN) **or**
  - Polymyositis **or**
  - Autologous Stem Cell Rescue for Progressive or relapsed disease (given before the stem cell rescue)

Rituxan Hycela may be covered when criteria listed below are 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 are 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 are 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
• Lanreotide (JI930 & JI932) • Somatuline Depot (JI930)	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

Sandostatin LAR may be covered when the criteria listed below are 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* medication	Non-preferred medication
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 are 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
• Depo-Testosterone (testosterone cypionate) • Delatestryl (testosterone enanthate)	• Aveed • Azmiro • Testopel • Xyosted

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, Azmiro, Testopel or Xyosted may be covered when the criteria listed below are satisfied:

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

Tocilizumab

Preferred* medication	Non-preferred medications
• Tyenne	• Actemra • Tofidence

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

Actemra or Tofidence may be covered when the criteria listed below are satisfied.

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

Trastuzumab

Preferred* medications	Non-preferred medications
• Kanjinti • Ogivri • Trazimera	• Herceptin Hylecta • Herceptin IV • Hercessi • 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 intravenious, Hercessi, Herzuma or Ontruzant may be covered when the criteria listed below are 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 are 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
• Monovisc • Orthovisc • Synvisc • Synvisc One	• Durolane • Euflexxa • Gel-One • Gelsyn-3 • GenVisc 850 • Hyalgan • Hymovis • Sodium Hyaluronate I% • Supartz FX • Synojoynt • 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, Euflexxa, Gel-One, Gelsyn-3, GenVisc 850, Hyalgan, Hymovis, Sodium Hyaluronate I%, Supartz FX, Synojoynt, Triluron, TriVisc or Visco-3 may be covered when the criteria listed below are 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* medication	Non-preferred medication
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 are 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* medication	Non-preferred medication
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 are 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	
J1626	Injection, granisetron hydrochloride, 100 mcg
J2405	Injection, ondansetron hydrochloride, per 1 mg
J2469	Injection, palonosetron HCl, 25 mcg
Non-preferred	
J1627	Injection, granisetron, extended-release, 0.1 mg

Antiemetic - Substance P/neurokinin-1 receptor antagonists (injectable) for oncology

HCPCS code	Description
Preferred	
J1453	Injection, fosaprepitant, 1 mg
Non-preferred	
J0185	Injection, aprepitant, 1 mg
J1454	Injection, fosnetupitant 235 mg and palonosetron 0.25 mg

Bevacizumab (oncology)

HCPCS code	Description
Preferred	
Q5107	Injection, bevacizumab-awwb, biosimilar (Mvasi), 10 mg
Q5118	Injection, bevacizumab-bvzr, biosimilar (Zirabev), 10 mg
Q5126	Injection, bevacizumab-maly, biosimilar (Alymsys), 10 mg
Non-preferred	
J9035	Injection, bevacizumab, 10 mg
Q5129	Injection, bevacizumab-adcd (Vegzelma), biosimilar 10 mg
	Injection, bevacizumab-tnjn (Avzivi), 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	
Q5101	Injection, filgrastim-sndz, biosimilar (Zarxio), 1 mcg
Q5110	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
Q5125	Injection, filgrastim-ayow, biosimilar (Releuko), 1 mcg
Q5148	Injection, filgrastim-txid, biosimilar (Nypozi), 1 mcg

Colony stimulating factors, long acting

HCPCS code	Description
Preferred	
J2506	Injection, pegfilgrastim, excludes biosimilar 0.5 mg
Q5111	Injection, pegfilgrastim-cbqv (Udenyca), biosimilar 0.5 mg
Q5122	Injection, pegfilgrastim-apgf (Nyvepria), biosimilar 0.5 mg
Non-preferred	
J1449	Injection, eflapegrastim-xnst, 0.1 mg
J9361	Injection, efbemalenograstim alfa-vuxw (Ryzneuta), 0.5 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	
J1572	Injection, Immune globulin (Flebogamma), 500 mg
J1569	Injection, Immune glogulin (Gammagard liquid), 500 mg
J1566	Injection, Immune globulin (powder), 500 mg
J1561	Injection, Immune globulin (Gamunex-C/Gammaked), 500 mg
J1557	Injection, Immune globulin (Gammaplex), 500 mg
J1568	Injection, Immune globulin (Octagam), 500 mg
J1459	Injection, immune globulin (Privigen), 500 mg
Non-preferred	
J1599	Injection, Immune globulin, (liquid), 500 mg
J1554	Injection, Immune globulin (Asceniv), 500 mg
J1556	Injection, Immune globulin (Bivigam), 500 mg
J1576	Injection, Immune globulin (Panzyga), 500 mg
	Injection, Immune globulin (Yimmugo)

Immune Globulins SC

HCPCS code	Description
Preferred	
J1551	Injection, Immune globulin (Cutaquig), 100 mg
J1569	Injection, Immune globulin (Gammagard liquid), 500 mg
J1561	Injection, Immune globulin (Gamunex-C/Gammaked), 500 mg
J1559	Injection, Immune globulin (Hizentra), 100 mg
J1558	Injection, immune globulin (Xembify), 100 mg
Non-preferred	
J1555	Injection, Immune globulin (Cuvitru), 100 mg
J1575	Injection, Immune globulin (Hyqvia), 100 mg

Immunomodulators

HCPCS code	Description
Preferred	
Q5103	Injection, infliximab-dyyb, biosimilar (Inflectra), 10 mg
Q5104	Injection, infliximab-abda, biosimilar (Renflexis), 10 mg
Q5121	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
Q0138	Injection, ferumoxytol 1 mg (for treatment of iron deficiency anemia)

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	
J0178	Injection, aflibercept, 1 mg
J0179	Injection, brolucizumab-dbll, 1 mg
J0177	Injection, aflibercept hd, 1 mg
J2777	Injection, faricimab-svoa, 0.1 mg
J2778	Injection, ranibizumab, 0.1 mg
Q5147	Injection, afilbercept-ayyh, (Pavblu), 1 mg
Q5124	Injection, ranibizumab-nuna, biosimilar (Byooviz), 0.1 mg
Q5128	Injection, ranibizumab-eqrn (Cimerli), biosimilar 0.1 mg

Paclitaxel Medications

HCPCS code	Description
Preferred	
J9267	Injection, paclitaxel, 1 mg
Non-preferred	
J9259	Injection, paclitaxel protein-bound particles (American Regent) not therapeutically equivalent to J9264, 1 mg
J9264	Injection, paclitaxel protein-bound particles, 1 mg

Rituximab

HCPCS code	Description
Preferred	
Q5115	Injection, rituximab-abbs, biosimilar (Truxima), 10 mg
Q5119	Injection, rituximab-pvvr, biosimilar (Ruxience), 10 mg
Q5123	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, 1 mg
J1932	Injection, lanreotide, (Cipla), 1 mg
Non-preferred	
J2353	Injection, octreotide depot, 1 mg

Systemic lupus erythematosus (SLE; lupus)

HCPCS code	Description
Preferred	
J0490	Injection, belimumab, 10 mg
Non-preferred	
J0491	Injection, anifrolumab-fnia, 1 mg

Testosterone Injectable

HCPCS code	Description
Preferred	
J1071	Injection, testosterone cypionate, 1 mg
J3121	Injection, testosterone enanthate, 1 mg
Non-preferred	
J1072	Injection, testosterone cypionate (Azmiro), 1 mg
J3145	Injection, testosterone undecanoate, 1 mg
J3490	Unclassified drugs, Testopel
J3490	Unclassified drugs, Xyosted

Tocilizumab

HCPCS code	Description
Preferred	
Q5135	Injection, Tyenne, 1 mg
Non-preferred	
J3262	Injection, Tocilizumab injection (Actemra), 1 mg
Q5133	Injection, Tofidence, 1 mg

Trastuzumab

HCPCS code	Description
Preferred	
Q5114	Injection, trastuzumab-dkst, biosimilar (Ogivri), 10 mg
Q5116	Injection, trastuzumab-qyyp, biosimilar (Trazimera), 10 mg
Q5117	Injection, trastuzumab-anns, biosimilar (Kanjinti), 10 mg
Non-preferred	
J9355	Injection, trastuzumab, excludes biosimilar 10 mg
J9356	Injection, trastuzumab, 10 mg and hyaluronidase-oysk
Q5112	Injection, trastuzumab-dttb, biosimilar (Ontruzant), 10 mg
Q5113	Injection, trastuzumab-pkrb, biosimilar (Herzuma), 10 mg
Q5146	Injection, trastuzumab-strf, biosimilar (Hercessi), 10 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, Synojoynt, 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 & 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. Palonosetron intravenous injection [prescribing information]. Lake Zurich, IL: Fresenius Kabi; December 2020.
2. Ondansetron intramuscular injection or intravenous infusion [prescribing information]. Lake Zurich, IL: Fresenius Kabi; November 2023.
3. Granisetron intravenous infusion [prescribing information]. Rockford, IL: Fresenius Kabi; November 2022.
4. Sustol® extended-release subcutaneous injection [prescribing information]. Redwood City, CA: Heron; September 2024.
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. Patel P, Robinson PD, Cohen M, et al. Prevention of acute and delayed chemotherapy-induced nausea and vomiting in pediatric cancer patients: A clinical practice guideline. Pediatr Blood Cancer. 2022;69(12):e30001.
7. 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; March 2024.
2. Emend® intravenous infusion [prescribing information]. Whitehouse Station, NJ: Merck; May 2022.
3. Akynzeo® intravenous infusion [prescribing information]. Iselin, NJ: Helsinn; December 2023.

Bevacizumab (oncology)

1. Avastin® intravenous infusion [prescribing information]. South San Francisco, CA: Genentech; September 2022.
2. Mvasi® intravenous infusion [prescribing information]. Thousand Oaks, CA: Amgen; February 2023.
3. Zirabev™ intravenous infusion [prescribing information]. New York, NY: Pfizer; August 2024.
4. Alymsys® intravenous infusion [prescribing information]. Bridgewater, NJ: Amneal; April 2022.
5. Vegzelma™ intravenous infusion [prescribing information]. Incheon, Republic of Korea: Celltrion; September 2022.
6. Avzivi™ intravenous infusion [prescribing information]. Guangzhou, Guangdong Province, China: Bio-Thera Solutions; October 2024.
7. Escudier B, Pluzanska A, Koralewski P, et al; AVOREN Trial investigators. Bevacizumab plus interferon alfa-2a for treatment of meta static renal cell carcinoma: a randomised, double-blind phase III trial. Lancet. 2007;370:2103-2111.
8. 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.
9. Ray-Coguard IL, Domont J, Tresch-Bruneel 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.
10. 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.
11. Park MS, Patel SR, Ludwig JA, et al. Activity of temozolomide and bevacizumab in the treatment of locally advanced, recurrent, and metastatic hemangiopericytoma and malignant solitary fibrous tumor. Cancer. 2011;117:4939-4947.
12. Grill J, Massimino M, Boufett 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.
13. 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.
14. 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.
15. 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.
16. 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.
17. 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; November 2023.
2. Charles AC, Digre KB, Goadsby PJ, Robbins MS, Hershey A; American Headache Society. Calcitonin gene-related peptide-targeting therapies are a first-line option for the prevention of migraine: An American Headache Society position statement update. Headache. 2024;64(4):333-341.
3. Brin MF, Blitzer A. The pluripotential evolution and journey of Botox (onabotulinumtoxinA). Medicine (Baltimore). 2023;102(SI):e32373.
4. Vaezi MF, Pandolfino JE, Yadlapati RH, et al. ACG Clinical Guidelines: diagnosis and management of achalasia. Am J Gastroenterol. 2020;115(9):1393-1411.
5. Wald A, Bharucha AE, Limketkai B, et al. ACG Clinical Guidelines: management of benign anorectal disorders. Am J Gastroenterol. 2021;116(10):1987-2008.
6. Adam OR, Jankovic J. Treatment of dystonia. Parkinsonism Relat Disord. 2007;13 Suppl 3:S362-S368. doi:10.1016/S1353-8020(08)70031-2.
7. 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.
8. 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;86:1818-1826.

9. Stachler RJ, Francis DO, Schwartz SR, et al. Clinical practice guideline: hoarseness (dysphonia). Otolaryngology – Head and Neck Surgery. 2018;Supplement:1-42.
10. France K, Stoopler ET. The American Academy of Oral Medicine Clinical Practice Statement: Oromandibular dystonia.Oral Surg Oral Med Oral Pathol Oral Radiol. 2018;125(4):283-285.
11. Müller J, Wenning GK, Wissel J, Seppi K, Poewe W. Botulinum toxin treatment in atypical parkinsonian disorders associated with disabling focal dystonia. J Neurol. 2002;249(3):300-304.
12. Jankovic J, Orman J. Botulinum A toxin for cranial-cervical dystonia: a double-blind, placebo-controlled study. Neurology. 1987;37(4):616-623.
13. Van den Bergh P, Francart J, Mourin S, Kollmann P, Laterre EC. Five-year experience in the treatment of focal movement disorders with low-dose Dysport botulinum toxin. Muscle Nerve. 1995;18(7):720-729.
14. 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.
15. International Hyperhidrosis Society. Primary focal craniofacial and gustatory hyperhidrosis (Frey's Syndrome). Updated January 15, 2012. https://sweathelp.org/treatments-hcp/clinical-guidelines/primary-focal-hyperhidrosis/primary-focal-facial-and-gustatory.html. Accessed on August 19, 2024.
16. International Hyperhidrosis Society. Primary focal palmar hyperhidrosis. Updated January 15, 2012. https://sweathelp.org/treatments-hcp/clinical-guidelines/primary-focal-hyperhidrosis/primary-focal-palmar.html. Accessed on August 19, 2024.
17. International Hyperhidrosis Society. Primary focal plantar hyperhidrosis. Updated January 15, 2012. https://sweathelp.org/treatments-hcp/clinical-guidelines/primary-focal-hyperhidrosis/primary-focal-plantar.html. Accessed on August 19, 2024.
18. Bhidayasiri R, Truong DD. Expanding use of botulinum toxin. J Neurol Sci. 2005;235(1-2):1-9.
19. Cheng CM, Chen JS, Patel RP. Unlabeled uses of botulinum toxins: A review, part 1. Am J Health Syst Pharm. 2006;63(2): 145–152.
20. Cheng CM, Chen JS, Patel RP. Unlabeled uses of botulinum toxins: A review, part 2. Am J Health Syst Pharm. 2006;63(3):225-232.
21. 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):1115-1122.
22. Scaglione F. Conversion ratio between Botox®, Dysport®, and Xeomin® in clinical practice. Toxins (Basel). 2016;8(3):65.
23. Lakraj AA, Moghimi N, Jabbari B. Sialorrhea: anatomy, pathophysiology and treatment with emphasis on the role of botulinum toxin. Toxins. 2013;5:1010-1031.
24. Cameron AP, Chung DE, Dielubanza EJ, et al. The AUA/SUFU Guideline on the Diagnosis and Treatment of Idiopathic Overactive Bladder.J Urol. 2024;212(1):11-20.
25. Camilleri M, Parkman HP, Shafi MA, et al. Clinical guideline: management of gastroparesis. Am J Gastroenterol. 2013;108(1):18-38.
26. Hassell TJW, Charles D. Treatment of Blepharospasm and Oromandibular Dystonia with Botulinum Toxins.Toxins (Basel). 2020;12(4):269. Published 2020 Apr 22.
27. Hallett M, Albanese A, Dressler D, Segal KR, Simpson DM, Truong D, Jankovic J. Evidence-based review, and assessment of botulinum neurotoxin for the treatment of movement disorders. Toxicon. 2013 Jun 1;67:94-114.
28. Myobloc® injection [prescribing information]. San Francisco, CA: Solstice Neurosciences; December 2023.
29. Walker TJ, Dayan SH. Comparison and overview of currently available neurotoxins. Clin Aesthet Dermatol. 2014;7(21):31-39.
30. Dysport® injection [prescribing information]. Cambridge, MA and Fort Worth, TX: Ipsen/Galderma; July 2023.
31. 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.
32. 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.
33. Clinical Pharmacology [database online]. Tampa, FL: Elsevier, Inc.; 2024. https://www.clinicalkey.com/pharmacology/. Accessed on September 17, 2024. Search terms: Dysport.
34. Berkel AE, Rosman C, Koop R, van Duijvendijk P, van der Palen J, Klaase JM. Isosorbide dinitrate ointment vs botulinum toxin A (Dysport) as the primary treatment for chronic anal fissure: a randomized multicentre study. Colorectal Dis. 2014;16(10):O360-O366.
35. Xeomin® injection [prescribing information]. Raleigh, NC and Franksville, WI: Merz; July 2024.
36. Daxxify® injection [prescribing information]. Newark, CA: Revance; January 2024.

Colony stimulating factors, short acting

1. Neupogen® intravenous or subcutaneous injection [prescribing information]. Thousand Oaks, CA: Amgen; April 2023.
2. Zarxio™ intravenous or subcutaneous injection [prescribing information]. Princeton, NJ: Sandoz; October 2024.
3. Nivestym™ intravenous or subcutaneous injection [prescribing information]. Lake Forest, IL: Hospira/Pfizer; February 2024.
4. Releuko® subcutaneous or intravenous injection [prescribing information]. Bridgewater, NJ: Amneal; August 2023.
5. Granix® subcutaneous injection [prescribing information]. North Wales, PA: Teva; April 2020.
6. Nypozi™ subcutaneous or intravenous injection [prescribing information]. San Diego, CA: Tanvex, June 2024.
7. 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.
8. 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.
9. 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.
10. Kurizkes 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.
11. Mitsuyasu R. Prevention of bacterial infections in patients with advanced HIV infection. AIDS. 1999;13(Suppl 2):S19-S23.
12. Tesfa D, Keisu M, Palblad J. Idiosyncratic drug-induced agranulocytosis: Possible mechanism and management. Am J Hematol. 2009;84:428-434.
13. Andersohn F, Konzen C, Garbe E. Systematic review: Agranulocytosis

14. Beaushesne MF, Shalansky SJ. Nonchemotherapy drug-induced agranulocytosis: A review of 118 patients treated with colony-stimulating factors. Pharmacother. 1999;19(3):299-305.
15. Bhatt V, Saleem A. Review: Drug-induced neutropenia-pathophysiology, clinical features, and management. Ann Clin Lab Sci. 2004;34(2):131-136.
16. Curtis BR. Drug-induced immune neutropenia/agranulocytosis. Immunohematology. 2014;30(2):95-101.
17. Andres E, Mourot-Cottet R. Non-chemotherapy drug-induced neutropenia – an update. Expert Opin Drug Saf. 2017;16(11):1235-1242.
18. 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

1. Neulasta® subcutaneous injection [prescribing information]. Thousand Oaks, CA: Amgen; March 2021.
2. Fulphila® subcutaneous injection [prescribing information]. Rockford, IL: Mylan; July 2023.
3. Udenyca™ subcutaneous injection [prescribing information]. Redwood City, CA: Coherus; August 2024.
4. Ziextenzo™ 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.
10. Ryzneuta® subcutaneous injection [prescribing information]. Singapore: Evive; March 2024.
11. Jakob 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

1. Zachary AA, Leffell MS. Desensitization for solid organ and hematopoietic stem cell transplantation. Immunol Rev. 2014;258:183-207.
2. Colvin MM, Cook JL, Chang P, et al; American Heart Association Heart Failure and Transplantation Committee of the Council on Clinical Cardiology; American Heart Association Heart Failure and Transplantation Committee of the Council on Cardiopulmonary Critical Care, Perioperative and Resuscitation, et al. Antibody-mediated rejection in cardiac transplantation emerging knowledge in diagnosis and management: a scientific statement from the American Heart Association. Circulation. 2015;131:1608-1639.
3. Hughes RA, Wijdicks, EF, Barohn R, et al. Quality Standards Subcommittee of the American Academy of Neurology. Practice parameter: immunotherapy for Guillain-Barre syndrome: report of the Quality Standards Subcommittee of the American Academy of Neurology. Neurology. 2003;61:736-740. Guideline Reaffirmed January 22, 2022.
4. Van Doorn PA, Van den Bergh PYK, Hadden RDM, et al. European Academy of Neurology/Peripheral Nerve Society guideline on diagnosis and treatment of Guillain-Barre syndrome. Eur J Neurol. 2023;30(12):3646-3674.
5. Tomblyn M, Chiller T, Einsele H, et al; Center for International Blood and Marrow Research; National Marrow Donor program; European Blood and Marrow Transplant Group; American Society of Blood and Marrow Transplantation; Canadian Blood and Marrow Transplant Group; Infectious Diseases Society of America; Society for Healthcare Epidemiology of America; Association of Medical Microbiology and Infectious Disease Canada; Centers for Disease Control and Prevention. Guidelines for preventing infectious complications among hematopoietic cell transplantation recipients: A global perspective. Biol Blood Marrow Transplant. 2009;1:1143-1238.
6. Panel on Opportunistic Infections in Children with and Exposed to HIV. Guidelines for the prevention and treatment of opportunistic infections in children with and exposed to HIV. Department of Health and Human Services. Last review July 3, 2024. Guidelines for the Prevention and Treatment of Opportunistic Infections in HIV-Exposed and HIV-Infected Children. Accessed on October 17, 2024.
7. American Academy of Pediatrics. Human Immunodeficiency Virus Infection. In: Kimberlin DW, Banerjee R, Barnett ED, eds. Red Book®: 2024 Report of the Committee on Infectious Diseases, 33rd Ed. American Academy of Pediatrics; 2024:489-503.
8. Hachem RR, Yusen RD, Meyers BF, et al. Anti-human leukocyte antigen antibodies and preemptive antibody-directed therapy after lung transplantation. J Heart Lung Transplant. 2010;29:973.
9. Lejeune A, Martin L, Santibanez S, et al. Postexposure prophylaxis with intravenous immunoglobulin G prevents infants from getting measles. Acta Paediatr. 2017;1066(1):174-177.
10. American Academy of Pediatrics. Varicella-Zoster Infections. In: Kimberlin DW, Banerjee R, Barnett ED, eds. Red Book®: 2024 Report of the Committee on Infectious Diseases, 33rd Ed. American Academy of Pediatrics; 2024:938-951.
11. VariZIG® for intramuscular injection [prescribing information]. Roswell, GA: Saol Therapeutics; September 2021. 48. Centers for Disease Control and Prevention. Tetanus. Clinical Care of Tetanus | Tetanus | CDC. Accessed on October 17, 2024.
12. Broliden K, Tolfyenstam T, Norbeck O. Clinical aspects of parvovirus B19 infection. J Intern Med. 2006;260:285-304.
13. Symington A, Paes B. Fetal and neonatal alloimmune thrombocytopenia: harvesting the evidence to develop a clinical approach to management. Am J Perinatal. 2011;28:137-144.
14. Townsley DM. Hematologic complications of pregnancy. Semin Hematol. 2013;50:222-231.
15. Kumpfel T, Giglhuber K, Aktas O, et al. Update on the diagnosis and treatment of neuromyelitis optica spectrum disorders (NMOSD) – revised recommendations of the Neuromyelitis Optica Study Group (NEMOS). Part II: Attack therapy and long-term management. J Neurol. 2024;271:141-176.
16. Yimmugo® 10% intravenous solution [prescribing information]. Dreieich, Germany. Biotest (Grifols); June 2024.
17. From the Global Strategy for Asthma Management and Prevention, Global Initiative for Asthma (GINA) 2024. https://ginasthma.org/. Accessed on October 17, 2024.
18. Eichenfield LF, Ahluwalia J, Waldman A, et al. Current guidelines for the evaluation and management of atopic dermatitis: A comparison of the Joint Task Force Practice Parameter and American Academy of Dermatology Guidelines. J Allergy Clin Immunol. 2017;139(4S):S49-S57.
19. Allenbach Y, Mammen AL, Benveniste O, et al. 224th ENMC International Workshop: Clinico-sero-pathological classification of immune-mediated necrotizing myopathies. Zandvoort, The Nehterlands, 14-16 October 2016. Neuromuscul Disord. 2018;28(1):87-99.

20. Goebel A, Baranowski A, Maurer K, et al. Intravenous immunoglobulin treatment of the complex regional pain syndrome: A randomized trial. Ann Intern Med. 2010;152:152-158.
21. Goebel A, Bisla J, Carganillo R, et al. Low-dose intravenous immunoglobulin treatment for long-standing complex regional pain syndrome: A randomized trial. Ann Intern Med. 2017;167(7):476-483.
22. Chrissafidou A, Malek M, Musch E. Experimental study on the use of intravenous immunoglobulin in patients with steroid-resistant Crohn's disease. Gastroenterol. 2007;45:605-608.
23. Balfour-Lynn IM, Mohan U, Bush A, Rosenthal M. Intravenous immunoglobulin for cystic fibrosis lung disease: a case series of 16 children. Arch Dis Child. 2004;89:315-319.
24. Relkin NR, Thomas RG, Rissman RA, et al. A phase 3 trial of IV immunoglobulin for Alzheimer disease. Neurology. 2017;88(18):1768-1775.
25. Christopher-Stine L. UpToDate® 2024. Clinical manifestations and diagnosis of immune-mediated necrotizing myopathy and Treatment of immune-mediated necrotizing myopathy. www.uptodate.com. Accessed on October 30, 2024.
26. Tavee J, Brannagan TH, Lenihan MW, et al. Updated consensus statement: Intravenous immunoglobulin in the treatment of neuromuscular disorders report of the AANEM ad hoc committee. Muscle Nerve. 2023;68(4):356-374.
27. Caro XJ, Winter EF, Dumas AJ. A subset of fibromyalgia patients have findings suggestive of chronic inflammatory demyelinating polyneuropathy and appear to respond to IVIG. Rheumatology (Oxford). 2008;47:208-211.
28. Sanders DB, Wolfe GI, Benatar M, et al. International consensus guidance for management of myasthenia gravis: Executive summary. Neurology. 2016;87(4):419-425.
29. Eid AJ, Ardura MI, AST Infectious Disease Community of Practice. Human parvovirus B19 in solid organ transplantation: Guidelines from the American Society of Transplantation Infectious Diseases Community of Practice. Clin Transplant. 2019 Sep;33(9):e13535.
30. Van den Bergh PY, van Doorn PA, Hadden RD, et al. European Academy of Neurology/Peripheral Nerve Society guideline on diagnosis and treatment of chronic inflammatory demyelinating polyradiculoneuropathy: Report of a joint Task Force – Second revision. J Peripher Nerv Syst. 2021 Sep;26(3):242-268.
31. Practice Committee of the American Society for Reproductive Medicine. The role of immunotherapy in in vitro fertilization: a guideline. Fertil Steril. 2018;110:387-400.
32. Banwell B, Bennett JL, Marignier R, et al. Diagnosis of myelin oligodendrocyte glycoprotein antibody-associated disease: International MOGAD Panel proposed criteria. Lancet Neurol. 2023;22:268-282.
33. Sechi E, Cacciaguerra L, Chen JJ, et al. Myelin Oligodendrocyte Glycoprotein Antibody-Associated Disease (MOGAD): A review of clinical and MRI features, diagnosis, and management. Front Neurol. 2022;13:885218.
34. Mcheik S, Peramo B, Quenby S, et al. ESHRE guideline: recurrent pregnancy loss: an update in 2022. Hum Reprod Open. 2023(1): hoad002. doi: 10.1093/hropen/hoad002.
35. The Practice Committee of the American Society for Reproductive Medicine. Evaluation and treatment of recurrent pregnancy loss: a committee opinion. Fertil Steril. 2012;95:1103-1111.
36. Schneider BJ, Naidoo J, Santomasso BD, et al. Management of immune-related adverse events in patients treated with immune checkpoint inhibitor therapy: American Society of Clinical Oncology guideline update. J Clin Oncol. 2021;39(36):4073--4126.
37. Garces JC, Biusti S, Giusti S, et al. Antibody-mediated rejection: A review. Ochsner J. 2017;17(1):46-55.
38. Wan SS, Yin TD, Wyburn K, et al. The treatment of antibody-mediated rejection in kidney transplantation: An updated systematic review and meta-analysis. Transplantation. 2018;102(4):557-568.
39. Kidney Disease: Improving Global Outcomes (KDIGO) Transplant Work Group. KDIGO clinical practice guideline for the care of kidney transplant recipients. Am J Transplant. 2009;9(Suppl 3):S1.
40. Witt CA, Gaut JP, Yusen RD, et al. Acute antibody-mediated rejection after lung transplantation. J Heart Lung Transplant. 2013;32:1034.
41. Ma Y, Man J, Niu J, et al. Progress of research on human parovirus B19 infection after renal transplantation. Tranplant Rev. 2022;36(4):100730.
42. Alyglo™ 10% intravenous solution [prescribing information]. Teaneck, NJ: GC Biopharma; December 2023.
43. Bivigam® 10% intravenous solution [prescribing information]. Boca Raton, FL: ADMA Biologics; March 2024.
44. Murrell D, Pena S, Joly P, et al. Diagnosis and management of pemphigus: Recommendations of an international panel of experts. J Am Acad Dermatol. 2020:82(3):575-585.
45. Flebogamma® 5% DIF intravenous solution [prescribing information]. Los Angeles, CA: Grifols; August 2024.
46. American College of Obstetricians and Gynecologists Practice Advisory. Management of obstetric-gynecologic patients during a measles outbreak. March 2024. www.acog.com. Accessed on 10/30/2024.
47. Gammagard® Liquid 10% solution [prescribing information]. Lexington, MA: Takeda; January 2024.
48. Gammagard® S/D IgA < 1 mcg/mL in a 5% intravenous solution [prescribing information]. Lexington, MA: Takeda; March 2023.
49. Gammaked™ 10% solution [prescribing information]. Fort Lee, NJ: Kedrion; January 2020.
50. Gammaplex® 5% intravenous solution [prescribing information]. Fort Lee, NJ: Kedrion; May 2024.
51. Gamunex®-C 10% solution [prescribing information]. Research Triangle Park, NJ: Grifols; January 2020.
52. Octagam® 5% intravenous solution [prescribing information]. Paramus, NJ: Octapharma; April 2022.
53. Octagam® 10% intravenous solution [prescribing information]. Paramus, NJ: Octapharma; April 2022.
54. Privigen® 10% intravenous solution [prescribing information]. Kankakee, IL: CSL Behring; March 2022.
55. 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.
56. Bonilla FA, Khan DA, Ballas ZK, et al. Practice parameter for the diagnosis and management of primary immunodeficiency. J Allergy Clin Immunol. 2015;136(5):1186-205.
57. Panzyga 10% intravenous solution [prescribing information]. New York; NY: Pfizer; February 2021.
58. Asceniv 10% intravenous solution [prescribing information]. Boca Raton, FL. ADMA Biologics; April 2019.
59. Bonilla FA, Barlan I, Chapel H, et al. International Consensus Document (ICON): Common variable immunodeficiency disorders. J Allergy Clin Immunol Pract. 2016;4(1):38-59.
60. 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.

61. Wasserman RL, Lumry W, Harris J, et al. Efficacy, safety, and pharmacokinetics of a new 10% liquid intravenous immunoglobulin containing high titer neutralizing antibody to RSV and other respiratory viruses in subjects with primary immunodeficiency disease. J Clin Immunol. 2016;36:590-599.
62. Otani S, Davis AK, Cantwell L, et al. Evolving experience of treating antibody-mediated rejection following lung transplantation. Transpl Immunol. 2014;31(2):75-80.
63. Anderson D, Ali K, Blanchette V, et al. Guidelines on the use of intravenous immune globulin for hematologic conditions. Transfus Med Rev. 2007;21(2 Suppl 1):s9-56.
64. Neunert C, Terrell DR, Arnold DM, et al. American Society of Hematology 2019 guidelines for immune thrombocytopenia. Blood Adv. 2019;3(23):3829-3866.
65. Neunert C, Lim W, Crowther M, et al. The American Society of Hematology 2011 evidenced-based practice guideline for immune thrombocytopenia. Blood. 2011;117:4190-4207.
66. Gammaplex 10% intravenous solution [prescribing information]. Fort Lee, NJ: Kedrion; May 2024.
67. American Academy of Pediatrics. Kawasaki disease. In: Kimberlin DW, Banerjee R, Barnett ED, , eds. Red Book; 2024 Report of the Committee on Infectious Diseases, 33rd Ed. American Academy of Pediatrics; 2024:522-529. 27. UK National Health Service. Commissioning position (2024). Clinical Commissioning Policy for the use of therapeutic immunoglobulin (Ig) England (2024). Accessed on October 17, 2024.
68. Ahmed AR. Use of intravenous immunoglobulin therapy in autoimmune blistering diseases. Int Immunopharmacol. 2006;6(4):557-578.
69. Enk A, Hadaschik E, Eming R, et al. European guidelines on the use of high-dose intravenous immunoglobulin in dermatology. J Dtsch Dermatol Ges. 2017;15(2):228-241.
70. Gurean HM, Jeph S, Ahmed AR. Intravenous immunoglobulin therapy in autoimmune mucocutaneous blistering diseases: a review of the evidence for its efficacy and safety. Am J Clin Dermatol. 2010;11:315-326.
71. Glisson CC. UpToDate® 2024. Neuromyelitis optica spectrum disorder (NMOSD): Clinical features and diagnosis. www.uptodate.com. Accessed on October 30, 2024.
72. Aggarwal R, Charles-Schoeman C, Schessl J, et al. Prospective, double-blind, randomized, placebo-controlled, phase III study evaluating efficacy and safety of Octagam 10% in patients with dermatomyositis (ProDERM Study). Medicine (Baltimore). 2021;100(1):e23677.
73. Marfo K, Lu A, Ling M, Akalin E. Desensitization protocols and their outcome. Clin J Am Soc Nephrol. 2011;6:922-936.

Immune globulins, SC

1. Gammagard® Liquid 10% [prescribing information]. Lexington, MA: Takeda; January 2024.
2. Gammaked™ 10% solution [prescribing information]. Fort Lee, NJ: Kedrion; January 2020.
3. Gamunex®-C 10% solution [prescribing information]. Research Triangle Park, NC: Grifols; July 2024.
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; July 2024.
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.
11. Bonilla FA, Khan DA, Ballas ZK, et al. Practice parameter for the diagnosis and management of primary immunodeficiency. J Allergy Clin Immunol. 2015;136:1186-1205.

Immunomodulators

1. Infliximab intravenous infusion [prescribing information]. Horsham, PA: Janssen; October 2021.
2. Inflectra injection [prescribing information]. Lake Forest, IL: Hospira/Pfizer; June 2021.
3. Renflexis injection [prescribing information]. Jersey City, NJ: Samsung Bioepis/Organon; December 2023.
4. 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;(10):1599-1613.
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):481-517.
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):1029-1072.
8. Singh JA, Guyatt G, Ogdie A, et al. 2018 American College of Rheumatology/National Psoriasis Foundation Guideline for the treatment of psoriatic arthritis. Arthritis Care Res (Hoboken). 2019;71(1):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):1108-1123.
10. Rubin DT, Ananthakrishnan AN, Siegel CA, et al. ACG clinical guideline: ulcerative colitis in adults. Am J Gastroenterol. 2019;114(3):384-413.
11. Pardi DS, D'Haens G, Shen B, et al. Clinical guidelines for the management of pouchitis. Inflamm Bowel Dis. 2009;15(9):1424-1431.
12. 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.
13. Hatemi G, Christensen R, Bang D, et al. 2018 update of the EULAR recommendations for the management of Behçet's syndrome. Ann Rheum Dis. 2018;77(6):808-818.

14. 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.
15. The NCCN Hematopoietic Cell Transplantation (HCT) Clinical Practice Guidelines in Oncology (version 2.2024 – August 30, 2024). © 2024 National Comprehensive Cancer Network. http://www.nccn.org. Accessed on December 6, 2024.
16. Alikhan A, Sayed C, Alavi A, et al. North American clinical management guidelines for hidradenitis suppurativa: a publication from the United States and Canadian Hidradenitis Suppurativa Foundations: Part II: topical, intralesional, and systemic medical management. J Am Acad Dermatol. 2019;81(1):91-101.
17. Papadakis KA, Treyzon L, Abreu MT, et al. Infliximab in the treatment of medically refractory indeterminate colitis. Aliment Pharmacol Ther. 2003;18:741-747.
18. 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;18:175-181.
19. 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.
20. 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.
21. 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.
22. Dabade TS, Davis MD. Diagnosis and treatment of the neutrophilic dermatoses (pyoderma gangrenosum, Sweet's syndrome). Dermatol Ther. 2011;24(2):273-284.
23. Baughman RP, Valeyre D, Korsten P, et al. ERS clinical practice guidelines on treatment of sarcoidosis. Eur Respir J. 2021;58(6):2004079.
24. Riera E, Olivé A, Narváez J, et al. Adult onset Still's disease: review of 41 cases. Clin Exp Rheumatol. 2011;29(2):331-336.
25. Pouchot J, Arlet JB. Biological treatment in adult-onset Still's disease. Best Pract Res Clin Rheumatol. 2012;26(4):477-487.
26. Kontzias A, Efthimiou P. Adult-onset Still's disease: pathogenesis, clinical manifestations and therapeutic advances. Drugs. 2008;68:319-337.

Intravenous iron

1. 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. Monoferric® intravenous infusion [prescribing information]. Morristown, NJ: Pharmacosmos Therapeutics; September 2024.
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. Heidenreich PA, Bozkurt B, Aguilar D, et al. 2022 AHA/ACC/HFSA Guideline for the Management of Heart Failure: A Report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines [published correction appears in J Am Coll Cardiol. 2023 Apr 18;81(15):1551]. J Am Coll Cardiol. 2022;79(17):e263-e421.

Ophthalmic disorders, intravitreal vascular endothelial growth factor (VEGF) inhibitors

1. Beovu® intravitreal injection [prescribing information]. Hanover, NJ: Novartis; July 2024.
2. Eylea® intravitreal injection [prescribing information]. Tarrytown, NY: Regeneron; December 2023.
3. Lucentis® intravitreal injection [prescribing information]. South San Francisco, CA: Genentech; February 2024.
4. Byooviz™ intravitreal injection [prescribing information]. Cambridge, MA: Biogen; October 2023.
5. Vabysmo™ intravitreal injection [prescribing information]. South San Francisco, CA: Genentech; October 2023.
6. Cimerli™ intravitreal injection [prescribing information]. Redwood City, CA: Coherus; May 2024.
7. Eylea™ HD intravitreal injection [prescribing information]. Tarrytown, NY: Regeneron; December 2023.
8. Pavblu™ intravitreal injection [prescribing information]. Thousand Oaks, CA: Amgen; August 2024.
9. American Academy of Ophthalmology Retina/Vitreous Panel. Preferred Practice Pattern® Guidelines. Age-related macular degeneration. San Francisco, CA: American Academy of Ophthalmology; 2019. https://www.aao.org/preferred-practice-pattern/age-related-macular-degeneration-ppp. Accessed on August 1, 2024.
10. American Academy of Ophthalmology Retina/Vitreous Panel. Preferred Practice Pattern® Guidelines. Diabetic retinopathy. San Francisco, CA: American Academy of Ophthalmology; 2019. https://www.aao.org/preferred-practice-pattern/diabetic-retinopathy-ppp. Accessed on August 1, 2024.
11. Barakat MR, Kaiser PK. VEGF inhibitors for the treatment of neovascular age-related macular degeneration. Expert Opin Investig Drugs. 2009;18(5):637-646.
12. Tolentino M. Systemic and ocular safety of intravitreal anti-VEGF therapies for ocular neovascular disease. Surv Ophthalmol. 2011;56(2):95-113.
13. Kinnunen K, Ylä-Herttuala S. Vascular endothelial growth factors in retinal and choroidal neovascular diseases. Ann Med. 2012;44(1):1-17.
14. Horsley MB, Kahook MY. Anti-VEGF therapy for glaucoma. Curr Opin Ophthalmol. 2010;21(2):112-117.

Paclitaxel medications

1. 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;4:1707-1712.
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.

6. Hersh EM, O'Day SJ, Ribas A, et al. A phase 2 clinical trial of nab-paclitaxel in previously treated and chemotherapy-naïve patients with metastatic melanoma. Cancer. 2010;116:155-163.
7. Coleman RL, Brady WE, McMeekin DS, et al. A phase II evaluation of nanoparticle, albumin-bound (nab) paclitaxel in the treatment of recurrent or persistent platinum-resistant ovarian, fallopian tube, or primary peritoneal cancer: A Gynecologic Oncology Group Study. Gynecol Oncol. 2011;122(1):111-115.

Rituximab

1. Rituxan [prescribing information]. South San Francisco, CA: Genentech; December 2021.
2. Ruxience [prescribing information]. New York, NY: Pfizer; October 2023.
3. Truxima [prescribing information]. North Wales, PA: Teva/Celltrion; July 2024.
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; February 2023.
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):1108-1123.
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.
10. A Consensus Paper by the Multiple Sclerosis Coalition. The use of disease-modifying therapies in multiple sclerosis. Updated June 2019. http://ms-coalition.org/wp-content/uploads/2019/06/MSC_DMTPaper_062019.pdf. Accessed on July 18, 2023.
11. 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.
12. Kűmpfel T, Giglhuber K, Aktas O, et al. Update on the diagnosis and treatment of neuromyelitis optica spectrum disorders (NMOSD) – revised recommendations of the Neuromyelitis Optica Study Group (NEMOS). Part II: Attack therapy and long-term management. J Neurol. 2024;271:141-176.
13. Fanouriakis A, Kostopoulou M, Andersen J, et al. EULAR recommendations for the management of systemic lupus erythematosus: 2023 update. Ann Rheum Dis. 2024 Jan 2;83(1):15-29.
14. 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):1170-1201.
15. 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; July 2024.
2. Lanreotide subcutaneous injection [prescribing information]. Warren, NJ: Cipla; September 2024.
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.
5. Kong X, Cao Y, Yang D, Zhang X. Continuous irrigation and suction with a triple-cavity drainage tube in combination with sequential somatostatin-somatotropin administration for the management of postoperative high-output enterocutaneous fistulas: Three case reports and literature review. Medicine. 2019;98(46):e18010.
6. Tian W, Zhao R, Luo S, et al. Effect of postoperative utilization of somatostatin on clinical outcome after definitive surgery for duodenal fistula. Eur J Med Res. 2023;28(1):63.
7. Alghamdi AA, Jawas AM, Hart RS. Use of octreotide for the prevention of pancreatic fistula after elective pancreatic surgery: a systematic review and meta-analysis. Can J Surg. 2007;50(6):459-466.
8. Veillette G, Dominguez I, Ferrone C, et al. Implications and management of pancreatic fistulas following pancreaticoduodenectomy: the Massachusetts General Hospital experience. Arch Surg. 2008;143(5):476-481.
9. Sundaram S, Patra BR, Choksi D, et al. Outcomes and predictors of response to endotherapy in pancreatic ductal disruptions with refractory internal and high-output external fistulae. Ann Hepatobiliary Pancreat Surg. 2022;26(4):347-354.
10. Noori I. Postoperative enterocutaneous fistulas: Management outcomes in 23 consecutive patients. Ann Med Surg. 2021;66:102413.
11. Maroun JA, Anthony LB, Blais N, et al. Prevention and management of chemotherapy-induced diarrhea in patients with colorectal cancer: a consensus statement by the Canadian Working Group on Chemotherapy-Induced Diarrhea. Curr Oncol. 2007;14(1):13-20.

Systemic lupus erythematosus (SLE; lupus)

1. Benlysta® injection [prescribing information]. Rockville, MD: Human Genome Sciences/GlaxoSmithKline; May 2024.
2. Saphnelo® injection [prescribing information]. Wilmington, DE: AstraZeneca; September 2022.
3. 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.
4. Kidney Disease: Improving Global Outcomes (KDIGO) Lupus Nephritis Work Group. KDIGO 2024 Clinical Practice Guideline for the management of LUPUS NEPHRITIS. Kidney Int. 2024;105(1S):S1-S69.
5. 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; September 2018.
2. Testosterone enanthate injection [prescribing information]. Berkeley Heights, NJ: Hikma; January 2021.
3. Testopel® [prescribing information]. Malvern, PA: Endo; March 2024.

4. Aveed™ [prescribing information]. Malvern, PA: Endo; August 2021.
5. Xyosted [prescribing information]. Ewing, NJ: Antares; August 2023.
6. Azmiro™ [prescribing information]. Woburn, MA: Azurity; May 2024.
7. Lee M. Erectile Dysfunction. Urologic Disorders. In: Dipiro JT, Talbert RL, Yee GC, et al, eds. Pharmacotherapy: A pathophysiologic approach. 8th ed. New York: McGraw Hill Medical; 2008: 1437-1454.
8. Mulhall JP, Trost LW, Brannigan RE, et al. Evaluation and Management of Testosterone Deficiency. American Urological Association. 2018. Testosterone Deficiency Guideline - American Urological Association (auanet.org). Accessed on September 1, 2023.
9. Bhasin 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.
10. 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.
11. Galvan-Roman JM, Rodriguez-Garcia SC, Roy-Vallejo E, et al. IL-6 serum levels predict severity and response to tocilizumab in COVID-19: An observational study. J Allergy Clin Immunol. 2021;147(1):72-80.
12. Zhao H, Zhu Q, Zhang C, et al. Tocilizumab combined with favipiravir in the treatment of COVID-19: A multicenter trial in a small sample size. Biomed Pharmacother. 2021;133:110825.
13. Tuckwell K, Collinson N, Dimonaco S, et al. Newly diagnosed vs. relapsing giant cell arteritis: baseline data from the GiACTA trial. Semin Arthritis Rheum. 2017;46(5):657-664.
14. Stone JH, Tuckwell K, Dimonaco S, et al. Trial of tocilizumab in giant-cell arteritis. N Engl J Med. 2017 ;377(4):317-328.

Tocilizumab

1. Actemra® intravenous infusion [prescribing information]. South San Francisco, CA: Genentech; September 2024.
2. Tofidence™ intravenous infusion [prescribing information]. Cambridge, MA: Biogen; July 2024.
3. Tyenne® intravenous infusion [prescribing information]. Lake Zurich, IL: Fresenius Kabi; March 2024.
4. Schoels MM, van der Heijde D, Breedveld FC, et al. Blocking the effects of interleukin-6 in rheumatoid arthritis and other inflammatory rheumatic diseases: systematic literature review and meta-analysis informing a consensus statement. Ann Rheum Dis. 2013;72(4):583-589.
5. Yescarta™ intravenous infusion [prescribing information]. Santa Monica, CA: Kite Pharma; May 2019.
6. Kymriah™ intravenous infusion [prescribing information]. East Hanover, NJ: Novartis Oncology; June 2019.
7. Lee DW, Gardner R, Porter DL, et al. Current concepts in the diagnosis and management of cytokine release syndrome. Blood. 2014;124(2):188-195.
8. 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 Care Res (Hoboken). 2019;71(6):717-734.
9. 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.
10. 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):1108-1123.
11. Riera E, Olivé A, Narváez J, et al. Adult onset Still's disease: review of 41 cases. Clin Exp Rheumatol. 2011;29(2):331-336.
12. Puéchal X, de Bandt M, Berthelot JM, et al. Tocilizumab in refractory adult Still's disease. Arthritis Care Res (Hoboken). 2011;63(1):155-159.
13. Perdan-Pirkmajer K, Praprotnik S, Tomšič M. A case of refractory adult-onset Still's disease successfully controlled with tocilizumab and a review of the literature. Clin Rheumatol. 2010;29(12):1465-1467.
14. Sabnis GR, Gokhale YA, Kulkarni UP. Tocilizumab in Refractory Adult-Onset Still's Disease with Aseptic Meningitis-Efficacy of Interleukin-6 Blockade and Review of the Literature. Semin Arthritis Rheum. 2011;40(4):365-368.
15. De Bandt M, Saint-Marcoux B. Tocilizumab for multirefractory adult-onset Still's disease. Ann Rheum Dis. 2009;68(1):153-154.
16. Yoshimura M, Makiyama J, Koga T, et al. Successful treatment with tocilizumab in a patient with refractory adult-onset Still's disease (AOSD). Clin Exp Rheumatol. 2010;28(1):141-142.
17. Nakahara H, Mima T, Yoshio-Hoshino N, et al. A case report of a patient with refractory adult-onset Still's disease who was successfully treated with tocilizumab over 6 years. Mod Rheumatol. 2009;19(1):69-72.
18. Matsumoto K, Nagashima T, Takatori S, et al. Glucocorticoid and cyclosporine refractory adult onset Still's disease successfully treated with tocilizumab. Clin Rheumatol. 2009;28(4):485-487.
19. Iwamoto M, Nara H, Hirata D, et al. Humanized monoclonal anti-interleukin-6 receptor antibody for treatment of intractable adult-onset Still's disease. Arthritis Rheum. 2002;46(12):3388-3389.
20. Rech J, Ronneberger M, Englbrecht M, et al. Successful treatment of adult-onset Still's disease refractory to TNF and IL-1 blockade by IL-6 receptor blockade. Ann Rheum Dis. 2011;70(2):390-392.
21. Furst DE, Keystone EC, So AK, et al. Updated consensus statement on biological agents for the treatment of rheumatic diseases, 2012. Ann Rheum Dis. 2013;72 Suppl 2:ii2-34.
22. Xeljanz® tablets [prescribing information]. New York, NY: Pfizer; February 2016.
23. Ito H, Takazoe M, Fukuda Y, et al. A pilot randomized trial of a human anti-interleukin-6 receptor monoclonal antibody in active Crohn's disease. Gastroenterology. 2004;126:989-996.
24. Centers for Disease Control and Prevention (Web site). Coronavirus (COVID-19). https://www.cdc.gov/coronavirus/2019-ncov/index.html/. Accessed on April 21, 2024.
25. Dejaco C, Ramiro S, Bond M, eta al. EULAR recommendations for the use of imaging in large vessel vasculitis in clinical practice: 2023 update. Ann Rheum Dis. 2023:ard-2023-224543.
26. Xu X, Han M, Li T, et al. Effective treatment of severe COVID-19 patients with tocilizumab. Proc Natl Acad Sci U S A. 2020;117(20):10970-10975.
27. Strohbehn GW, Heiss BL, Rouhani SJ, et al. COVIDOSE: A Phase II Clinical Trial of Low-Dose Tocilizumab in the Treatment of Noncritical COVID-19 Pneumonia. Clin Pharmacol Ther. 2021;109(3):688-696.

28. Dastan F, Saffaei A, Haseli S, et al. Promising effects of tocilizumab in COVID-19: A non-controlled, prospective clinical trial. Int Immunopharmacol. 2020;88:106869.
29. Galvan-Roman JM, Rodriguez-Garcia SC, Roy-Vallejo E, et al. IL-6 serum levels predict severity and response to tocilizumab in COVID-19: An observational study. J Allergy Clin Immunol. 2021;147(1):72-80.
30. Zhao H, Zhu Q, Zhang C, et al. Tocilizumab combined with favipiravir in the treatment of COVID-19: A multicenter trial in a small sample size. Biomed Pharmacother. 2021;133:110825.
31. Tuckwell K, Collinson N, Dimonaco S, et al. Newly diagnosed vs. relapsing giant cell arteritis: baseline data from the GiACTA trial. Semin Arthritis Rheum. 2017;46(5):657-664.
32. Stone JH, Tuckwell K, Dimonaco S, et al. Trial of tocilizumab in giant-cell arteritis. N Engl J Med. 2017 ;377(4):317-328.

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. Ogivri® 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; June 2024.
7. Ontruzant® intravenous infusion [prescribing information]. Whitehouse Station, NJ: Merck; March 2020.
8. Hercessi™ intravenous infusion [prescribing information]. Raleigh, NC: Accord BioPharma; September 2024.

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.
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.
11. 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. 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):1306-1311.
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):1246-1252.
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):1079-1086.
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):162-165.

Calcitonin gene-related peptide inhibitors**

1. 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. Cephalalgia. 2018;38:1-211.
6. MacGregor EA. In the clinic. Migraine. Ann Intern Med. 2017;166(7):ITC49-ITC64.
7. Lipton RB, Silberstein SD. Episodic and chronic migraine headache: breaking down barriers to optimal treatment and prevention. Headache. 2015;52:103-122.
8. American Headache Society. The American Headache Society position statement on integrating new migraine treatments into clinical practice. Headache. 2019;59:1-18.
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;00:1–19.
10. Charles AC, Digre KB, Goadsby PJ, et al; American Headache Society. Calcitonin gene-related peptide-targeting therapies are a first-line option for the prevention of migraine: An American Headache Society position statement update. Headache. 2024 Mar 11. Epub ahead of print.
11. Ashina M, Saper J, Cady R, et al. Eptinezumab in episodic migraine: a randomized, double-blind, placebo-controlled study (PROMISE-1). Cephalalgia. 2020;40(3):241-254.
12. Data on file. Eptinezumab-jjmr Pre-Approval Dossier, version 1.7. Lundbeck, Inc.; Deerfield, IL; received on March 2, 2020.
13. Qulipta® tablets [prescribing information]. Madison, NJ: AbbVie; April 2023.
14. Nurtec® ODT [prescribing information]. New Haven, CT: Biohaven; April 2022.

Proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitors**

1. Praluent® subcutaneous injection [prescribing information]. Tarrytown, NY: Regeneron; March 2024.
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):1366-1418.
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):S1-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;139:e1082-e1143.
7. American Diabetes Association Professional Practice Committee. Cardiovascular Disease and Risk Management: Standards of Care in Diabetes-2024. Diabetes Care. 2024;47(Suppl 1):S179-S218.
8. 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;82(9):833-955.
9. Gidding SS, Champagne MA, de Ferranti SD, et al. The agenda for familial hypercholesterolemia. A scientific statement from the American Heart Association. Circulation. 2015;132(22):2167-2192.
10. Haase A, Goldberg AC. Identification of people with heterozygous familial hypercholesterolemia. Curr Opin Lipidol. 2012;23:282-289.
11. Hect HS, Cronin P, Blaha M, et al. 2016 SCCT/STR guidelines for coronary artery calcium scoring of noncontrast noncardiac chest CT scans: A report of the Society of Cardiovascular Computed Tomography and Society of Thoracic Radiology. J Thorac Imaging. 2017;32(5):W54-S66.
12. Greenland P, Blaha MJ, Budoff MJ, et al. Coronary calcium score and cardiovascular risk. J Am Coll Cardiol. 2018;72(4):434-447.
13. Razavi AC, Agatston AS, Shaw LJ, et al. Evolving role of calcium density in coronary artery calcium scoring and atherosclerotic cardiovascular disease risk. JACC Cardiovas Imaging. 2022;15:1648-1662.
14. Lehker A, Mukherjee D. Coronary calcium risk score and cardiovascular risk. Curr Vasc Pharmacol. 2021;19(3):280-284.

Revision history

Date	Summary of changes
7/1/2025	**Coverage criteria** • **Somatostatin analogs long acting** › Moved Lanreotide (JI932) from non-preferred to preferred **Applicable codes** • **Somatostatin analogs long acting** › JI932.....Preferred