

## Preferred Physician-Administered Drugs

### Disclaimer

*Clinical guidelines are developed and adopted to establish evidence-based clinical criteria for utilization management decisions. Oscar may delegate utilization management decisions of certain services to third-party delegates, who may develop and adopt their own clinical criteria.*

*Clinical guidelines are applicable to certain plans. Clinical guidelines are applicable to members enrolled in Medicare Advantage plans only if there are no criteria established for the specified service in a Centers for Medicare & Medicaid Services (CMS) national coverage determination (NCD) or local coverage determination (LCD) on the date of a prior authorization request. Services are subject to the terms, conditions, limitations of a member's policy and applicable state and federal law. Please reference the member's policy documents (e.g., Certificate/Evidence of Coverage, Schedule of Benefits) or contact Oscar at 855-672-2755 to confirm coverage and benefit conditions.*

### Summary

Oscar's Preferred Medication List encourages the utilization of clinically appropriate and cost-effective physician-administered specialty drugs. The table below lists both the preferred and non-preferred medications within a therapeutic class.

In most cases, and as long as it's considered safe by your provider, the preferred medications must be used first. Requests for non-preferred medications will be subject to **CVS Exceptions Criteria**, and this criteria is available upon request. Approval for non-preferred medications may require that the member has a contraindication to the preferred medication(s); has tried and failed the preferred medication(s); had an inadequate response to the preferred medication(s); or had an intolerable adverse event with the preferred medication(s). For more information, please call 855-672-2755.

### Medical Preferred Drug List

Drug Class	Preferred Medication(s)	Non-Preferred Medication(s)
Acromegaly	Somatuline Depot (lanreotide)	Sandostatin LAR Depot (octreotide)

	Somavert (pegvisomant)	acetate) Signifor LAR (pasireotide)
<b>Alpha-1 Antitrypsin Deficiency</b>	Prolastin-C (alpha1-proteinase inhibitor[human])	Aralast (alpha1-proteinase inhibitor[human]) Glassia (alpha1-proteinase inhibitor[human]) Zemaira (alpha1-proteinase inhibitor[human])
<b>Autoimmune</b>	Remicade (infliximab) Simponi Aria (golimumab)	Actemra (tocilizumab) Cimzia (certolizumab pegol) Entyvio (vedolizumab) Ilumya (tildrakizumab-asmn) Inflectra (infliximab-dyyb) Orencia (abatacept) Renflexis (infliximab-abda) Stelara (ustekinumab)
<b>Botulinum Toxins</b>	Botox (onabotulinumtoxinA) Dysport (abobotulinumtoxinA)	Myobloc (rimabotulinumtoxinB) Xeomin (incobotulinumtoxinA )
<b>Hematologic, Erythropoiesis-Stimulating Agents (ESA)</b>	Retacrit (epoetin alfa-epbx)	Aranesp (darbepoetin alfa) Epogen (epoetin alfa) Mircera (methoxy polyethylene glycol-epoetin beta) Procrit (epoetin alfa)
<b>Hemophilia - Factor VIII</b>	Adynovate (antihemophilic factor (recombinant), PEGylated) Jivi (antihemophilic factor (recombinant), PEGylated-aucI) Kogenate FS (antihemophilic factor (recombinant)) Kovaltry (antihemophilic Factor (Recombinant)) Novoeight (antihemophilic factor (recombinant), glycopegylated-exei)	Eloctate (antihemophilic factor (recombinant), Fc fusion protein) Helixate FS (Antihemophilic Factor (Recombinant)) Nuwiq (Antihemophilic Factor (Recombinant))
<b>Hemophilia - Factor IX</b>	Idelvion [Coagulation Factor IX (Recombinant), Albumin Fusion Protein (rIX-FP)] Rebinyn (Coagulation Factor IX (Recombinant), GlycoPEGylated)	Alprolix (Coagulation Factor IX (Recombinant), Fc Fusion Protein)
<b>Hematologic, Neutropenia Colony</b>	Zarxio (filgrastim-sndz)	Neupogen (filgrastim) Granix (tbo-filgrastim) Injection

<b>Stimulating Factors</b>		Leukine (sargramostim)
<b>Hereditary Angioedema</b>	Ruconest (C1 esterase inhibitor [recombinant]) for Intravenous Injection	Berinert (C1 Esterase Inhibitor, Human)
<b>Lysosomal Storage Disorders - Gaucher Disease</b>	Cerezyme (Imiglucerase)	Eluelyso (taliglucerase alfa) VPRIV (velaglucerase alfa for injection)
<b>Multiple Sclerosis</b>	Tysabri (natalizumab)	Lemtrada (alemtuzumab)
<b>Retinal Disorders Agents</b>	Avastin (bevacizumab) Eylea (aflibercept) Lucentis (ranibizumab)	Macugen (pegaptanib sodium injection) Visudyne (verteporfin for injection)

## Rationale

### Acromegaly:

- Sandostatin LAR is a form of long-acting octreotide (octreotide LAR). Somavert is also known as pegvisomant. There have been a number of random controlled trials comparing the two in the treatment of acromegaly. Ghigo et al compared the two in 118 patients randomized to one or the other in a multi-center trial, concluding that "Pegvisomant and octreotide LAR were equally effective in normalizing IGF-I in the overall population, and pegvisomant was more effective in patients with higher baseline IGF-I levels. Pegvisomant had a more favorable effect on parameters of glycemic control." A separate study by Trainer et al compared Pegvisomant and a combination of Pegvisomant and octreotide LAR and found no differences in toxicity or efficacy. Other studies have largely replicated these findings. Additionally, an UpToDate review on treatment for acromegaly recommends pegvisomant as first-line medical therapy.<sup>1-3</sup>

### Alpha-1-antitrypsin deficiency

- These medications are alpha-1-proteinase inhibitors used to treat emphysema as a result of deficiency in this the alpha-1-antitrypsin enzyme. There have been no studies to date demonstrating any clinically significant differences in efficacy or toxicity among the different formulations.

### Autoimmune

- There are a number of immunomodulator medications on the market, many of which are FDA-approved biosimilars. There is currently no level 1 evidence in the form of randomized trials that demonstrate greater benefit in efficacy or side effects between the biosimilars.<sup>29-30</sup>

#### Botulinum toxin

- There are 4 FDA approved and clinically implemented formulations of botulinum toxin. Botox and Dysport have the broadest number of indications and applicability. There is no evidence suggesting there are indications unique to Myobloc or Xeomin.

#### Hematologic, Erythropoiesis-Stimulating Agents (ESA)

- Retacrit is a biosimilar to the other non-preferred ESA drugs. A biosimilar, per the FDA, is defined as a "biological product that is highly similar to and has no clinically meaningful differences from an existing FDA-approved reference product." A 2018 study by Thadhani et al compared Epogen to Retacrit in a randomized open-label non-inferiority study in 432 patients on hemodialysis. The study found that Retacrit was non-inferior to Epogen at maintaining hemoglobin levels in this population. There have been no clinical studies demonstrating any meaningful difference between these biosimilar agents.<sup>4-5</sup>

#### Hemophilia - Factor VIII

- Factor VIII treatments for hemophilia A come in several different formulations including recombinant (Helixate, Nuwiq, Jivi, Kogenate, Kovaltry, Novoeight) and plasma derived (Adynovate, Eloctate). The plasma derived factors are considered "long-acting" as they have longer half-lives than the others. The recent randomized SIPPET trial found that plasma-derived products had lower rates of inhibitor development (e.g. reduced immunogenicity) than the recombinant medications. The most current guidelines from the National Hemophilia Foundation Medical and Scientific Advisory Council addressed this new study but reinforced their recommendation that both recombinant and plasma derived products could be used in new and already treated patients.<sup>6-11</sup>

#### Hemophilia - Factor IX

- Idelvion and alprolix are both long acting factor IX options. There have been no clinical studies demonstrating a significant difference in efficacy or toxicity between the two, and thus the lower cost option is preferred. Rebinyn has a slightly longer half-life than alprolix and is roughly equivalent to idelvion, again with no studies directly comparing them.<sup>12</sup>

#### Hematologic, Neutropenia Colony Stimulating Factors

- Zarxio is a biosimilar G-CSF to neupogen. The most recently updated ASCO guidelines recommend that "all preparations of G-CSF, including biosimilars, can be used for the prevention of treatment-related febrile neutropenia and that the choice of agent should be based on convenience, cost, and clinical situation"<sup>18</sup>

- Leukine is a GM-CSF, meaning that in addition to granulocytes it also stimulates macrophages. The data comparing GM-CSF to G-CSF medications is limited. The only randomized data comes from a 1998 study comparing the two in 181 patients, finding comparable efficacy between the two and no clinically meaningful differences. This has been largely reflected in other prospective and retrospective comparisons.<sup>13-16</sup>

#### Hereditary Angioedema:

- Ruconest is a recombinant medication and berinert is human plasma-derived medication to inhibit C1-esterase. Both are used to treat hereditary angioedema. There have been no clinical studies demonstrating a meaningful difference in efficacy or toxicity between the two options. Ruconest is also more readily accessible as it does not rely on human donors, and thus is the preferred option.<sup>17</sup>

#### Lysosomal Storage Disorders - Gaucher Disease

- Per an UpToDate review on the different enzyme replacement therapies for Gaucher's disease, "Although there is limited direct and published evidence from head-to-head studies, the available evidence suggests that all the ERTs are approximately equivalent in efficacy". There have otherwise been no studies demonstrating a clear benefit in any one product over another.<sup>19-22</sup>

#### Multiple Sclerosis (Infused)

- Data comparing the available treatment options for MS is limited. However, a recent study looked at 41,000 MS patients in a worldwide registry found no differences between the Tysabri and Lemtrada across all outcome measures, except that Tysabri may be superior in providing improvement in function during the first year. Several other studies have found superiority in outcomes using Tysabri or at a minimum, equivalent outcomes across a number of outcome measures and disease stages.<sup>23-26</sup>

#### Retinal Disorders Agents

- Lucentis (Ranibizumab) is a recombinant humanized monoclonal antibody with specificity for VEGF and is essentially an antibody fragment of Avastin (Bevacizumab). Randomized trials have found no difference in visual acuity for the treatment of wet AMD between these two agents.<sup>33-34</sup> Eylea (Aflibercept) is similar but functions as a recombinant fusion protein that competitively binds to VEGF and thus has a similar effect to the VEGF inhibitors (Lucentis and Avastin). There have been two recent randomized trials comparing Eylea to Lucentis, showing comparable visual acuity at 1- and 2-years, as well as a prospective non-randomized comparison to Avastin

showing improved acuity at 24 weeks.<sup>35-37</sup> Macugen (Pagaptanib) was one of the first approved VEGF inhibitors for AMD, and although it has shown improved visual acuity compared to placebo in randomized trials, the newer agents appear to provide great benefit with less adverse effects and toxicity.<sup>38-39</sup> Finally, Visudyne (Verteporfin) is a light activated photodynamic medication that causes endothelial damage to treat retinal disorders. It was compared to Lucentis in the ANCHOR trial but was found to be inferior in visual acuity outcomes.<sup>38</sup>

### Applicable Billing Codes

\*Indicates non-preferred medications subject to CVS Exceptions Criteria

<b>Acromegaly</b>	
J1930	Somatuline Depot Injection, lanreotide, 1 mg
J2353*	SandoSTATIN LAR Depot Injection, octreotide, depot form for intramuscular injection, 1 mg
J2502*	Signifor LAR Injection, pasireotide long acting, 1 mg
J3490	Somavert Unclassified drugs
<b>Alpha-1 Antitrypsin Deficiency</b>	
J0256*	Aralast NP Injection, alpha 1-proteinase inhibitor (human), not otherwise specified, 10 mg
J0256	Prolastin-C Injection, alpha 1-proteinase inhibitor (human), not otherwise specified, 10 mg
J0256*	Zemaira Injection, alpha 1-proteinase inhibitor (human), not otherwise specified, 10 mg
J0257*	Glassia Injection, alpha 1 proteinase inhibitor (human), (GLASSIA), 10 mg
<b>Autoimmune</b>	
J0129*	Orencia; Orenica ClickJect Injection, abatacept, 10 mg
J0717*	Cimzia; Cimzia Prefilled; Cimzia Starter Kit Injection, certolizumab pegol, 1 mg

J1602	Simponi Aria Injection, golimumab, 1 mg, for intravenous use
J1745	Remicade Injection, infliximab, excludes biosimilar, 10 mg
J3262*	Actemra Injection, tocilizumab, 1 mg
J3357*	Stelara Ustekinumab, for subcutaneous injection, 1 mg
J3358*	Stelara Ustekinumab, for intravenous injection, 1 mg
J3380*	Entyvio Injection, vedolizumab, 1 mg
J3490*	Entyvio Unclassified drugs
Q5103*	Inflectra Injection, infliximab-dyyb, biosimilar, (Inflectra), 10 mg
Q5104*	Renflexis Injection, infliximab-abda, biosimilar, (Renflexis), 10 mg
J3245	Ilumya Injection, tildrakizumab, 1 mg
J3590	Ilumya Unclassified biologics
<b>Botulinum Toxins</b>	
J0585	Botox Injection, onabotulinumtoxinA, 1 unit
J0586	Dysport Injection, abobotulinumtoxinA, 5 units
J0587*	Myobloc Injection, rimabotulinumtoxinB, 100 units
J0588*	Xeomin Injection, incobotulinumtoxinA, 1 unit
<b>Hematologic, Erythropoiesis-Stimulating Agents (ESA)</b>	
J0881*	Aranesp

	Injection, darbepoetin alfa, 1 mcg (non-ESRD use)
J0882*	Aranesp Injection, darbepoetin alfa, 1 mcg (for ESRD on dialysis)
J0885*	Epogen Injection, epoetin alfa, (for non-ESRD use), 1000 units
Q4081*	Epogen Injection, epoetin alfa, 100 units (for ESRD on dialysis)
J0885*	Procrit Injection, epoetin alfa, (for non-ESRD use), 1000 units
Q4081*	Procrit Injection, epoetin alfa, 100 units (for ESRD on dialysis)
J0887*	Mircera Injection, epoetin beta, 1 microgram, (for ESRD on dialysis)
J0888*	Mircera Injection, epoetin beta, 1 microgram, (for non-ESRD use)
Q5105	Retacrit Injection, epoetin alfa, biosimilar, (Retacrit) (for ESRD on dialysis), 100 units
Q5106	Retacrit Injection, epoetin alfa, biosimilar, (Retacrit) (for non-ESRD use), 1000 units
<b>Hemophilia - Factor VIII</b>	
J7182	Novoeight Injection, Factor VIII, (antihemophilic factor, recombinant), (NovoEight), per IU
J7192*	Helixate FS Factor VIII (antihemophilic factor, recombinant) per IU, not otherwise specified
J7192	Kogenate FS; Kogenate FS Bio-Set Factor VIII (antihemophilic factor, recombinant) per IU, not otherwise specified
J7205*	Eloctate Injection, Factor VIII Fc fusion protein (recombinant), per IU
J7207	Adynovate Injection, Factor VIII, (antihemophilic factor, recombinant), PEGylated, 1 IU
J7208	Jivi Injection, Factor VIII, (antihemophilic factor, recombinant), PEGylated-aucl, (Jivi), 1 IU



J7209*	Nuwiq Injection, Factor VIII, (antihemophilic factor, recombinant), (Nuwiq), 1 IU
J7211	Kovaltry Injection, Factor VIII, (antihemophilic factor, recombinant), (Kovaltry), 1 IU
<b>Hemophilia - Factor IX</b>	
J7201*	Alprolix Injection, Factor IX, Fc fusion protein, (recombinant), Alprolix, 1 IU
J7202	Idelvion Injection, Factor IX, albumin fusion protein, (recombinant), Idelvion, 1 IU
J7203	Rebinyn Injection Factor IX, (antihemophilic factor, recombinant), glycoPEGylated, (Rebinyn), 1 IU
<b>Hematologic, Neutropenia Colony Stimulating Factors</b>	
J1442*	Neupogen Injection, filgrastim (G-CSF), excludes biosimilars, 1 microgram
J1447*	Granix Injection, tbo-filgrastim, 1 microgram
J2820*	Leukine Injection, sargramostim (GM-CSF), 50 mcg
Q5101	Zarxio Injection, filgrastim-sndz, biosimilar, (Zarxio), 1 mcg
<b>Hereditary Angioedema</b>	
J0596	Ruconest Injection, C1 esterase inhibitor (recombinant), Ruconest, 10 units
J0597*	Berinert Injection, C-1 esterase inhibitor (human), Berinert, 10 units
<b>Lysosomal Storage Disorders - Gaucher Disease</b>	
J1786	Cerezyme Injection, imiglucerase, 10 units
J3060*	Elelyso Injection, taliglucerase alfa, 10 units
J3385*	VPRIV

	Injection, velaglucerase alfa, 100 units
<b>Multiple Sclerosis (Infused)</b>	
J0202*	Lemtrada Injection, alemtuzumab, 1 mg
J2323	Tysabri Injection, natalizumab, 1 mg
<b>Retinal Disorders Agents</b>	
C9257	Avastin Injection, bevacizumab, 0.25 mg
J0178	Eylea Injection, aflibercept, 1 mg
J2503*	Macugen Injection, pegaptanib sodium, 0.3 mg
J2778	Lucentis Injection, ranibizumab, 0.1 mg
J3396*	Visudyne Injection, verteporfin, 0.1 mg
J9035	Avastin Injection, bevacizumab, 10 mg

\*Indicates non-preferred medications subject to CVS Exceptions Criteria

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#### Clinical Guideline Revision / History Information

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