



## Clinical Guideline

Oscar Clinical Guideline: (Medicare Part B Step Therapy) Preferred Physician-Administered Specialty Drugs (CG066, Ver. 6)

### (Medicare Part B Step Therapy) Preferred Physician-Administered Specialty Drugs

#### Disclaimer

*Clinical guidelines are developed and adopted to establish evidence-based clinical criteria for utilization management decisions. Clinical guidelines are applicable according to policy and plan type. The Plan may delegate utilization management decisions of certain services to third parties who may develop and adopt their own clinical criteria.*

*Coverage of services is subject to the terms, conditions, and limitations of a member's policy, as well as applicable state and federal law. Clinical guidelines are also subject to in-force criteria such as the Centers for Medicare & Medicaid Services (CMS) national coverage determination (NCD) or local coverage determination (LCD) for Medicare Advantage plans. Please refer to the member's policy documents (e.g., Certificate/Evidence of Coverage, Schedule of Benefits, Plan Formulary) or contact the Plan to confirm coverage.*

#### Summary

Biosimilars-first Medical Preferred Medication Drug list List for Medicare Part B Step Therapy 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 drug class or group.

In most cases, the preferred medications must be used first as long as they are considered safe and effective for use by your provider. Preferred medications are selected based upon clinical effectiveness and safety in alignment with FDA approved labeling or medically accepted compendia-supported literature or treatment guidelines that represent best practices. 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 be provided if the member has tried and failed, or is unable to use the Plan's preferred drug(s). Qualifying exceptions may include, but are not limited to the following:

1. The member has a documented trial and failure, inadequate response, intolerance, or contraindication to the preferred drug(s); **or**
2. The member has a risk factor(s) for poor response to the preferred drug(s); **or**
3. The member is not a candidate for the preferred drug(s) based on the member's condition(s), individual needs, treatment history, or accepted standards of medical practice.

For more information or to request an exception, please contact the Plan.

### **Medical Preferred Drug List**

<b>Drug Class</b>	<b>Preferred Medications</b>	<b>Non-Preferred Medications subject to CVS Exceptions Criteria</b>
Acromegaly	<ul style="list-style-type: none"> <li>❖ Sandostatin LAR Depot (octreotide acetate)</li> <li>❖ Somatuline Depot (lanreotide)</li> </ul>	<ul style="list-style-type: none"> <li>❖ Signifor LAR (pasireotide)</li> <li>❖ Somavert (pegvisomant)</li> </ul>
Alpha-1 Antitrypsin Deficiency	<ul style="list-style-type: none"> <li>❖ Prolastin-C (alpha1-proteinase inhibitor [human])</li> </ul>	<ul style="list-style-type: none"> <li>❖ Aralast NP (alpha1-proteinase inhibitor [human])</li> <li>❖ Glassia (alpha1-proteinase inhibitor[human])</li> <li>❖ Zemaira (alpha1-proteinase inhibitor [human])</li> </ul>
Autoimmune - Drugs for autoimmune conditions	<ul style="list-style-type: none"> <li>❖ Entyvio (vedolizumab)</li> <li>❖ Simponi Aria (golimumab)</li> </ul>	<ul style="list-style-type: none"> <li>❖ Actemra (tocilizumab)</li> <li>❖ Cimzia (certolizumab pegol)</li> <li>❖ Ilumya (tildrakizumab-asmn)</li> <li>❖ Orencia (abatacept)</li> <li>❖ Stelara (ustekinumab)</li> </ul>
Autoimmune - Infliximab products	<ul style="list-style-type: none"> <li>❖ Avsola (infliximab-axxq)</li> <li>❖ Inflectra (infliximab-dyyb)</li> <li>❖ Renflexis (infliximab-abda)</li> </ul>	<ul style="list-style-type: none"> <li>❖ Infliximab</li> <li>❖ Remicade (infliximab)</li> </ul>
Avastin/Biosimilars (Oncology)	<ul style="list-style-type: none"> <li>❖ Mvasi (Bevacizumab-awwb)</li> <li>❖ Zirabev (Bevacizumab-bvzr)</li> </ul>	<ul style="list-style-type: none"> <li>❖ Avastin (Bevacizumab)</li> </ul>
Botulinum Toxins	<ul style="list-style-type: none"> <li>❖ Dysport (abobotulinumtoxinA)</li> </ul>	<ul style="list-style-type: none"> <li>❖ Botox (onabotulinumtoxinA)</li> <li>❖ Myobloc</li> </ul>

	<ul style="list-style-type: none"> <li>❖ Xeomin (incobotulinumtoxinA)</li> </ul>	(rimabotulinumtoxinB)
Complement Inhibitors (aHUS, gMG, PNH)	<ul style="list-style-type: none"> <li>❖ Soliris (eculizumab)</li> <li>❖ Ultomiris (ravulizumab-cwvz)</li> </ul>	
Complement Inhibitors (NMOSD)	<ul style="list-style-type: none"> <li>❖ Soliris (eculizumab)</li> </ul>	<ul style="list-style-type: none"> <li>❖ Uplizna (inebilizumab-cdon)</li> </ul>
Hematologic, Erythropoiesis-Stimulating Agents (ESA)	<ul style="list-style-type: none"> <li>❖ Aranesp (darbepoetin alfa)</li> <li>❖ Retacrit (epoetin alfa-epbx)</li> </ul>	<ul style="list-style-type: none"> <li>❖ Epogen (epoetin alfa)</li> <li>❖ Mircera (epoetin beta)</li> <li>❖ Procrit (epoetin alfa)</li> </ul>
Hematologic, Neutropenia Colony Stimulating Factors, Long-Acting	<ul style="list-style-type: none"> <li>❖ Fulphila (pegfilgrastim-jmdb)</li> <li>❖ Zixtenzo (pegfilgrastim-bmez)</li> </ul>	<ul style="list-style-type: none"> <li>❖ Neulasta (including Onpro kit) (pegfilgrastim)</li> <li>❖ Nyvepria (pegfilgrastim-apgf)</li> <li>❖ Udenyca (pegfilgrastim-cbqv)</li> </ul>
Hematologic, Neutropenia Colony Stimulating Factors, Short-Acting	<ul style="list-style-type: none"> <li>❖ Nivestym (filgrastim-aafi)</li> <li>❖ Zarxio (filgrastim-sndz)</li> </ul>	<ul style="list-style-type: none"> <li>❖ Granix (tbo-filgrastim) Injection</li> <li>❖ Leukine (sargramostim)</li> <li>❖ Neupogen (filgrastim)</li> </ul>
Lysosomal Storage Disorders - Gaucher Disease	<ul style="list-style-type: none"> <li>❖ Elelyso (taliglucerase alfa)</li> </ul>	<ul style="list-style-type: none"> <li>❖ Cerezyme (imiglucerase)</li> <li>❖ VPRIV (velaglucerase alfa for injection)</li> </ul>
Multiple Sclerosis (Infused)	<ul style="list-style-type: none"> <li>❖ Tysabri (natalizumab)</li> </ul>	<ul style="list-style-type: none"> <li>❖ Lemtrada (alemtuzumab)</li> </ul>
Osteoarthritis, Viscosupplements (Single Injection)	<ul style="list-style-type: none"> <li>❖ Synvisc-One (hyaluronic acid F 20)</li> <li>❖ Monovisc (high molecular weight hyaluronan)</li> </ul>	<ul style="list-style-type: none"> <li>❖ Durolane (hyaluronic acid)</li> <li>❖ Gel-One (cross-linked hyaluronate)</li> </ul>
Osteoarthritis, Viscosupplements (Multi Injection)	<ul style="list-style-type: none"> <li>❖ Orthovisc (high molecular weight hyaluronan)</li> <li>❖ Synvisc (hyaluronic acid F 20)</li> </ul>	<ul style="list-style-type: none"> <li>❖ Euflexxa (1% sodium hyaluronate)</li> <li>❖ Gelsyn-3 (sodium hyaluronate 0.84%)</li> <li>❖ GenVisc 850 (sodium hyaluronate)</li> <li>❖ Hyalgan (sodium hyaluronate)</li> <li>❖ Hymovis (high molecular weight viscoelastic hyaluronan)</li> </ul>

		<ul style="list-style-type: none"> <li>❖ Trivisc (sodium hyaluronate)</li> <li>❖ Visco-3 (sodium hyaluronate)</li> </ul>
Prostate Cancer – Luteinizing Hormone Releasing Hormone (LHRH) Agents	<ul style="list-style-type: none"> <li>❖ Eligard (leuprolide acetate)</li> </ul>	<ul style="list-style-type: none"> <li>❖ Lupron Depot (leuprolide acetate for depot suspension)</li> <li>❖ Trelstar (triptorelin pamoate for injectable suspension)</li> <li>❖ Zoladex (goserelin implant)</li> </ul>
Prostate Cancer – Luteinizing Hormone Releasing Hormone (LHRH) Antagonists Agents	<ul style="list-style-type: none"> <li>❖ Firmagon (degarelix for injection)</li> </ul>	
Retinal Disorders Agents	<ul style="list-style-type: none"> <li>❖ Avastin (bevacizumab)</li> <li>❖ Byooviz (ranibizumab-nuna)</li> </ul>	<ul style="list-style-type: none"> <li>❖ Beovu (brolucizumab-dbll)</li> <li>❖ Eylea (afibercept)</li> <li>❖ Lucentis (ranibizumab)</li> </ul>
Rituximab Products	<ul style="list-style-type: none"> <li>❖ Riabni (rituximab-arrx)</li> <li>❖ Ruxience (rituximab-pvvr)</li> <li>❖ Truxima (rituximab-abbs)</li> </ul>	<ul style="list-style-type: none"> <li>❖ Rituxan (rituximab)</li> <li>❖ Rituxan Hycela (rituximab/hyaluronidase human)</li> </ul>
Severe Asthma	<ul style="list-style-type: none"> <li>❖ Fasenra (benralizumab)</li> <li>❖ Nucala (mepolizumab)</li> <li>❖ Xolair (omalizumab)</li> </ul>	<ul style="list-style-type: none"> <li>❖ Cinqair (reslizumab)</li> </ul>
Trastuzumab	<ul style="list-style-type: none"> <li>❖ Herzuma (trastuzumab-pkrb)</li> <li>❖ Kanjinti (trastuzumab-anns)</li> <li>❖ Ogviri (trastuzumab-dkst)</li> <li>❖ Ontruzant (trastuzumab-dttb)</li> <li>❖ Trazimera (trastuzumab-qyyp)</li> </ul>	<ul style="list-style-type: none"> <li>❖ Herceptin (trastuzumab)</li> <li>❖ Herceptin Hylecta (trastuzumab and hyaluronidase-oysk)</li> </ul>

## Applicable Billing Codes

<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 J3590	Somavert Unclassified drugs Unclassified biologics
<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; Orencia 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
J1745	Injection, infliximab, 10 mg
J3245	Ilumya

	Injection, tildrakizumab, 1 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
Q5103	Inflectra Injection, infliximab-dyyb, biosimilar, (Inflectra), 10 mg
Q5104	Renflexis Injection, infliximab-abda, biosimilar, (Renflexis), 10 mg
Q5121	Avsola Injection, infliximab-axxq, biosimilar, (Avsola), 10 mg
<b>Avastin/Biosimilars (Oncology)</b>	
J9035	Avastin Injection, bevacizumab, 10 mg
Q5107	Mvasi Inj mvasi 10 mg
Q5118	Zirabev Inj., zirabev, 10 mg
<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

**Complement Inhibitors [paroxysmal nocturnal hemoglobinuria (PNH), atypical hemolytic uremic syndrome (aHUS), anti-acetylcholine receptor antibody positive generalized myasthenia gravis (gMG)]**

J1300	Soliris Injection, eculizumab, 10 mg
J1303	Ultomiris Injection, ravulizumab-cwvz, 10 mg

**Complement Inhibitors [neuromyelitis optica spectrum disorder (NMOSD)]**

J1300	Soliris Injection, eculizumab, 10 mg
J1823	Uplizna Inj. inebilizumab-cdon, 1 mg

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

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
J0885	Procrit Injection, epoetin alfa, (for non-ESRD use), 1000 units
J0887	Mircera Injection, epoetin beta, 1 mcg, (for ESRD on dialysis)
J0888	Mircera Injection, epoetin beta, 1 mcg, (for non-ESRD use)
Q4081	Epogen Injection, epoetin alfa, 100 units (for ESRD on dialysis)
Q4081	Procrit Injection, epoetin alfa, 100 units (for ESRD on dialysis)
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>Hematologic, Neutropenia Colony Stimulating Factors, Long-Acting</b>	
J2506	Neulasta Injection, pegfilgrastim, excludes biosimilar, 0.5 mg
Q5108	Fulphila Injection, pegfilgrastim-jmdb, biosimilar, (Fulphila), 0.5 mg
Q5111	Udenyca Injection, pegfilgrastim-cbqv, biosimilar, (Udenyca), 0.5 mg
Q5120	Ziextenzo Injection, pegfilgrastim-bmez, biosimilar, (Ziextenzo), 0.5 mg
Q5122	Nyvepria Injection, pegfilgrastim-apgf, biosimilar, (Nyvepria), 0.5 mg
<b>Hematologic, Neutropenia Colony Stimulating Factors, Short-Acting</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
Q5110	Nivestym Injection, filgrastim-aafi, biosimilar, (Nivestym), 1 mcg
<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>Osteoarthritis, Viscosupplements Single Injection</b>	
J7318	Durolane Hyaluronan or derivative, Durolane, for intra-articular injection, 1 mg
J7325	Synvisc-One Hyaluronan or derivative, Synvisc or Synvisc-One, for intra-articular injection, 1 mg
J7326	Gel-One Hyaluronan or derivative, Gel-One, for intra-articular injection, per dose
J7327	Monovisc Hyaluronan or derivative, Monovisc, for intra-articular injection, per dose
<b>Osteoarthritis, Viscosupplements Multi Injection</b>	
J7320	GenVisc 850 Hyaluronan or derivative, GenVisc 850, for intra-articular injection, 1 mg
J7321	Hyalgan Hyaluronan or derivative, Hyalgan, Supartz or Visco-3, for intra-articular injection, per dose
J7321	Visco-3 Hyaluronan or derivative, Hyalgan, Supartz or Visco-3, for intra-articular injection, per dose
J7322	Hymovis Hyaluronan or derivative, Hymovis, for intra-articular injection, 1 mg
J7323	Euflexxa Hyaluronan or derivative, Euflexxa, for intra-articular injection, per dose
J7324	Orthovisc Hyaluronan or derivative, Orthovisc, for intra-articular injection, per dose
J7325	Synvisc Hyaluronan or derivative, Synvisc or Synvisc-One, for intra-articular injection, 1 mg

J7328	Gelsyn-3 Hyaluronan or derivative, Gelsyn-3, for intra-articular injection, 0.1 mg
J7329	Trivisc Hyaluronan or derivative, Trivisc, for intra-articular injection, 1 mg
<b>Prostate Cancer – Luteinizing Hormone Releasing Hormone (LHRH) Agents</b>	
J3315	Trelstar Injection, triptorelin pamoate, 3.75 mg
J9202	Zoladex Goserelin acetate implant, per 3.6 mg
J9217	Eligard Leuprolide acetate (for depot suspension), 7.5 mg
J9217	Leuprolide acetate (for depot suspension), 7.5 mg
<b>Prostate Cancer – Luteinizing Hormone Releasing Hormone (LHRH) Antagonists Agents</b>	
J9155	Firmagon Injection, degarelix, 1 mg
<b>Retinal Disorders Agents</b>	
C9257	Avastin Injection, bevacizumab, 0.25 mg
J0178	Eylea Injection, afibbercept, 1 mg
J0179	Beovu Injection, brolucizumab-dbll, 1 mg
J2778	Lucentis Injection, ranibizumab, 0.1 mg
J9035	Avastin Injection, bevacizumab, 10 mg
Q5124	Byooviz Injection, ranibizumab-nuna, biosimilar, (Byooviz), 0.1 mg
<b>Rituximab Products</b>	
J9311	Rituxan Hycela (rituximab/hyaluronidase human)

	Injection, rituximab 10 mg and hyaluronidase
J9312	Rituxan (rituximab) Injection, rituximab, 10 mg
Q5123	Riabni (rituximab-arrx) Injection, rituximab-arrx, biosimilar, (Riabni), 10 mg
Q5115	Truxima (rituximab-abbs) Injection, rituximab-abbs, biosimilar, (Truxima), 10 mg
Q5119	Ruxience (rituximab-pvvr) Injection, rituximab-pvvr, biosimilar, (Ruxience), 10 mg
<b>Severe Asthma</b>	
J0517	Fasenra Injection, benralizumab, 1 mg
J2182	Nucala Injection, mepolizumab, 1 mg
J2357	Xolair Injection, omalizumab, 5 mg
J2786	Cinqair Injection, reslizumab, 1 mg
<b>Trastuzumab</b>	
J9355	Herceptin Injection, trastuzumab, excludes biosimilar, 10 mg
J9356	Herceptin Hylecta Injection, trastuzumab, 10 mg and hyaluronidase-oysk
Q5112	Ontruzant Injection, trastuzumab-dttb, biosimilar, (Ontruzant), 10 mg
Q5113	Herzuma Injection, trastuzumab-pkrb, biosimilar, (Herzuma), 10 mg
Q5114	Ogivri Injection, trastuzumab-dkst, biosimilar, (Ogivri), 10 mg
Q5116	Trazimera Injection, trastuzumab-qyyp, biosimilar, (Trazimera), 10 mg
Q5117	Kanjinti Injection, trastuzumab-anns, biosimilar, (Kanjinti), 10 mg

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