

Oscar Clinical Guideline: (Commercial) Preferred Physician-Administered Specialty Drugs (CG052, Ver. 28)

(Commercial) 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

The Plan's Preferred Medication List encourages the utilization of clinically appropriate and cost-effective physician-administered specialty drugs. The [Medical Preferred Drug List](#) Table below lists both the preferred and non-preferred medications within a therapeutic class or drug 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 may be subject to the Plan's **Medical Benefit Preferred Physician-Administered Drug 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 ALL preferred drug(s), as applicable; **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.

Authorization Requirements and Submission Process

Indication Type	Review Entity	Submission Methods	Contact Information
Oncology	EviCore	Provider Portal	www.evicore.com
		Phone	855-252-1118
		Fax	800-540-2406
Non-Oncology	The Plan (Oscar)	Online Portal	Use the authorization tool at provider.hioscar.com
		Phone	855-672-2755
		Fax	Submit form from www.hioscar.com/forms
Need to check requirements or status? Visit provider.hioscar.com or call 1-855-672-2755			

Definitions

"**505(b)(2) Products**" refers to drug products approved through the FDA's 505(b)(2) pathway, which allows approval of drugs that rely partly on FDA's prior findings of safety and effectiveness for a previously approved drug (the reference listed drug) or on published literature. These products may contain the same active ingredient as the reference drug but with certain modifications (e.g., new formulation, dosage form, strength, route of administration, or indication) or may involve new active ingredients supported by existing data and additional studies.

"**Biosimilar**" refers to a biological product that is highly similar to and has no clinically meaningful differences from an existing FDA-approved reference product in terms of safety, purity, and potency.

"**Compendia**" are summaries of drug information and medical evidence to support decision-making about the appropriate use of drugs and medical procedures. Examples include, but are not limited to:

1. American Hospital Formulary Service Drug Information

2. Elsevier Clinical Pharmacology
3. National Comprehensive Cancer Network Drugs and Biologics Compendium
4. Thomson Micromedex DrugDex
5. United States Pharmacopeia-National Formulary (USP-NF)

"**Contraindication**" refers to a pre-existing condition or factor that precludes use of a drug due to risk of harm.

"**Intolerance**" refers to the inability to tolerate or endure something, often due to experiencing subjectively difficult or harmful side effects, reactions, or hypersensitivities when using a medication or treatment that negatively impacts quality of life, ability to adhere, or overall health. Documentation is expected to detail the specific intolerable effects and their impact on treatment.

"**Documentation**" refers to written information, including but not limited to:

1. Up-to-date chart notes, relevant test results, and/or relevant imaging reports to support diagnoses;
2. Prescription claims records, and/or prescription receipts to support prior trials of alternatives.

"**Experimental or Investigational**" are procedures, drugs, or devices that haven't been proven effective or which have not been approved by the appropriate regulatory bodies.

"**FDA**" refers to the Federal Food and Drug Administration.

"**Medical Benefit Preferred Drug Exceptions Criteria**" are Plan requirements that must be met for a non-preferred drug to be approved for coverage, such as trial and failure of preferred drugs first.

"**Non-Preferred Product**" refers to medications that may require meeting exception criteria before approval and typically require trial of preferred product(s) first when clinically appropriate.

"**Physician-Administered Drug**" refers to medications that are administered by a healthcare provider rather than self-administered by the patient, typically in an outpatient setting.

"**Preferred Product**" refers to medications selected by the Plan based on clinical effectiveness, safety, FDA approval, and treatment guidelines that should be used first when clinically appropriate.

"**Reference Listed Drug (RLD)**" refers to the previously approved product that a 505(b)(2) application references for FDA's finding of safety and effectiveness. The RLD is typically the original brand name product.

Medical Preferred Drug List

Drug Class	Preferred Medications*	Non-Preferred Medications ^{2/3*}
ACTH and Analogs	❖ Acthar Gel (corticotropin)	
Agents for Amyloidosis-Associated Polyneuropathy	❖ Amvuttra (vutrisiran) ❖ Onpattro (patisiran)	❖ Tegsedi (inotersen)
	Exception Criteria: Agents for Amyloidosis-Associated Polyneuropathy - Medical Benefit Preferred Physician-Administered Drug Exceptions Criteria (CG109)	
Agents for Opioid-Related Disorders	❖ Brixadi (buprenorphine) ❖ Sublocade (buprenorphine extended release)	
Alpha-1 Antitrypsin Deficiency	❖ Prolastin-C (alpha1-proteinase inhibitor [human])	❖ Aralast (alpha1-proteinase inhibitor [human]) ❖ Glassia (alpha1-proteinase inhibitor [human]) ❖ Zemaira (alpha1-proteinase inhibitor [human])
	Exception Criteria: Plan's Preferred Physician-Administered Drug(s) Exceptions Criteria	
Antiemetics - Substance P/Neurokinin 1 (NK1) Antagonist (i.e., Fosaprepitant Products)	❖ Emend (fosaprepitant) [J1453]	❖ Focinvez (fosaprepitant; Amneal) [J1434] ❖ Fosaprepitant (Teva/Actavis) [J1456]
	Exception Criteria: Antiemetics - Substance P/Neurokinin 1 (NK1) Antagonist (i.e., Fosaprepitant Products) - Medical Benefit Preferred Physician-Administered Drug Exceptions Criteria (CG103)	
Antineoplastics - Bendamustine Products	❖ Treanda (bendamustine) [J9033]	❖ Bendamustine HCl (Apotex) [J9058] ❖ Bendamustine HCl (Baxter) [J9059] ❖ Bendamustine HCl (Belrapzo) [J9036] ❖ Bendamustine HCl (Bendeka) [J9034] ❖ Bendamustine HCl (Vivimusta) [J9056]

	Exception Criteria: Antineoplastics - Bendamustine Products - Medical Benefit Preferred Physician-Administered Drug Exceptions Criteria (CG102)	
Antineoplastics - Bevacizumab for Cancer Indications	❖ Zirabev (Bevacizumab-bvzr)	<ul style="list-style-type: none"> ❖ Avastin (Bevacizumab) ❖ Alymsys (Bevacizumab-maly) ❖ Avzivi (bevacizumab-tnjn) ❖ Mvasi (Bevacizumab-awwb) ❖ Vegzelma (bevacizumab-adcd)
	Exception Criteria: Antineoplastics - Bevacizumab for Cancer Indications - Medical Benefit Preferred Physician-Administered Drug Exceptions Criteria (CG083)	
Antineoplastics - Cytostatic Gonadotropin-Releasing Hormone Antagonists	❖ Firmagon (degarelix)	
Antineoplastics - Gemcitabine Products	❖ Gemcitabine HCl (Accord) [J9196]	<ul style="list-style-type: none"> ❖ Gemzar (gemcitabine) [J9201] ❖ Infugem (gemcitabine in sodium chloride) [J9198]
	Exception Criteria: Antineoplastics - Gemcitabine Products - Medical Benefit Preferred Physician-Administered Drug Exceptions Criteria (CG104)	
Antineoplastics - Gonadotropin-Releasing Hormone Agonists for Prostate Cancer	❖ Eligard (leuprolide acetate)	<ul style="list-style-type: none"> ❖ Camcevi (leuprolide) ❖ Lupron Depot (leuprolide acetate) ❖ Trelstar (triptorelin pamoate) ❖ Zoladex (goserelin acetate)
	Exception Criteria: Gonadotropin-Releasing Hormone Agonists for Prostate Cancer - Medical Benefit Preferred Physician-Administered Drug Exceptions Criteria (CG085)	
Antineoplastics - HER2-Targeted Agents	<ul style="list-style-type: none"> ❖ Enhertu (fam-trastuzumab deruxtecan-nxki) ❖ Kadcyła (ado-trastuzumab emt) ❖ Perjeta (pertuzumab) ❖ Phesgo (pertuzumab / trastuzumab / hyaluronidase-zzxf) 	❖ Margenza (margetuximab-cmkb)

	Exception Criteria: Antineoplastics - HER2-Targeted Agents - Medical Benefit Preferred Physician-Administered Drug Exceptions Criteria (CG101)	
Antineoplastics - Pemetrexed Products	<ul style="list-style-type: none"> ❖ pemetrexed (Accord) [J9296] ❖ pemetrexed (Hospira) [J9294] ❖ pemetrexed (Sandoz) [J9297] 	<ul style="list-style-type: none"> ❖ Alimta (pemetrexed) [J9305] ❖ pemetrexed (Bluepoint) [J9322] ❖ Pemfexy (pemetrexed) [J9304] ❖ Pemrydi RTU (pemetrexed) [J9324] ❖ Pemetrexed ditromethamine (Hospira) [J9323] ❖ pemetrexed (Teva) [J9314]
	Exception Criteria: Antineoplastics - Pemetrexed Products - Medical Benefit Preferred Physician-Administered Drug Exceptions Criteria (CG105)	
Antineoplastics - Proteasome Inhibitors	<ul style="list-style-type: none"> ❖ Velcade (bortezomib) [J9041] ❖ Bortezomib (Maia/Fosun) [J9051] 	<ul style="list-style-type: none"> ❖ Bortezomib (Dr. Reddy's) [J9046] ❖ Bortezomib (Fresenius Kabi) [J9048] ❖ Bortezomib (Hospira) [J9049] ❖ Boruzu (bortezomib; Amneal/Shilpa) [C9399, J9999] ❖ Kyprolis (carfilzomib) [J9047]
	Exception Criteria: Antineoplastics - Proteasome Inhibitors (i.e., bortezomib, carfilzomib) - Medical Benefit Preferred Physician-Administered Drug Exceptions Criteria (CG106)	
Antineoplastics - Trastuzumab Products	<ul style="list-style-type: none"> ❖ Kanjinti (trastuzumab-anns) ❖ Trazimera (trastuzumab-qyyp) 	<ul style="list-style-type: none"> ❖ Herceptin (trastuzumab) ❖ Herceptin Hylecta (trastuzumab and hyaluronidase-oysk) ❖ Herzuma (trastuzumab-pkrb) ❖ Ontruzant (trastuzumab-dttb) ❖ Ogivri (trastuzumab-dkst)
	Exception Criteria: Antineoplastics - Trastuzumab Products - Medical Benefit Preferred Physician-Administered Drug Exceptions Criteria (CG082)	
Antineoplastic and Immunomodulating	<ul style="list-style-type: none"> ❖ Cimzia (certolizumab pegol) ❖ Cosentyx (secukinumab) IV 	<ul style="list-style-type: none"> ❖ Ilumya (tildrakizumab-asmn) ❖ Omvoh (mirikizumab-mrkz) IV

Agents - Biologics for Autoimmune and Inflammatory Conditions	<ul style="list-style-type: none"> ❖ Entyvio (vedolizumab) IV ❖ Simponi Aria (golimumab) ❖ Skyrizi (risankizumab-rzaa) IV ❖ Stelara (ustekinumab) IV ❖ Tremfya (guselkumab) IV 	<ul style="list-style-type: none"> ❖ Orencia (abatacept)
	<p>Exception Criteria: Antineoplastic and Immunomodulating Agents - (Select) Agents that Suppress the Immune System - Medical Benefit Preferred Physician-Administered Drug Exceptions Criteria (CG086)</p>	
Antineoplastic and Immunomodulating Agents - Infliximab Products	<ul style="list-style-type: none"> ❖ Avsola (infliximab-axxq) ❖ Inflectra (infliximab-dyyb) 	<ul style="list-style-type: none"> ❖ Infliximab ❖ Remicade (infliximab) ❖ Renflexis (infliximab-abda)
	<p>❖ Exception Criteria: Infliximab Products - Medical Benefit Preferred Physician-Administered Drug Exceptions Criteria (CG087)</p>	
Antineoplastic and Immunomodulating Agents - Rituximab Products	<ul style="list-style-type: none"> ❖ Ruxience (rituximab-pvvr) ❖ Truxima (rituximab-abbs) 	<ul style="list-style-type: none"> ❖ Riabni (rituximab-arrx) ❖ Rituxan (rituximab) ❖ Rituxan Hycela (rituximab/hyaluronidase human)
	<p>Exception Criteria: Antineoplastic and Immunomodulating Agents - Rituximab Products - Medical Benefit Preferred Physician-Administered Drug Exceptions Criteria (CG081)</p>	
Antineoplastic and Immunomodulating Agents - Tocilizumab Products	<ul style="list-style-type: none"> ❖ Tyenne (tocilizumab-aazg) IV 	<ul style="list-style-type: none"> ❖ Actemra (tocilizumab) IV ❖ Tofidence (tocilizumab-bavi)
	<p>Exception Criteria: Antineoplastic and Immunomodulating Agents - Tocilizumab Products - Medical Benefit Preferred Physician-Administered Drug Exceptions Criteria (CG108)</p>	
Biologics for Chronic Respiratory and Allergic Conditions	<ul style="list-style-type: none"> ❖ Dupixent (dupilumab) ❖ Fasenna (benralizumab) ❖ Nucala (mepolizumab) ❖ Tezspire (tezepelumab-ekko) ❖ Xolair (omalizumab) 	<ul style="list-style-type: none"> ❖ Cinqair (reslizumab)
	<p>Exception Criteria: Biologics for Chronic Respiratory and Allergic Conditions - Medical Benefit Preferred Physician-Administered Drug Exceptions Criteria (CG100)</p>	
Botulinum Toxins	<ul style="list-style-type: none"> ❖ Botox (onabotulinumtoxinA) ❖ Dysport 	<ul style="list-style-type: none"> ❖ Daxxify (daxibotulinumtoxinA-lanm)

	<ul style="list-style-type: none"> (abobotulinumtoxinA) ❖ Xeomin (incobotulinumtoxinA) 	<ul style="list-style-type: none"> ❖ Myobloc (rimabotulinumtoxinB)
	<p>Exception Criteria: Botulinum Toxins - Medical Benefit Preferred Physician-Administered Drug Exceptions Criteria (CG088)</p>	
Complement Inhibitors	<ul style="list-style-type: none"> ❖ Soliris (eculizumab) ❖ Ultomiris (ravulizumab-cwvz) 	<ul style="list-style-type: none"> ❖ Empaveli (pegcetacoplan) ❖ PiaSky (crovalimab-akkz)
	<p>Exception Criteria: Complement Inhibitors - Medical Benefit Preferred Physician-Administered Drug Exceptions Criteria (CG098)</p>	
Fertility Regulators - FSH	<ul style="list-style-type: none"> ❖ Gonal-F (follitropin alfa) 	<ul style="list-style-type: none"> ❖ Follistim AQ (follitropin beta)
	<p>Exception Criteria: Follicle Stimulating Hormone (FSH) Products - Medical Benefit Preferred Physician-Administered Drug Exceptions Criteria (CG092)</p>	
Gene Therapy for Hemophilia A	<ul style="list-style-type: none"> ❖ Roctavian (valoctocogene roxaparvovec-rvox) 	
Gonadotropin-Releasing Hormone Agonists	<ul style="list-style-type: none"> ❖ Fensolvi (leuprolide acetate) ❖ Lupron Depot-Ped (leuprolide acetate for depot suspension) ❖ Supprelin LA (histrelin acetate) ❖ Triptodur (triptorelin) 	
Hematologic. Erythropoiesis-Stimulating Agents (ESA)	<ul style="list-style-type: none"> ❖ Aranesp (darbepoetin alfa) ❖ Procrit (epoetin alfa) ❖ Retacrit (epoetin alfa-epbx) 	<ul style="list-style-type: none"> ❖ Epogen (epoetin alfa) ❖ Mircera (methoxy polyethylene glycol-epoetin beta)
	<p>Exception Criteria: Erythropoiesis-Stimulating Agent (ESA) - Medical Benefit Preferred Physician-Administered Drug Exceptions Criteria (CG084)</p>	
Hematologic. Neutropenia Colony Stimulating Factors. Long-Acting	<ul style="list-style-type: none"> ❖ Fulphila (pegfilgrastim-jmdb) ❖ Udenyca (pegfilgrastim-cbqv) 	<ul style="list-style-type: none"> ❖ Fynetra (pegfilgrastim-pbbk) ❖ Neulasta (pegfilgrastim) ❖ Neulasta Onpro (pegfilgrastim) ❖ Nyvepria (pegfilgrastim-ppgf)

	<ul style="list-style-type: none"> ❖ Udenyca Onbody (pegfilgrastim-cbqv) 	<ul style="list-style-type: none"> ❖ Rolvedon (eflapegrastim-xnst) ❖ Ryzneuta (efbemalenograstim alfa) ❖ Stimufend (pegfilgrastim-fpgk) ❖ Ziextenzo (pegfilgrastim-bmez)
	<p>Exception Criteria: Long-Acting Granulocyte Colony-Stimulating Factors - Medical Benefit Preferred Physician-Administered Drug Exceptions Criteria (CG079)</p>	
<p>Hematologic, Neutropenia Colony Stimulating Factors, Short-Acting</p>	<ul style="list-style-type: none"> ❖ Nivestym (filgrastim-aafi) 	<ul style="list-style-type: none"> ❖ Granix (tbo-filgrastim) Injection ❖ Leukine (sargramostim) ❖ Neupogen (filgrastim) ❖ Releuko (filgrastim-ayow) ❖ Zarxio (filgrastim-sndz)
	<p>Exception Criteria: Short-Acting Granulocyte Colony-Stimulating Factors - Medical Benefit Preferred Physician-Administered Drug Exceptions Criteria (CG080)</p>	
<p>Hematological Agents, Other - Aminolevulinate Synthase 1-Directed Small Interfering Ribonucleic Acid (siRNA)</p>	<ul style="list-style-type: none"> ❖ Givlaari (givosiran) 	
<p>Hemophilia - Factor IX</p>	<ul style="list-style-type: none"> ❖ Alprolix (Coagulation Factor IX (Recombinant), Fc Fusion Protein) ❖ BeneFIX [coagulation factor IX (recombinant)] ❖ Idelvion [Coagulation Factor IX (Recombinant), Albumin Fusion Protein (rIX-FP)] ❖ Rebinyn (Coagulation Factor IX (Recombinant), GlycoPEGylated) 	<ul style="list-style-type: none"> ❖ Ixinity [coagulation factor IX (recombinant)] ❖ Rixubis [Coagulation Factor IX (Recombinant)]
	<p>Exception Criteria: Factor IX Antihemophilic Agents - Medical Benefit Preferred Physician-Administered Drug Exceptions Criteria (CG089)</p>	
<p>Hemophilia - Factor VIII, Long-Acting</p>	<ul style="list-style-type: none"> ❖ Adynovate (antihemophilic factor (recombinant), PEGylated) 	<ul style="list-style-type: none"> ❖ Esperoct [antihemophilic factor (recombinant)]

	<ul style="list-style-type: none"> ❖ Altuviiiio (antihemophilic factor (recombinant), Fc-VWF-XTEN fusion protein-ehtl) ❖ Eloctate (antihemophilic factor (recombinant), Fc fusion protein) ❖ Jivi (antihemophilic factor (recombinant)) 	
	<p>Exception Criteria: Factor VIII (Long-Acting) Antihemophilic Agents - Medical Benefit Preferred Physician-Administered Drug Exceptions Criteria (CG090)</p>	
Hemophilia - Factor VIII	<ul style="list-style-type: none"> ❖ Advate [antihemophilic factor (recombinant)] ❖ Afstyla [Antihemophilic Factor (Recombinant), Single Chain] ❖ Kogenate FS (antihemophilic factor (recombinant)) ❖ Kovaltry (antihemophilic Factor (Recombinant)) ❖ Novoeight (antihemophilic factor (recombinant), glycopegylated-exei) ❖ Nuwiq (Antihemophilic Factor (Recombinant)) ❖ Xyntha (antihemophilic factor [recombinant]) 	<ul style="list-style-type: none"> ❖ Recombinate [Antihemophilic Factor (Recombinant)]
	<p>Exception Criteria: Factor VIII Antihemophilic Agents - Medical Benefit Preferred Physician-Administered Drug Exceptions Criteria (CG91)</p>	
Hereditary Angioedema	<ul style="list-style-type: none"> ❖ Ruconest (C1 esterase inhibitor [recombinant]) 	<ul style="list-style-type: none"> ❖ Berinert (C1 Esterase Inhibitor, Human)
	<p>Exception Criteria: Plan's Preferred Physician-Administered Drug(s) Exceptions Criteria</p>	
Immune globulin	<ul style="list-style-type: none"> ❖ Flebogamma DIF (immune globulin intravenous [human]) ❖ Gammagard Liquid (immune globulin 	<ul style="list-style-type: none"> ❖ Alyglo (immune globulin intravenous [human]) ❖ Asceniv (immune globulin intravenous [human]) ❖ Bivigam (immune globulin

	<p>intravenous and subcutaneous [human])</p> <ul style="list-style-type: none"> ❖ Gammaked (immune globulin intravenous and subcutaneous [human]) ❖ Gamunex-C (immune globulin [human]) ❖ Octagam (immune globulin intravenous [human]) 	<p>intravenous [human])</p> <ul style="list-style-type: none"> ❖ Cutaquig (immune globulin subcutaneous human) ❖ Cuvitru (immune globulin subcutaneous [human]) ❖ Gammagard S/D (immune globulin intravenous [human]) ❖ Gammaplex (immune globulin intravenous [human]) ❖ Hizentra (immune globulin) ❖ Hyqvia (immune globulin infusion 10% [human] with recombinant human hyaluronidase) ❖ Panzyga (immune globulin intravenous [human] - ifas) ❖ Privigen (immune globulin intravenous [human]) ❖ Xembify (immune globulin subcutaneous [human-klhw]) ❖ Yimmugo (immune globulin intravenous, human – dira)
<p>Exception Criteria: Plan’s Preferred Physician-Administered Drug(s) Exceptions Criteria</p>		
<p>Injectable Iron Supplements</p>	<ul style="list-style-type: none"> ❖ INFeD (iron dextran complex) ❖ Ferrlecit (sodium ferric gluconate complex in sucrose) ❌ Venofer (iron sucrose) 	<ul style="list-style-type: none"> ❖ Feraheme (ferumoxytol) ❖ Injectafer (ferric carboxymaltose) ❖ Monoferric (ferric derisomaltose)
<p>Exception Criteria: Injectable Iron Supplements - Medical Benefit Preferred Physician-Administered Drug Exceptions Criteria (CG107)</p>		
<p>Long-Acting Reversible Contraceptives</p>	<ul style="list-style-type: none"> ❖ Kyleena (levonorgestrel) ❖ Mirena (levonorgestrel) ❖ Skyla (levonorgestrel) 	<ul style="list-style-type: none"> ❖ Liletta (levonorgestrel) ❖ Nexplanon (etonogestrel)
<p>Exception Criteria: Long-Acting Reversible Contraceptives - Medical Benefit Preferred Physician-Administered Drug Exceptions Criteria (CG095)</p>		

Lysosomal Storage Disorder Agents - Fabry Disease Agents	<ul style="list-style-type: none"> ❖ Elfabrio (pegunigalsidase alfa) ❖ Fabrazyme (agalsidase beta) 	
Lysosomal Storage Disorders - Gaucher Disease	<ul style="list-style-type: none"> ❖ Cerezyme (Imiglucerase) ❖ VPRIV (velaglucerase alfa for injection) 	<ul style="list-style-type: none"> ❖ Eleyso (taliglucerase alfa)
	<p>Exception Criteria: Gaucher's Disease Agents - Medical Benefit Preferred Physician-Administered Drug Exceptions Criteria (CG093)</p>	
Multiple Sclerosis (Infused)	<ul style="list-style-type: none"> ❖ Briumvi (ublituximab) ❖ Ocrevus (ocrelizumab) ❖ Ocrevus Zunovo (ocrelizumab and hyaluronidase-ocsq) ❖ Tysabri (natalizumab) 	<ul style="list-style-type: none"> ❖ Lemtrada (alemtuzumab)
	<p>Exception Criteria: Multiple Sclerosis Agents - Medical Benefit Preferred Physician-Administered Drug Exceptions Criteria (CG096)</p>	
Neonatal Fc Receptor Antagonist	<ul style="list-style-type: none"> ❖ Rystiggo (rozanolixizumab-noli) ❖ Vyvgart (efgartigimod alfa) ❖ Vyvgart Hytrulo (efgartigimod alfa and hyaluronidase (human recombinant)) 	
Osteoarthritis, Viscosupplements (Single Injection)	<ul style="list-style-type: none"> ❖ Monovisc (high molecular weight hyaluronan) 	<ul style="list-style-type: none"> ❖ Durolane (hyaluronic acid) ❖ Gel-One (cross-linked hyaluronate) ❖ Synvisc-One (hylan G-F 20)
	<p>Exception Criteria: Hyaluronate and Derivatives - Medical Benefit Preferred Physician-Administered Drug Exceptions Criteria (CG094)</p>	
Osteoarthritis, Viscosupplements (Multi Injection)	<ul style="list-style-type: none"> ❖ Euflexxa (1% sodium hyaluronate) ❖ Orthovisc (high molecular weight hyaluronan) 	<ul style="list-style-type: none"> ❖ Gelsyn-3 (sodium hyaluronate 0.84%) ❖ GenVisc 850 (sodium hyaluronate) ❖ Hyalgan (sodium hyaluronate) ❖ Hymovis (high molecular weight viscoelastic hyaluronan) ❖ Supartz FX (sodium hyaluronate)

		<ul style="list-style-type: none"> ❖ Synjoynt (sodium hyaluronate) ❖ Synvisc (hylan G-F 20) ❖ Triluron (sodium hyaluronate) ❖ Trivisc (sodium hyaluronate) ❖ Visco-3 (sodium hyaluronate)
	<p>Exception Criteria: Hyaluronate and Derivatives - Medical Benefit Preferred Physician-Administered Drug Exceptions Criteria (CG094)</p>	
Primary Hyperoxaluria Type 1 (PH1) Agents	<ul style="list-style-type: none"> ❖ Oxlumo (lumasiran) 	
Pulmonary Hypertension (PAH) Agents, Prostacyclin Analogs/Receptor Agonists for PAH	<ul style="list-style-type: none"> ❖ Treprostinil 	<ul style="list-style-type: none"> ❖ Remodulin (treprostinil)
	<p>Exception Criteria: Prostacyclin Analogs/Receptor Agonists for Pulmonary Hypertension (PAH) - Medical Benefit Preferred Physician-Administered Drug Exceptions Criteria (CG097)</p>	
Somatostatin Analogs	<ul style="list-style-type: none"> ❖ Lanreotide (Exelan) [J1930] 	<ul style="list-style-type: none"> ❖ lanreotide (Cipla) [J1932] ❖ Sandostatin (octreotide, non-depot) [J2354] ❖ Sandostatin LAR Depot (octreotide acetate) [J2353] ❖ Signifor LAR (pasireotide long acting) [J2502] ❖ Somatuline Depot (lanreotide) [J1930] ❖ Somavert (pegvisomant) [J3590]
	<p>Exception Criteria: Somatostatin Analogs - Medical Benefit Preferred Physician-Administered Drug Exceptions Criteria (CG078)</p>	
Spinal Muscular Atrophy	<ul style="list-style-type: none"> ❖ Zolgensma (onasemnogene abeparvovec-xioi) 	
Systemic Lupus Erythematosus (SLE) Agents	<ul style="list-style-type: none"> ❖ Benlysta IV (belimumab) 	<ul style="list-style-type: none"> ❖ Saphnelo (anifrolumab-fnia)
	<p>Exception Criteria: Plan's Preferred Physician-Administered Drug(s) Exceptions Criteria</p>	
Vascular Endothelial Growth Factor (VEGF) Inhibitor	<ul style="list-style-type: none"> ❖ Avastin (bevacizumab) 	<ul style="list-style-type: none"> ❖ Beovu (brolocizumab-dbll) ❖ Byooviz (ranibizumab-nuna) ❖ Cimerli (ranibizumab-eqrm)

<p>Ophthalmic Agents (i.e., Retinal Disorders Agents)</p>		<ul style="list-style-type: none"> ❖ Eylea (aflibercept) ❖ Eylea HD (aflibercept) ❖ Lucentis (ranibizumab) ❖ Opuviz (aflibercept-yszy) ❖ Pavblu (aflibercept-ayyh) ❖ Susvimo (ranibizumab) ❖ Vabysmo (faricimab-svoa) ❖ Yesafili (aflibercept-jbvf)
	<p>Exception Criteria: Vascular Endothelial Growth Factor (VEGF) Inhibitor Ophthalmic Agents - Medical Benefit Preferred Physician-Administered Drug Exceptions Criteria (CG099)</p>	

⁷subject to Plan's Preferred Physician-Administered Drug(s) Exceptions Criteria

*Other drug-specific or class-specific clinical guidelines may also be applicable.

- Coverage varies by plan type - products considered Preferred for the Plan may still require a clinical prior authorization review.
- The Plan may review all requests made under the Medical or Pharmacy benefit against specific prior authorization criteria, as applicable and at its discretion.

Exception Criteria

NOTE: This exception criteria applies when the Plan does not have a product or class specific Medical Benefit Preferred Physician-Administered Drug Exceptions Criteria for the requested product or drug class.

Coverage of a **Non-Preferred Product** will be provided when the member meets **BOTH** of the following criteria:

1. Inadequate response, intolerance, or contraindication to **ALL** preferred products in the same class, when these are FDA, compendia, or evidence-based guideline-supported options, unless:
 - a. There are no preferred products available in the same class; **or**
 - b. The member is currently receiving treatment with the requested product and coverage is required to complete the current course of treatment; **or**
 - c. The request is for cancer treatment in a state prohibiting prerequisite trials per regulations; **AND**
2. Clinical documentation is provided showing:
 - a. The specific reason(s) why preferred products cannot be used (e.g. inadequate response, adverse event, contraindication); **and/or**

- b. Relevant clinical information supporting the use of the requested Non-Preferred Product (e.g. office notes, lab results, diagnostic reports); **and/or**
- c. If applicable, confirmation that coverage is needed to complete a current course of treatment with the requested Non-Preferred Product.

Experimental or Investigational / Not Medically Necessary

The Plan does not cover non-preferred products when used for experimental, investigational, or medically unnecessary indications. Use of non-preferred products is considered experimental, investigational, or not medically necessary if the indication is outside FDA-approved labeling or not supported by current medical evidence and standards of care. The Plan does not cover non-preferred products for the following non-approved indications (not all-inclusive):

- 1. Uses not considered clinically appropriate based on indication, including age, dosing (dosage, frequency, duration of therapy, and site of administration), and contraindication.
 - a. Non-FDA approved indications or off label use without sufficient evidence supporting safety and efficacy
 - b. Doses exceeding the FDA-approved label or clinical practice guidelines without sufficient evidence supporting safety and efficacy
- 2. Uses not required for treatment or management of the member's medical condition.
- 3. Uses not aligned with generally accepted medical practice.
- 4. Uses primarily for the convenience of the member, family, or provider.

Applicable Billing Codes

ACTH and Analogs	
J0801	Acthar Gel Injection, corticotropin (acthar gel), up to 40 units
Agents for Amyloidosis-Associated Polyneuropathy	
C9399	Tegsedi(inotersen) Unclassified drugs or biologicals
J0225	Amvuttra Injection, vutrisiran, 1 mg
J0222	Onpattro Injection, patisiran, 0.1 mg

J3490	Tegsedi(inotersen) Unclassified drugs
Agents for Opioid-Related Disorders	
J0577	Brixadi Injection, buprenorphine extended-release (brixadi), less than or equal to 7 days of therapy
J0578	Brixadi Injection, buprenorphine extended release (brixadi), greater than 7 days and up to 28 days of therapy
Q9991	Sublocade Injection, buprenorphine extended-release (sublocade), less than or equal to 100 mg
Q9992	Sublocade Injection, buprenorphine extended-release (sublocade), greater than 100 mg
Alpha-1 Antitrypsin Deficiency	
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
Antiemetics - Substance P/Neurokinin 1 (NK1) Antagonist (i.e., Fosaprepitant Products)	
J1434	Focinvez Injection, fosaprepitant (focinvez), 1 mg
J1453	Emend Injection, fosaprepitant, 1 mg
J1456	Teva/Actavis 505(b)(2) Injection, fosaprepitant (teva), not therapeutically equivalent to J1453, 1 mg
Antineoplastics - Bendamustine Products	

J9033	Treanda Injection, bendamustine hcl (treanda), 1 mg
J9034	Bendeka Injection, bendamustine hcl (bendeka), 1 mg
J9036	Belrapzo Injection, bendamustine hydrochloride, (belrapzo/bendamustine), 1 mg
J9056	Vivimusta Injection, bendamustine hydrochloride (vivimusta), 1 mg
J9058	Apotex 505(b)(2) Injection, bendamustine hydrochloride (apotex), 1 mg
J9059	Baxter 505(b)(2) Injection, bendamustine hydrochloride (baxter), 1 mg
Antineoplastics - Bevacizumab for Cancer Indications	
J9035	Avastin Injection, bevacizumab, 10 mg
Q5107	Mvasi Injection, bevacizumab-awwb, biosimilar, (mvasi), 10 mg
Q5118	Zirabev Injection, bevacizumab-bvzr, biosimilar, (zirabev), 10 mg
Q5126	Alymsys Injection, bevacizumab-maly, biosimilar, (alymsys), 10 mg
Q5129	Vegzelma Injection, bevacizumab-adcd (vegzelma), biosimilar, 10 mg
C9399	Avzivi (bevacizumab-tjnj) Unclassified drugs or biologicals
J9999	Avzivi (bevacizumab-tjnj) Not otherwise classified, antineoplastic drugs
Antineoplastics - Cytostatic Gonadotropin-Releasing Hormone Antagonists	
J9155	Firmagon Injection, degarelix, 1 mg
Antineoplastics - Gonadotropin-Releasing Hormone Agonists for Prostate Cancer	

J9217	Eligard Leuprolide acetate (for depot suspension), 7.5 mg
J9217	Lupron Depot Leuprolide acetate (for depot suspension), 7.5 mg
J1950	Lupron Depot Injection, leuprolide acetate (for depot suspension), per 3.75 mg
J3315	Trelstar Injection, triptorelin pamoate, 3.75 mg
J9202	Zoladex Goserelin acetate implant, per 3.6 mg
Antineoplastics - Gemcitabine Products	
J9196	Accord 505(b)(2) Injection, gemcitabine hydrochloride (accord), not therapeutically equivalent to J9201, 200 mg
J9198	Infugem Injection, gemcitabine hydrochloride, (infugem), 100 mg
J9201	Gemzar Injection, gemcitabine hydrochloride, not otherwise specified, 200 mg
Antineoplastics - HER2-Targeted Agents	
J9306	Perjeta Injection, pertuzumab, 1 mg
J9316	Phesgo Injection, pertuzumab, trastuzumab, and hyaluronidase-zzxf, per 10 mg
J9353	Margenza Inj, margetuximab-cmkb, 5 mg
J9354	Kadcyla Inj, ado-trastuzumab emt 1mg
J9358	Enhertu Inj, fam-trastuzumab deruxtecan-nxki, 1 mg
Antineoplastics - Pemetrexed Products	
J9294	Hospira 505(b)(2) Injection, pemetrexed (hospira) not therapeutically equivalent to j9305, 10 mg

J9296	Accord 505(b)(2) Injection, pemetrexed (accord) not therapeutically equivalent to j9305, 10 mg
J9297	Sandoz 505(b)(2) Injection, pemetrexed (sandoz), not therapeutically equivalent to j9305, 10 mg
J9304	Pemfexy Injection, pemetrexed (pemfexy), 10 mg
J9305	Alimta Injection, pemetrexed, not otherwise specified, 10 mg
J9314	Teva 505(b)(2) Injection, pemetrexed (teva) not therapeutically equivalent to J9305, 10 mg
J9322	Bluepoint 505(b)(2) Injection, pemetrexed (bluepoint) not therapeutically equivalent to J9305, 10 mg
J9323	Hospira 505(b)(2) Injection, pemetrexed ditromethamine, 10 mg
J9324	Pemrydi RTU Injection, pemetrexed (pemrydi rtu), 10 mg
Antineoplastics - Proteasome Inhibitors (i.e., bortezomib, carfilzomib)	
J9041	Velcade Injection, bortezomib, 0.1 mg
J9046	Dr. Reddy's 505(b)(2) Injection, bortezomib, (dr. reddy's), not therapeutically equivalent to J9041, 0.1 mg
J9047	Kyprolis Injection, carfilzomib, 1 mg
J9048	Fresenius Kabi 505(b)(2) Injection, bortezomib (fresenius kabi), not therapeutically equivalent to J9041, 0.1 mg
J9049	Hospira 505(b)(2) Injection, bortezomib (hospira), not therapeutically equivalent to J9041, 0.1 mg
J9051	Maia/Fosun 505(b)(2) Injection, bortezomib (maia), not therapeutically equivalent to J9041, 0.1 mg
C9399	Boruzu (bortezomib; Amneal/Shilpa) Unclassified drugs or biologicals

J9999	Boruzu (bortezomib; Amneal/Shilpa) Not otherwise classified, antineoplastic drugs
Antineoplastics - Trastuzumab Products	
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
Antineoplastic and Immunomodulating Agents - Biologics for Autoimmune and Inflammatory Conditions	
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
J1628	Tremfya IV Injection, guselkumab, 1 mg
J2267	Omvoh IV Injection, mirikizumab-mrkz, 1 mg
J2327	Skyrizi (intravenous) Injection, risankizumab-rzaa, intravenous, 1 mg
J3245	Ilumya Injection, tildrakizumab, 1 mg
J3358	Stelara IV Ustekinumab, for intravenous injection, 1 mg

J3380	Entyvio IV Injection, vedolizumab, intravenous, 1 mg
J3247	Cosentyx IV Injection, secukinumab, intravenous, 1 mg
Antineoplastic and Immunomodulating Agents - Infliximab Products	
J1745	Remicade Injection, infliximab, excludes biosimilar, 10 mg
J1745	Injection, infliximab, 10 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
Antineoplastic and Immunomodulating Agents - Rituximab Products	
J9311	Rituxan Hycela (rituximab/hyaluronidase human) Injection, rituximab 10 mg and hyaluronidase
J9312	Rituxan (rituximab) Injection, rituximab, 10 mg
Q5115	Truxima (rituximab-abbs) Injection, rituximab-abbs, biosimilar, (Truxima), 10 mg
Q5119	Ruxience (rituximab-pvvr) Injection, rituximab-pvvr, biosimilar, (Ruxience), 10 mg
Q5123	Riabni (rituximab-arrx) Injection, rituximab-arrx, biosimilar, (Riabni), 10 mg
Antineoplastic and Immunomodulating Agents - Tocilizumab Products	
J3262	Actemra IV Injection, tocilizumab, 1 mg
	Tofidence

Q5133	Injection, tocilizumab-bavi (tofidence), biosimilar, 1 mg
Q5135	Tyenne IV Injection, tocilizumab-aazg (tyenne), biosimilar, 1 mg
Biologics for Chronic Respiratory and Allergic Conditions	
J0517	Fasenra Injection, benralizumab, 1 mg
J2182	Nucala Injection, mepolizumab, 1 mg
J2356	Tezspire Injection, tezepelumab-ekko, 1 mg
J2357	Xolair Injection, omalizumab, 5 mg
J2786	Cinqair Injection, reslizumab, 1 mg
C9399	Dupixent (dupilumab) Unclassified drugs or biologicals
J3590	Dupixent (dupilumab) Unclassified biologics
Botulinum Toxins	
J0585	Botox Injection, onabotulinumtoxinA, 1 unit
J0586	Dysport Injection, abobotulinumtoxinA, 5 units
J0587	Myobloc Injection, rimabotulinumtoxinB, 100 units
J0588	Xeomin Injection, incobotulinumtoxinA, 1 unit
J0589	Daxxify Injection, daxibotulinumtoxina-lanm, 1 unit
Complement Inhibitors	

C9151	Empaveli (pegcetacoplan) Injection, pegcetacoplan, 1 mg
J1300	Soliris Injection, eculizumab, 10 mg
J1303	Ultomiris Injection, ravulizumab-cwvz, 10 mg
J1307	PiaSky Injection, crovalimab-akkz, 10 mg
Fertility Regulators - FSH	
S0126	Gonal-F Injection, follitropin alfa, 75 IU
S0128	Follistim AQ Injection, follitropin beta, 75 IU
Gene Therapy for Hemophilia A	
J1412	Roctavian Injection, valoctocogene roxaparvovec-rvox, per mL, containing nominal 2×10^{13} vector genomes
Gonadotropin-Releasing Hormone Agonists	
J1950	Lupron Depot Injection, leuprolide acetate (for depot suspension), per 3.75 mg
J1951	Fensolvi Injection, leuprolide acetate for depot suspension (fensolvi), 0.25 mg
J1952	Camcevi Leuprolide injectable, camcevi, 1 mg
J3316	Triptodur Injection, triptorelin, extended-release, 3.75 mg
J9226	Supprelin LA Histrelin implant (supprelin la), 50 mg
Hematologic, Erythropoiesis-Stimulating Agents (ESA)	
J0881	Aranesp Injection, darbepoetin alfa, 1 mcg (for 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 microgram, (for ESRD on dialysis)
J0888	Mircera Injection, epoetin beta, 1 microgram, (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
Hematologic, Neutropenia Colony Stimulating Factors, Long-Acting	
J1449	Rolvedon Injection, eflapegrastim-xnst, 0.1 mg
J2506	Neulasta Injection, pegfilgrastim, excludes biosimilar, 0.5 mg
J9361	Ryzneuta Injection, efbemalenograstim alfa-vuxw, 0.5 mg
Q5108	Fulphila Injection, pegfilgrastim-jmdb, biosimilar, (Fulphila), 0.5 mg
Q5111	Udenyca Injection, pegfilgrastim-cbqv, biosimilar, (Udenyca), 0.5 mg
Q5111	Udenyca Onbody Injection, pegfilgrastim-cbqv (udenyca), biosimilar, 0.5 mg
Q5120	Ziextenzo Injection, pegfilgrastim-bmez, biosimilar, (Ziextenzo), 0.5 mg

Q5122	Nyvepria Injection, pegfilgrastim-apgf, biosimilar, (Nyvepria), 0.5 mg
Q5127	Stimufend Injection, pegfilgrastim-fpgk (Stimufend), biosimilar, 0.5 mg
Q5130	Fylnetra Injection, pegfilgrastim-pbbk (Fylnetra), biosimilar, 0.5 mg
Hematologic, Neutropenia Colony Stimulating Factors, Short-Acting	
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
Q5125	Releuko Injection, filgrastim-ayow, biosimilar, (Releuko), 1 mcg
Hematological Agents, Other - Aminolevulinic Synthase 1-Directed Small Interfering Ribonucleic Acid (siRNA)	
J0223	Givlaari Injection, givosiran, 0.5 mg
Hemophilia - Factor IX	
J7195	BeneFIX Injection, factor ix (antihemophilic factor, recombinant) per IU, not otherwise specified
J7195	Ixinity Injection, factor ix (antihemophilic factor, recombinant) per IU, not otherwise specified
J7200	Rixubis Injection, factor ix, (antihemophilic factor, recombinant), Rixubis, per IU

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
J7213	Ixinity Injection, coagulation factor IX (recombinant), Ixinity, 1 IU
Hemophilia - Factor VIII	
J7182	Novoeight Injection, Factor VIII, (antihemophilic factor, recombinant), (NovoEight), per IU
J7185	Xyntha Injection, factor viii (antihemophilic factor, recombinant) (Xyntha), per IU
J7192	Advate 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
J7192	Recombinate Factor viii (antihemophilic factor, recombinant) per IU, not otherwise specified
J7204	Esperoct Injection, Factor VIII, antihemophilic factor (recombinant), (Esperoct), glycopegylated-exei, per IU
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
J7210	Afstyla Injection, factor viii, (antihemophilic factor, recombinant), (Afstyla), 1 IU

J7211	Kovaltry Injection, Factor VIII, (antihemophilic factor, recombinant), (Kovaltry), 1 IU
J7214	Altuviiiio Injection, factor viii/von willebrand factor complex, recombinant (altuviiiio), per factor viii i.u.
Hereditary Angioedema	
J0596	Ruconest Injection, C1 esterase inhibitor (recombinant), Ruconest, 10 units
J0597	Berinert Injection, C-1 esterase inhibitor (human), Berinert, 10 units
Immune globulin	
J1459	Privigen Injection, immune globulin (privigen), intravenous, non-lyophilized (e.g., liquid), 500 mg
J1551	Cutaquig Injection, immune globulin (cutaquig), 100 mg
J1554	Asceniv Injection, immune globulin (asceniv), 500 mg
J1555	Cuvitru Injection, immune globulin (cuvitru), 100 mg
J1556	Bivigam Injection, immune globulin (bivigam), 500 mg
J1557	Gammplex Injection, immune globulin, (gammplex), intravenous, non-lyophilized (e.g., liquid), 500 mg
J1558	Xembify Injection, immune globulin (xembify), 100 mg
J1559	Hizentra Injection, immune globulin (hizentra), 100 mg
J1561	Gammaked Injection, immune globulin, (Gamunex/Gamunex-C/Gammaked), nonlyophilized (e.g., liquid), 500 mg
J1561	Gamunex-C Injection, immune globulin, (Gamunex/Gamunex-C/Gammaked), nonlyophilized

	(e.g., liquid), 500 mg
J1566	Gammagard S/D Injection, immune globulin, intravenous, lyophilized (e.g., powder), not otherwise specified, 500 mg
J1568	Octagam Injection, immune globulin, (octagam), intravenous, non-lyophilized (e.g., liquid), 500 mg
J1569	Gammagard Injection, immune globulin, (gammagard liquid), non-lyophilized, (e.g., liquid), 500 mg
J1572	Flebogamma; Flebogamma DIF Injection, immune globulin, (Flebogamma/Flebogamma Dif), intravenous, nonlyophilized (e.g., liquid), 500 mg
J1575	Hyqvia Injection, immune globulin/hyaluronidase, (hyqvia), 100 mg immune globulin
J1576	Panzyga Injection, immune globulin (panzyga), intravenous, non-lyophilized (e.g., liquid), 500 mg
J1599	Alyglo (immune globulin intravenous [human]) Injection, immune globulin, intravenous, nonlyophilized (e.g., liquid), not otherwise specified, 500 mg
J3590	Yimmugo (immune globulin intravenous, human – dira) Unclassified biologics
Injectable Iron Supplements	
J1437	Monoferic Injection, ferric derisomaltose, 10 mg
J1439	Injectafer Injection, ferric carboxymaltose, 1 mg
J1750	Infed Injection, iron dextran, 50 mg
J1756	Venofer Injection, iron sucrose, 1 mg
J2916	Ferlecit Injection, sodium ferric gluconate complex in sucrose injection, 12.5 mg

Q0138	Feraheme Injection, ferumoxytol, for treatment of iron deficiency anemia, 1 mg (non-esrd use)
Q0139	Feraheme Injection, ferumoxytol, for treatment of iron deficiency anemia, 1 mg (for esrd on dialysis)
Long- Acting Reversible Contraceptives	
J7296	Kyleena Levonorgestrel-releasing intrauterine contraceptive system, (Kyleena), 19.5 mg
J7297	Liletta Levonorgestrel-releasing intrauterine contraceptive system (Liletta), 52 mg
J7298	Mirena Levonorgestrel-releasing intrauterine contraceptive system (Mirena), 52 mg
J7301	Skyla Levonorgestrel-releasing intrauterine contraceptive system (Skyla), 13.5 mg
J7307	Nexplanon Etonogestrel (contraceptive) implant system, including implant and supplies
Lysosomal Storage Disorder Agents - Fabry Disease Agents	
J0180	Fabrazyme Injection, agalsidase beta, 1 mg
J2508	Elfabrio Injection, pegunigalsidase alfa-iwxj, 1 mg
Lysosomal Storage Disorders - Gaucher Disease	
J1786	Cerezyme Injection, imiglucerase, 10 units
J3060	Elelyso Injection, taliglucerase alfa, 10 units
J3385	VPRIV Injection, velaglucerase alfa, 100 units
Multiple Sclerosis (Infused)	
	Ocrevus Zunovo (ocrelizumab and hyaluronidase-ocsq)

C9399	Unclassified drugs or biologicals
J0202	Lemtrada Injection, alemtuzumab, 1 mg
J2323	Tysabri Injection, natalizumab, 1 mg
J2350	Ocrevus Injection, ocrelizumab, 1 mg
J2329	Briumvi Injection, ublituximab-xiyy, 1mg
J3590	Ocrevus Zunovo (ocrelizumab and hyaluronidase-ocsq) Unclassified biologics
Neonatal Fc Receptor Antagonist	
J9332	Vyvgart Injection, efgartigimod alfa-fcab, 2mg
J9334	Vyvgart Hytrulo Injection, efgartigimod alfa, 2 mg and hyaluronidase-qvfc
J9333	Rystiggo (rozanolixizumab-noli) Injection, rozanolixizumab-noli, 1 mg
Osteoarthritis, Viscosupplements Single Injection	
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
Osteoarthritis, Viscosupplements Multi Injection	
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	Supartz FX 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-One 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
J7331	Synojynt Hyaluronan or derivative, Synojynt, for intra-articular injection, 1 mg
J7332	Triluron Hyaluronan or derivative, triluron, for intra-articular injection, 1 mg
Primary Hyperoxaluria Type 1 (PH1) Agents	
J0224	Oxlumo Injection, lumasiran, 0.5 mg
Pulmonary Hypertension (PAH) Agents, Prostacyclin Analogs/Receptor Agonists for PAH	
J3285	Injection, treprostinil, 1 mg
J3285	Remodulin Injection, treprostinil, 1 mg

Somatostatin Analogs	
J1930	Somatuline Depot Injection, lanreotide, 1 mg
J1932	Cipla 505(b)(2) Injection, lanreotide, (Cipla), 1 mg
J2353	SandoSTATIN LAR Depot Injection, octreotide, depot form for intramuscular injection, 1 mg
J2354	SandoSTATIN Injection, octreotide, non-depot form for subcutaneous or intravenous injection, 25 mcg
J2502	Signifor LAR Injection, pasireotide long acting, 1 mg
C9399	Exelan 505(b)(2) Lanreotide Unclassified drugs or biologicals
J3490	Exelan 505(b)(2) Lanreotide Unclassified drugs
J3590	Somavert Unclassified biologics
Spinal Muscular Atrophy	
J3399	Zolgensma Injection, onasemnogene abeparvovec-xioi, per treatment, up to 5×10^{15} vector genomes
Systemic Lupus Erythematosus (SLE) Agents	
J0490	Benlysta IV (belimumab) Injection, belimumab, 10 mg
J0491	Saphnelo (anifrolumab-fnia) Injection, anifrolumab-fnia, 1 mg
Vascular Endothelial Growth Factor (VEGF) Inhibitor Ophthalmic Agents (i.e., Retinal Disorders Agents)	
C9257	Avastin Injection, bevacizumab, 0.25 mg

C9399	Pavblu (aflibercept-ayyh) Unclassified drugs or biologicals
J0177	Eylea HD Injection, aflibercept hd, 1 mg
J0178	Eylea Injection, aflibercept, 1 mg
J0179	Beovu Injection, brolocizumab-dbl, 1 mg
J2777	Vabysmo Injection, faricimab-svoa, 0.1 mg
J2778	Lucentis Injection, ranibizumab, 0.1 mg
J2779	Susvimo Injection, ranibizumab, via intravitreal implant (susvimo), 0.1 mg
J3590	Pavblu (aflibercept-ayyh) Unclassified biologics
J9035	Avastin Injection, bevacizumab, 10 mg
Q5124	Byooviz Injection, ranibizumab-nuna, biosimilar, (Byooviz), 0.1 mg
Q5128	Cimerli Injection, ranibizumab-eqrn (cimerli), biosimilar, 0.1 mg

References

1. Anderson LJ, Henley W, Wyatt KM, et al. Long-term effectiveness of enzyme replacement therapy in adults with Gaucher disease: results from the NCS-LSD cohort study. *J Inherit Metab Dis* 2014; 37:953.
2. Anderson LJ, Henley W, Wyatt KM, et al. Long-term effectiveness of enzyme replacement therapy in children with Gaucher disease: results from the NCS-LSD cohort study. *J Inherit Metab Dis* 2014; 37:961.
3. Baroncini D, Ghezzi A, Annovazzi PO, et al. Natalizumab versus fingolimod in patients with relapsing-remitting multiple sclerosis non-responding to first-line injectable therapies. *Mult Scler*. 2016;22(10):1315-26.

4. Beveridge RA, Miller JA, Kales AN, et al. A comparison of efficacy of sargramostim (yeast-derived RhuGM-CSF) and filgrastim (bacteria-derived RhuG-CSF) in the therapeutic setting of chemotherapy-induced myelosuppression. *Cancer Invest* 1998; 16:366.
5. Biosimilar and interchangeable products. US Food and Drug Administration. Updated 10/23/2017. Available at <https://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/TherapeuticBiologicApplications/Biosimilars/ucm580419.htm>.
6. Bridges, S. Louis et al. "The Science Behind Biosimilars: Entering a New Era of Biologic Therapy." *Arthritis & rheumatology* 70 3 (2018): 334-344.
7. Brophy RH, Fillingham YA. AAOS Clinical Practice Guideline Summary: Management of Osteoarthritis of the Knee (Nonarthroplasty), Third Edition. *J Am Acad Orthop Surg*. 2022 May 1;30(9):e721-e729. doi: 10.5435/JAAOS-D-21-01233. PMID: 35383651.
8. Brown DM, Kaiser PK, Michels M, et al. Ranibizumab versus verteporfin for neovascular age-related macular degeneration. *N Engl J Med*. 2006;355(14):1432-44.
9. Busse W, Chupp G, Nagase H, et al. Anti-IL-5 treatments in patients with severe asthma by blood eosinophil thresholds: Indirect treatment comparison. *J Allergy Clin Immunol*. 2019;143(1):190-200.e20.
10. Chakravarthy U, Adamis AP, Cunningham ET, et al. Year 2 efficacy results of 2 randomized controlled clinical trials of pegaptanib for neovascular age-related macular degeneration. *Ophthalmology*. 2006;113(9):1508.e1-25.
11. Chakravarthy U, Harding SP, Rogers CA, et al. Alternative treatments to inhibit VEGF in age-related choroidal neovascularisation: 2-year findings of the IVAN randomised controlled trial. *Lancet*. 2013;382(9900):1258-67.
12. Chang AA, Li H, Broadhead GK, et al. Intravitreal aflibercept for treatment-resistant neovascular age-related macular degeneration. *Ophthalmology*. 2014;121(1):188-192.
13. Charrow J, Andersson HC, Kaplan P, et al. Enzyme replacement therapy and monitoring for children with type 1 Gaucher disease: consensus recommendations. *J Pediatr* 2004; 144:112.
14. Chingcuenco F, Segal J, Kim S, Alexander C. Bioequivalence of Biosimilar Tumor Necrosis Factor- α Inhibitors Compared With Their Reference Biologics: A Systematic Review. *Ann Intern Med*. 2016;165(8):565-74. doi: 10.7326/M16-0428.
15. Cicardi M. Hereditary angioedema (due to C1 inhibitor deficiency): General care and long-term prophylaxis. Ed. Saini S. UpToDate. Waltham, MA. UpToDate.com
16. Choudhry NK, Denberg TD, Qaseem A; Clinical Guidelines Committee of American College of Physicians. Improving Adherence to Therapy and Clinical Outcomes While Containing Costs: Opportunities From the Greater Use of Generic Medications: Best Practice Advice From the

- Clinical Guidelines Committee of the American College of Physicians. *Ann Intern Med.* 2016 Jan 5;164(1):41-9. doi: 10.7326/M14-2427. Epub 2015 Nov 24. PMID: 26594818.
17. Ghigo E, Biller BM, Colao A, et al. Comparison of pegvisomant and long-acting octreotide in patients with acromegaly naïve to radiation and medical therapy. *J Endocrinol Invest.* 2009;32(11):924-33.
 18. Gragoudas ES, Adamis AP, Cunningham ET, Feinsod M, Guyer DR. Pegaptanib for neovascular age-related macular degeneration. *N Engl J Med.* 2004;351(27):2805-16.
 19. Heier JS, Brown DM, Chong V, et al. Intravitreal aflibercept (VEGF trap-eye) in wet age-related macular degeneration. *Ophthalmology.* 2012;119(12):2537-48.
 20. Hoots WK. Hemophilia A and B: Routine management including prophylaxis. Ed. Mahony DH. UpToDate. Waltham, MA. UpToDate.com
 21. Hughes DA, Pastores GM. Gaucher Disease. 2000 Jul 27 [Updated 2023 Dec 7]. In: Adam MP, Feldman J, Mirzaa GM, et al., editors. GeneReviews® [Internet]. Seattle (WA): University of Washington, Seattle; 1993-2024. Available from: <https://www.ncbi.nlm.nih.gov/books/NBK1269/>
 22. Kalincik T, Brown JW, Robertson N, et al. Treatment effectiveness of alemtuzumab compared with natalizumab, fingolimod, and interferon beta in relapsing-remitting multiple sclerosis: a cohort study. *Lancet Neurol.* 2017;16(4):271-281.
 23. Kalincik T, et al "Comparison of 5-year treatment outcomes between alemtuzumab versus natalizumab, fingolimod and interferon β -1a" ECTRIMS 2016; Abstract 251.
 24. Kannicht C, Ramström M, Kohla G, et al. Characterisation of the post-translational modifications of a novel, human cell line-derived recombinant human factor VIII. *Thromb Res.* 2013;131(1):78-88.
 25. Kolasinski SL, Neogi T, Hochberg MC, Oatis C, Guyatt G, Block J, Callahan L, Copenhaver C, Dodge C, Felson D, Gellar K, Harvey WF, Hawker G, Herzig E, Kwok CK, Nelson AE, Samuels J, Scanzello C, White D, Wise B, Altman RD, DiRenzo D, Fontanarosa J, Giradi G, Ishimori M, Misra D, Shah AA, Shmagel AK, Thoma LM, Turgunbaev M, Turner AS, Reston J. 2019 American College of Rheumatology/Arthritis Foundation Guideline for the Management of Osteoarthritis of the Hand, Hip, and Knee. *Arthritis Care Res (Hoboken).* 2020 Feb;72(2):149-162. doi: 10.1002/acr.24131. Epub 2020 Jan 6. Erratum in: *Arthritis Care Res (Hoboken).* 2021 May;73(5):764. doi: 10.1002/acr.24615. PMID: 31908149; PMCID: PMC11488261.
 26. Klukowska A, Szczepański T, Vdovin V, Knaub S, Jansen M, Liesner R. Novel, human cell line-derived recombinant factor VIII (Human-cl rhFVIII, Nuwiq) in children with severe haemophilia A: efficacy, safety and pharmacokinetics. *Haemophilia.* 2016;22(2):232-239.
 27. Leonart LP, Fachi MM, Böger B, Silva MRD, Szpak R, Lombardi NF, Pedrosa MLA, Pontarolo R. A Systematic Review and Meta-analyses of Longitudinal Studies on Drug Treatments for Gaucher

- Disease. *Ann Pharmacother*. 2023 Mar;57(3):267-282. doi: 10.1177/10600280221108443. Epub 2022 Jul 11. PMID: 35815393.
28. Lieuw K. Many factor VIII products available in the treatment of hemophilia A: an embarrassment of riches? *J Blood Med*. 2017;8:67-73.
 29. Martin DF, Maguire MG, Fine SL, et al. Ranibizumab and bevacizumab for treatment of neovascular age-related macular degeneration: two-year results. *Ophthalmology*. 2012;119(7):1388-98.
 30. MASAC . MASAC Recommendation on SIPPET (Survey of Inhibitors in Plasma-Product-Exposed Toddlers): REsults and Recommendations for Treatment Products for Previously Untreated Patients with Hemophilia A. MASAC; 2016.
 31. Melmed S. Treatment of acromegaly. Ed. Snyder PJ. UpToDate. Waltham, MA. UpToDate.com)
 32. Milkovich G, Moleski RJ, Reitan JF, et al. Comparative safety of filgrastim versus sargramostim in patients receiving myelosuppressive chemotherapy. *Pharmacotherapy* 2000; 20:1432.
 33. Peyvandi F, Mannucci PM, Garagiola I, et al. A Randomized Trial of Factor VIII and Neutralizing Antibodies in Hemophilia A. *N Engl J Med*. 2016;374(21):2054-64.
 34. Schmidt-erfurth U, Kaiser PK, Korobelnik JF, et al. Intravitreal aflibercept injection for neovascular age-related macular degeneration: ninety-six-week results of the VIEW studies. *Ophthalmology*. 2014;121(1):193-201.
 35. Smith TJ, Bohlke K, Lyman GH, 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):3199-212.
 36. Stull DM, Bilmes R, Kim H, Fichtl R. Comparison of sargramostim and filgrastim in the treatment of chemotherapy-induced neutropenia. *Am J Health Syst Pharm* 2005; 62:83.
 37. Thadhani R, Guilatco R, Hymes J, Maddux FW, Ahuja A. Switching from Epoetin Alfa (Epoegen®) to Epoetin Alfa-Epbx (Retacrit™) Using a Specified Dosing Algorithm: A Randomized, Non-Inferiority Study in Adults on Hemodialysis. *Am J Nephrol*. 2018;48(3):214-224.
 38. Tiede A, Brand B, Fischer R, et al. Enhancing the pharmacokinetic properties of recombinant factor VIII: first-in-human trial of glycoPEGylated recombinant factor VIII in patients with hemophilia A. *J Thromb Haemost*. 2013;11(4):670-8.
 39. Trainer PJ, Ezzat S, D'souza GA, Layton G, Strasburger CJ. A randomized, controlled, multicentre trial comparing pegvisomant alone with combination therapy of pegvisomant and long-acting octreotide in patients with acromegaly. *Clin Endocrinol (Oxf)*. 2009;71(4):549-57.
 40. Vangsness CT Jr, Adamson TC 3rd, Daley MJ. Consequences on Private Insurance Coverage: The AAOS Clinical Practice Guidelines and Hyaluronic Acid Injections. *J Bone Joint Surg Am*. 2020 May 20;102(10):920-926. doi: 10.2106/JBJS.19.00272. PMID: 32079873; PMCID: PMC7508284.

41. Wang L, Qi CH, Zhong R, Yuan C, Zhong QY. Efficacy of alemtuzumab and natalizumab in the treatment of different stages of multiple sclerosis patients. *Medicine (Baltimore)*. 2018;97(8):e9908.
42. Weinreb NJ, Charrow J, Andersson HC, et al. Effectiveness of enzyme replacement therapy in 1028 patients with type 1 Gaucher disease after 2 to 5 years of treatment: a report from the Gaucher Registry. *Am J Med* 2002; 113:112.
43. Wenzel S. Treatment of severe asthma in adolescents and adults. Ed Bochner BS. UpToDate. Waltham, MA.
44. Wong SF, Chan HO. Effects of a formulary change from granulocyte colony-stimulating factor to granulocyte-macrophage colony-stimulating factor on outcomes in patients treated with myelosuppressive chemotherapy. *Pharmacotherapy* 2005; 25:372.
45. Wranik WD, Jakubczyk M, Drachal K. Ranking the Criteria Used in the Appraisal of Drugs for Reimbursement: A Stated Preferences Elicitation With Health Technology Assessment Stakeholders Across Jurisdictional Contexts. *Value Health*. 2020 Apr;23(4):471-480. doi: 10.1016/j.jval.2019.10.012. Epub 2019 Dec 16. PMID: 32327164.
46. Yeung K, Cruz M, Tsiao E, Watkins JB, Sullivan SD. Drug use and spending under a formulary informed by cost-effectiveness. *J Manag Care Spec Pharm*. 2023 Nov;29(11):1175-1183. doi: 10.18553/jmcp.2023.29.11.1175. PMID: 37889867; PMCID: PMC10778804.

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