Oscar Clinical Guideline: (Commercial) Preferred Physician-Administered Specialty Drugs (CG052, Ver. 34)

(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.

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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. This policy and its associated exceptions criteria (see Medical Preferred Drug List Table below) applies to physician-administered drugs that may be covered through the medical benefit.

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.

"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 have not been proven effective or which have not been approved by the appropriate regulatory bodies.

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

"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.

"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.

"New-to-Market Product" refers to any drug/biologic approved by the FDA within the past 12 months that is within a therapeutic class with existing preferred agents.

"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.

"[s]" indicates state mandates may apply.

Medical Preferred Drug List

New-to-Market Products*,**

All newly FDA-approved medications, including but not limited to biosimilars, interchangeable biosimilars, 505(b)(2) products, and other therapeutic agents, will automatically be designated as Non-Preferred upon FDA approval and market availability, regardless of:

1. Their therapeutic class or category;
2. The preferred/non-preferred status of their Reference Listed Drug (RLD);
3. Their FDA-approved indication(s);
4. Their biosimilarity or interchangeability designation.

These products will remain Non-Preferred and are subject to the Plan's Medical Benefit Preferred Physician-Administered Drug(s) Exceptions Criteria until:

1. A formal evaluation is completed by the Plan's P&T Committee*; AND*
2. The product is explicitly assigned Preferred status through the Plan's standard clinical and preferred drug list (PDL) maintenance processes.

Table 1		
Drug Class	*Preferred Medications*[*]	*Non-Preferred Medications*[⇅*]
ACTH and Analogs	❖ Acthar Gel (corticotropin) [J0801]	
Agents for Amyloidosis-Associated Polyneuropathy	❖ Amvuttra (vutrisiran) [J0225] ❖ Onpattro (patisiran) [J0222]	
	Exception Criteria: Agents for Amyloidosis-Associated Polyneuropathy - Medical Benefit Preferred Physician-Administered Drug Exceptions Criteria (CG109)	
Agents for Opioid-Related Disorders	❖ Brixadi (buprenorphine) [J0577/J0578] ❖ Sublocade (buprenorphine extended release) [Q9991/Q9992]	
Alpha-1 Antitrypsin Deficiency	❖ Prolastin-C (alpha1-proteinase inhibitor [human]) [J0256]	❖ Aralast (alpha1-proteinase inhibitor [human]) [J0256] ❖ Glassia (alpha1-proteinase inhibitor [human]) [J0257] ❖ Zemaira (alpha1-proteinase inhibitor [human]) [J0256]
	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]	❖ Cinvanti (aprepitant) [J0185] ❖ 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, Baxter) [J9036] ❖ Bendamustine HCl (Belrapzo) [J9036] ❖ Bendamustine HCl (Bendeka)

Table 1		
Drug Class	*Preferred Medications*[*]	*Non-Preferred Medications*[⇳*]
		[J9034] ❖ Bendamustine HCl (Vivimusta) [J9056]
	Exception Criteria: Plan's Preferred Physician-Administered Drug(s) Exceptions Criteria	
Antineoplastics - Bevacizumab for Cancer Indications	❖ Mvasi (Bevacizumab-awwb) [Q5107] ❖ Zirabev (Bevacizumab-bvzr) [Q5118]	❖ Avastin (Bevacizumab) [J9035] ❖ Alymsys (Bevacizumab-maly) [Q5126] ❖ Avzivi (bevacizumab-tnjn) ❖ Vegzelma (bevacizumab-adcd) [Q5129] ❖ Jobevne (bevacizumab-nwgd)
	Exception Criteria: Plan's Preferred Physician-Administered Drug(s) Exceptions Criteria	
Antineoplastics - Cyclophosphamide Products	❖ cyclophosphamide [Auromedics 505(b)(2)] [J9071] ❖ cyclophosphamide [505(b)(2) Dr. Reddy's] [J9073] ❖ cyclophosphamide, not otherwise specified [J9075] ❖ cyclophosphamide [Baxter 505(b)(2)] [J9076]	❖ cyclophosphamide [Avyxa 505(b)(2)] [J9072] ❖ cyclophosphamide [Sandoz 505(b)(2)] [J9074]
	Exception Criteria: Antineoplastics - Cyclophosphamide Products Medical Benefit Preferred Physician-Administered Drug Exceptions Criteria (CG120)	
Antineoplastics - Cytostatic Gonadotropin-Releasing Hormone Antagonists	❖ Firmagon (degarelix) [J9155]	
Antineoplastics - Gemcitabine Products	❖ Gemcitabine HCl (Accord) [J9196] ❖ Gemzar (gemcitabine) [J9201]	❖ Avgemsi (gemcitabine hydrochloride)
	Exception Criteria: Plan's Preferred Physician-Administered Drug(s) Exceptions Criteria	

Table 1		
Drug Class	*Preferred Medications*[*]	*Non-Preferred Medications*[ℵ*]
Antineoplastics - Gonadotropin-Releasing Hormone Agonists for Prostate Cancer	❖ Eligard (leuprolide acetate) [J9217]	❖ Camcevi (leuprolide mesylate) [J1952] ❖ Lupron Depot (leuprolide acetate) [J1950] ❖ Lutrate Depot (leuprolide acetate), 7.5 mg [J1954] ❖ Trelstar (triptorelin pamoate) [J3315] ❖ Vabrinty (leuprolide acetate) [J9217] ❖ Zoladex (goserelin acetate) [J9202]
	Exception Criteria: Gonadotropin-Releasing Hormone Agonists for Prostate Cancer - Medical Benefit Preferred Physician-Administered Drug Exceptions Criteria (CG085)	
Antineoplastics - HER2-Targeted Agents	❖ Enhertu (fam-trastuzumab deruxtecan-nxki) [J9358] ❖ Kadcyla (ado-trastuzumab emtansine) [J9354] ❖ Perjeta (pertuzumab) [J9306] ❖ Phesgo (pertuzumab/trastuzumab/hyaluronidase-zzxf) [J9316]	❖ Margenza (margetuximab-cmkb) [J9353]
	Exception Criteria: Antineoplastics - HER2-Targeted Agents - Medical Benefit Preferred Physician-Administered Drug Exceptions Criteria (CG101)	
Antineoplastics - Pemetrexed Products	❖ pemetrexed (Accord) [J9296] ❖ pemetrexed (Hospira) [J9294] ❖ pemetrexed (Sandoz) [J9297]	❖ Alimta (pemetrexed; RLD) [J9305] ❖ Axtle (pemetrexed; Avyxa) [J9292] ❖ 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)	

Table 1		
Drug Class	*Preferred Medications*[*]	*Non-Preferred Medications*[⇵*]
Antineoplastics - Proteosome Inhibitors	❖ Velcade (bortezomib) [J9041] ❖ Bortezomib (Maia/Fosun) [J9051]	❖ Bortezomib (Hospira) [J9049] ❖ Boruzu (bortezomib; Amneal/Shilpa) [J9054] ❖ Kyprolis (carfilzomib) [J9047]
	Exception Criteria: Plan's Preferred Physician-Administered Drug(s) Exceptions Criteria	
Antineoplastics - Trastuzumab Products	❖ Herzuma (trastuzumab-pkrb) [Q5113] ❖ Ogivri (trastuzumab-dkst) [Q5114]	❖ Herceptin (trastuzumab) [J9355] ❖ Herceptin Hylecta (trastuzumab and hyaluronidase-oysk) [J9356] ❖ Hercessi (trastuzumab-strf) [Q5146] ❖ Kanjinti (trastuzumab-anns) [Q5117] ❖ Ontruzant (trastuzumab-dttb) [Q5112] ❖ Trazimera (trastuzumab-qyyp) [Q5116]
	Exception Criteria: Plan's Preferred Physician-Administered Drug(s) Exceptions Criteria	
Antineoplastic and Immunomodulating Agents - Biologics for Autoimmune and Inflammatory Conditions	Biologics for Autoimmune and Inflammatory Conditions	
	❖ Cosentyx (secukinumab) IV [J3247] ❖ Entyvio (vedolizumab) IV[‡] J3380] ❖ Simponi Aria (golimumab) [J1602] ❖ Skyrizi (risankizumab-rzaa) IV [J2327] ❖ Tremfya (guselkumab) IV [J1628]	❖ Cimzia (certolizumab pegol)[↡] [J0717] ❖ Ilumya (tildrakizumab-asmn) [J3245] ❖ Omvoh (mirikizumab-mrkz) IV [J2267] ❖ Orencia (abatacept) [J0129] ❖ Stelara (ustekinumab) IV[‡] [J3358]
	Ustekinumab Products	
	❖ Steqeyma (ustekinumab-stba) IV [Q5099] ❖ Yesintek (ustekinumab-kfce) IV [Q5100]	❖ Imuldosa (ustekinumab-srlf) IV/SC [Q5098] ❖ Otulfi (ustekinumab-aauz) IV/SC [Q9999] ❖ Pyzchiva (ustekinumab-ttwe) IV [Q9997] ❖ Pyzchiva (ustekinumab-ttwe) SC [Q9996] ❖ Selarsdi (ustekinumab-aekn)

Table 1		
Drug Class	*Preferred Medications*[*]	*Non-Preferred Medications*[ǂ*]
		❖ IV/SC [Q9998] ❖ Starjemza (ustekinumab-hmny) IV ❖ Stelara (ustekinumab) IV[ǂ] [J3358] ❖ Wezlana (ustekinumab-auub) IV [Q5138] ❖ Wezlana (ustekinumab-auub) SC [Q5137]
	Exception Criteria: Antineoplastic and Immunomodulating Agents - (Select) Agents that Suppress the Immune System - Medical Benefit Preferred Physician-Administered Drug Exceptions Criteria (CG086)	
Antineoplastic and Immunomodulating Agents - Infliximab Products	❖ Avsola (infliximab-axxq) [Q5121] ❖ Inflectra (infliximab-dyyb) [Q5103]	❖ Infliximab [J1745] ❖ Remicade (infliximab) [Q5104] ❖ Renflexis (infliximbab-abda) [J1745]
	❖ Exception Criteria: Plan's Preferred Physician-Administered Drug(s) Exceptions Criteria	
Antineoplastic and Immunomodulating Agents - Rituximab Products	❖ Ruxience (rituximab-pvvr) [Q5119] ❖ Truxima (rituximab-abbs) [Q5115]	❖ Riabni (rituximab-arrx) [Q5123] ❖ Rituxan (rituximab) [J9312] ❖ Rituxan Hycela (rituximab/hyaluronidase human) [J9311]
	Exception Criteria: Plan's Preferred Physician-Administered Drug(s) Exceptions Criteria	
Antineoplastic and Immunomodulating Agents - Tocilizumab Products	❖ Tyenne (tocilizumab-aazg) IV [Q5135]	❖ Actemra (tocilizumab) IV[ǂ] [J3262] ❖ Avtozma (tocilizumab-anoh) IV [Q5156] ❖ Tofidence (tocilizumab-bavi) IV [Q5133]
	Exception Criteria: Antineoplastic and Immunomodulating Agents - Tocilizumab Products - Medical Benefit Preferred Physician-Administered Drug Exceptions Criteria (CG108)	
Bacillus Calmette-Guérin (BCG)-unresponsive non-muscle invasive bladder cancer (NMIBC)	❖ Adstiladrin (nadofaragene firadenovec-vncg) [J9029]	❖ Anktiva (nogapendekin alfa inbakicept-pmln) [J9028]
	Exception Criteria: Plan's Preferred Physician-Administered Drug(s) Exceptions Criteria	

Table 1		
Drug Class	*Preferred Medications*[*]	*Non-Preferred Medications*[ℵ*]
Biologics for Chronic Respiratory and Allergic Conditions	❖ Dupixent (dupilumab) ❖ Fasenra (benralizumab) [J0517] ❖ Nucala (mepolizumab) [J2182] ❖ Tezspire (tezepelumab-ekko) [J2356] ❖ Xolair (omalizumab) [J2357]	❖ Cinqair (reslizumab) [J2786] ❖ Exdensur (depemokimab-ulaa)
	Exception Criteria: Biologics for Chronic Respiratory and Allergic Conditions - Medical Benefit Preferred Physician-Administered Drug Exceptions Criteria (CG100)	
Botulinum Toxins	❖ Botox (onabotulinumtoxinA) [J0585] ❖ Dysport (abobotulinumtoxinA) [J0586] ❖ Xeomin (incobotulinumtoxinA) [J0588]	❖ Daxxify (daxibotulinumtoxinA-lanm) [J0589] ❖ Myobloc (rimabotulinumtoxinB) [J0587]
	Exception Criteria: Plan's Preferred Physician-Administered Drug(s) Exceptions Criteria	
Complement Inhibitors	❖ Bkemv (eculizumab-aeeb) [Q5152] ❖ Epysqli (eculizumab-aagh) [Q5151] ❖ Soliris (eculizumab) [J1299] ❖ Ultomiris (ravulizumab-cwvz) [J1303]	❖ Empaveli (pegcetacoplan) ❖ PiaSky (crovalimab-akkz) [J1307]
	Exception Criteria: Complement Inhibitors - Medical Benefit Preferred Physician-Administered Drug Exceptions Criteria (CG098)	
Denosumab Biosimilars (Osteoporosis)	❖ Jubbonti (denosumab-bbdz) [Q5136] ❖ Stoboclo (denosumab-bmwo) [Q5157]	❖ Bildyos (denosumab-nxxp) ❖ Bosaya (denosumab-kyqq) ❖ Conexxence (denosumab-bnht) [Q5158] ❖ Enoby (denosumab-qbde) ❖ Ospomyv (denosumab-dssb) [Q5159] ❖ Prolia (denosumab) [J0897] ❖ unbranded denosumab-bnht
	Exception Criteria: Plan's Preferred Physician-Administered Drug(s) Exceptions Criteria	

Table 1		
Drug Class	*Preferred Medications*[*]	*Non-Preferred Medications*[⇵*]
Denosumab Biosimilars (Antineoplastic)	❖ Osenvelt (denosumab-bmwo) [Q5157] ❖ Wyost (denosumab-bbdz) [Q5136]	❖ Aukelso (denosumab-kyqq) ❖ Bilprevda (denosumab-nxxp) ❖ Bomyntra (denosumab-bnht) [Q5158] ❖ Xbryk (denosumab-dssb) [Q5159] ❖ Xgeva (denosumab) [J0897] ❖ Xtrenbo (denosumab-qbde) ❖ unbranded denosumab-bnht
	Exception Criteria: Plan's Preferred Physician-Administered Drug(s) Exceptions Criteria	
Docetaxel	❖ docetaxel (generic of Taxoetere) [J9171]	❖ Docivyx (docetaxel) [J9172] ❖ Beizray (docetaxel) [J9174]
	Exception Criteria: Plan's Preferred Physician-Administered Drug(s) Exceptions Criteria	
Fertility Regulators - FSH	❖ Gonal-F (follitropin alfa) [S0126]	❖ Follistim AQ (follitropin beta) [S0128]
	Exception Criteria: Plan's Preferred Physician-Administered Drug(s) Exceptions Criteria	
Fulvestrant	❖ Faslodex (fulvestrant) [J9395]	❖ fulvestrant (Fresenius Kabi 505(b)(2)) [J9394]
	Exception Criteria: Plan's Preferred Physician-Administered Drug(s) Exceptions Criteria	
Gene Therapy for Hemophilia A	❖ Roctavian (valoctocogene roxaparvovec-rvox) [J1412]	
Gonadotropin-Releasing Hormone Agonists	❖ Fensolvi (leuprolide acetate) [J1951] ❖ Lupron Depot-Ped (leuprolide acetate for depot suspension) [J1950] ❖ Supprelin LA (histrelin acetate) [J9226] ❖ Triptodur (triptorelin) [J3316]	
Hematologic, Erythropoiesis-Stimulating Agents (ESA)	❖ Mircera (methoxy polyethylene glycol-epoetin beta) [J0887/J0888] ❖ Procrit (epoetin alfa)	❖ Aranesp (darbepoetin alfa) [J0881/J0882] ❖ Epogen (epoetin alfa) J0885/Q4081]

Table 1		
Drug Class	*Preferred Medications*[*]	*Non-Preferred Medications*[⇵*]
	[J0885/Q4081] ❖ Retacrit (epoetin alfa-epbx) [Q5106]	
	Exception Criteria: Erythropoiesis-Stimulating Agent (ESA) - Medical Benefit Preferred Physician-Administered Drug Exceptions Criteria (CG084)	
Hematologic, Neutropenia Colony Stimulating Factors, Long-Acting	❖ Fulphila (pegfilgrastim-jmdb) [Q5108] ❖ Udenyca (pegfilgrastim-cbqv) [Q5111] ❖ Udenyca Onbody (pegfilgrastim-cbqv) [Q5111]	❖ Fylnetra (pegfilgrastim-pbbk) [Q5130] ❖ Neulasta (pegfilgrastim) [J2506] ❖ Neulasta Onpro (pegfilgrastim) [J2506] ❖ Nyvepria (pegfilgrastim-apgf) [Q5122] ❖ Rolvedon (eflapegrastim-xnst) [J1449] ❖ Ryzneuta (efbemalenograstim alfa) [J9361] ❖ Stimufend (pegfilgrastim-fpgk) [Q5127] ❖ Ziextenzo (pegfilgrastim-bmez) [Q5120]
	Exception Criteria: Plan's Preferred Physician-Administered Drug(s) Exceptions Criteria	
Hematologic, Neutropenia Colony Stimulating Factors, Short-Acting	❖ Nivestym (filgrastim-aafi) [Q5110] ❖ Zarxio (filgrastim-sndz) [Q5101]	❖ Granix (tbo-filgrastim) [J1447] ❖ Leukine (sargramostim) [J2820] ❖ Neupogen (filgrastim) [J1442] ❖ Nypozi (filgrastim-txid) [Q5148] ❖ Releuko (filgrastim-ayow) [Q5125]
	Exception Criteria: Short-Acting Granulocyte Colony-Stimulating Factors - Medical Benefit Preferred Physician-Administered Drug Exceptions Criteria (CG080)	
Hematological Agents, Other - Aminolevulinate Synthase 1-Directed Small Interfering Ribonucleic Acid (siRNA)	❖ Givlaari (givosiran) [J0223]	

Table 1		
Drug Class	*Preferred Medications*[*]	*Non-Preferred Medications*[⇵*]
Hemophilia - Factor IX	❖ Alprolix (Coagulation Factor IX (Recombinant), Fc Fusion Protein) [J7201] ❖ BeneFIX [coagulation factor IX (recombinant)] [J7195 ❖ Rebinyn (Coagulation Factor IX (Recombinant), GlycoPEGylated) [J7203]	❖ Idelvion [Coagulation Factor IX (Recombinant), Albumin Fusion Protein (rIX-FP)] [J7202] ❖ Ixinity [coagulation factor IX (recombinant)] [J7213/J7195] ❖ Rixubis[Coagulation Factor IX (Recombinant)] [J7200]
	Exception Criteria: Plan's Preferred Physician-Administered Drug(s) Exceptions Criteria	
Hemophilia - Factor VIII, Long-Acting	❖ Adynovate (antihemophilic factor (recombinant), PEGylated) [J7207] ❖ Altuviiio (antihemophilic factor (recombinant), Fc-VWF-XTEN fusion protein-ehtl) [J7214] ❖ Eloctate (antihemophilic factor (recombinant), Fc fusion protein) [J7205] ❖ Jivi (antihemophilic factor (recombinant) [J7208]	❖ Esperoct [antihemophilic factor (recombinant) [J7204]
	Exception Criteria: Factor VIII (Long-Acting) Antihemophilic Agents - Medical Benefit Preferred Physician-Administered Drug Exceptions Criteria (CG090)	
Hemophilia - Factor VIII	❖ Advate [antihemophilic factor (recombinant)] [J7192] ❖ Afstyla [Antihemophilic Factor (Recombinant), Single Chain] [J7210] ❖ Kovaltry (antihemophilic Factor (Recombinant)) [J7211] ❖ Novoeight (antihemophilic factor (recombinant), glycopegylated-exei) [J7182] ❖ Nuwiq (Antihemophilic Factor (Recombinant)) [J7209] ❖ Xyntha (antihemophilic factor [recombinant]) [J7185]	❖ Kogenate FS (antihemophilic factor (recombinant)) [J7192] ❖ Recombinate [Antihemophilic Factor (Recombinant)] [J7192]

Table 1		
Drug Class	*Preferred Medications*[*]	*Non-Preferred Medications*[⇵*]
	Exception Criteria: Factor VIII Antihemophilic Agents - Medical Benefit Preferred Physician-Administered Drug Exceptions Criteria (CG091)	
Hereditary Angioedema	❖ Berinert (C1 Esterase Inhibitor, Human) [J0597]	❖ Kalbitor (ecallantide) [J1290] ❖ Ruconest (C1 esterase inhibitor [recombinant]) [J0596]
	Exception Criteria: Plan's Preferred Physician-Administered Drug(s) Exceptions Criteria	
Immune globulin	❖ Flebogamma DIF (immune globulin intravenous [human]) [J1572] ❖ Gammagard Liquid (immune globulin intravenous and subcutaneous [human]) [J1569] ❖ Gammaked (immune globulin intravenous and subcutaneous [human]) [J1561] ❖ Gamunex-C (immune globulin [human]) [J1561] ❖ Octagam (immune globulin intravenous [human]) [J1568]	❖ Alyglo (immune globulin intravenous [human]) [J1552] ❖ Asceniv (immune globulin intravenous [human]) [J1554] ❖ Bivigam (immune globulin intravenous [human]) [J1556] ❖ Cutaquig (immune globulin subcutaneous human) [J1551] ❖ Cuvitru (immune globulin subcutaneous [human]) [J1555] ❖ Gamastan S/D (immune globulin intramuscular [human]) [J1560] ❖ Gammagard S/D (immune globulin intravenous [human]) [J1566] ❖ Gammaplex (immune globulin intravenous [human]) [J1557] ❖ Hizentra (immune globulin) [J1559] ❖ Hyqvia (immune globulin infusion 10% [human] with recombinant human hyaluronidase) [J1575] ❖ Panzyga (immune globulin intravenous [human] - ifas) [J1576] ❖ Privigen (immune globulin intravenous [human]) [J1459] ❖ Xembify (immune globulin subcutaneous [human-klhw]) [J1558] ❖ Yimmugo (immune globulin intravenous, human – dira)
	Exception Criteria: Plan's Preferred Physician-Administered Drug(s) Exceptions Criteria	

Table 1		
Drug Class	*Preferred Medications*[*]	*Non-Preferred Medications*[⇵*]
Injectable Iron Supplements	❖ INFeD (iron dextran complex) [J1750] ❖ Ferrlecit (sodium ferric gluconate complex in sucrose) [J2916] ❖ Venofer (iron sucrose) [J1756]	❖ Feraheme (ferumoxytol) [Q0139/Q0138] ❖ Injectafer (ferric carboxymaltose) [J1439] ❖ Monoferric (ferric derisomaltose) [J1437]
	Exception Criteria: Injectable Iron Supplements - Medical Benefit Preferred Physician-Administered Drug Exceptions Criteria (CG107)	
Long-Acting Reversible Contraceptives	❖ Kyleena (levonorgestrel) [J7296] ❖ Liletta (levonorgestrel) [J7297] ❖ Miudella (copper intrauterine system) ❖ Mirena (levonorgestrel) [J7298] ❖ Paragard (intrauterine copper contraceptive) [J7300] ❖ Skyla (levonorgestrel) [J7301]	❖ Nexplanon (etonogestrel) [J7307]
	Exception Criteria: Plan's Preferred Physician-Administered Drug(s) Exceptions Criteria	
Lysosomal Storage Disorder Agents - Fabry Disease Agents	❖ Elfabrio (pegunigalsidase alfa) [J2508] ❖ Fabrazyme (agalsidase beta) [J0180]	
Lysosomal Storage Disorders - Gaucher Disease	❖ Cerezyme (Imiglucerase) [J1786] ❖ VPRIV (velaglucerase alfa for injection) [J3385]	❖ Elelyso (taliglucerase alfa) [J3060]
	Exception Criteria: Plan's Preferred Physician-Administered Drug(s) Exceptions Criteria	
Multiple Sclerosis (Infused)	❖ Briumvi (ublituximab) [J2329] ❖ Ocrevus (ocrelizumab) [J2350] ❖ Ocrevus Zunovo (ocrelizumab and hyaluronidase-ocsq) [J2351] ❖ Tysabri (natalizumab)	❖ Lemtrada (alemtuzumab) [J0202]

Table 1		
Drug Class	*Preferred Medications*[*]	*Non-Preferred Medications*[⇵*]
	[J2323] ❖ Tyruko (natalizumab-sztn) [Q5134]	
	Exception Criteria: Plan's Preferred Physician-Administered Drug(s) Exceptions Criteria	
Neonatal Fc Receptor Antagonist	❖ Imaavy (nipocalimab-aahu) [C9305] ❖ Vyvgart (efgartigimod alfa) [J9332] ❖ Vyvgart Hytrulo (efgartigimod alfa and hyaluronidase (human recombinant)) [J9334]	❖ Rystiggo (rozanolixizumab-noli) [J9333]
	Exception Criteria: Plan's Preferred Physician-Administered Drug(s) Exceptions Criteria	
Osteoarthritis, Viscosupplements (Single Injection)	❖ Monovisc (high molecular weight hyaluronan) [J7327]	❖ Durolane (hyaluronic acid) [J7318] ❖ Gel-One (cross-linked hyaluronate) [J7326] ❖ Synvisc-One (hylan G-F 20) [J7325]
	Exception Criteria: Hyaluronate and Derivatives - Medical Benefit Preferred Physician-Administered Drug Exceptions Criteria (CG094)	
Osteoarthritis, Viscosupplements (Multi Injection)	❖ Euflexxa (1% sodium hyaluronate) [J7323] ❖ Orthovisc (high molecular weight hyaluronan) [J7324]	❖ Gelsyn-3 (sodium hyaluronate 0.84%) [J7328] ❖ GenVisc 850 (sodium hyaluronate) [J7320] ❖ Hyalgan (sodium hyaluronate) [J7321] ❖ Hymovis (high molecular weight viscoelastic hyaluronan) [J7322] ❖ Supartz FX (sodium hyaluronate) [J7321] ❖ Synvisc (hylan G-F 20) [J7325] ❖ Synojoynt (sodium hyaluronate) [J7331] ❖ Triluron (sodium hyaluronate) [J7332] ❖ Trivisc (sodium hyaluronate) [J7329] ❖ Visco-3 (sodium hyaluronate) [J7321]

Table 1		
Drug Class	*Preferred Medications*[*]	*Non-Preferred Medications*[ℵ*]
	Exception Criteria: Hyaluronate and Derivatives - Medical Benefit Preferred Physician-Administered Drug Exceptions Criteria (CG094)	
Primary Hyperoxaluria Type 1 (PH1) Agents	❖ Oxlumo (lumasiran) [J0224]	
Pulmonary Hypertension (PAH) Agents, Prostacyclin Analogs/Receptor Agonists for PAH	❖ treprostinil [J3285]	❖ Remodulin (treprostinil) [J3285] ❖ Tyvaso (treprostinil) [J7686] ❖ Yutrepia (treprostinil inhalation powder)
	Exception Criteria: Prostacyclin Analogs/Receptor Agonists for Pulmonary Hypertension (PAH) - Medical Benefit Preferred Physician-Administered Drug Exceptions Criteria (CG097)	
Somatostatin Analogs	❖ Somatuline Depot (lanreotide) [J1930]	❖ lanreotide (Cipla) [J1932] ❖ Sandostatin (octreotide, non-depot) [J2354] ❖ Sandostatin LAR Depot (octreotide acetate) [J2353] ❖ Signifor LAR (pasireotide long acting) [J2502] ❖ Somavert (pegvisomant) [J3590]
	Exception Criteria: Somatostatin Analogs - Medical Benefit Preferred Physician-Administered Drug Exceptions Criteria (CG078)	
Spinal Muscular Atrophy	❖ Zolgensma (onasemnogene abeparvovec-xioi) [J3399]	
Systemic Lupus Erythematosus (SLE) Agents	❖ Benlysta IV (belimumab) [J0490]	❖ Saphnelo (anifrolumab-fnia) [J0491]
	Exception Criteria: Plan's Preferred Physician-Administered Drug(s) Exceptions Criteria	
Vascular Endothelial Growth Factor (VEGF) Inhibitor Ophthalmic Agents (i.e., Retinal Disorders Agents)	❖ Avastin (bevacizumab) [C9257]	❖ Ahzantive (aflibercept-mrbb) [Q5150] ❖ Beovu (brolucizumab-dbll) [J0179] ❖ Byooviz (ranibizumab-nuna) [Q5124] ❖ Cimerli (ranibizumab-eqrn) [Q5128] ❖ Enzeevu (aflibercept-abzv) [Q5149] ❖ Eylea (aflibercept) [J0178]

Table 1		
Drug Class	*Preferred Medications*[*]	*Non-Preferred Medications*[≈*]
		❖ Eylea HD (aflibercept) [J0177] ❖ Lucentis (ranibizumab) [J2778] ❖ Opuviz (aflibercept-yszy) [Q5153] ❖ Pavblu (aflibercept-ayyh) [Q5147] ❖ Susvimo (ranibizumab) [J2779] ❖ Vabysmo (faricimab-svoa) [J2777] ❖ Yesafili (aflibercept-jbvf)
	Exception Criteria: Vascular Endothelial Growth Factor (VEGF) Inhibitor Ophthalmic Agents - Medical Benefit Preferred Physician-Administered Drug Exceptions Criteria (CG099)	
von Willebrand Disease	❖ Alphanate (antihemophilic factor, human/von Willebrand Factor, human) [J7186]	❖ Humate-P (antihemophilic factor, human/von willebrand factor, human) [J7187] ❖ Wilate [von Willebrand Factor/coagulation factor VIII complex (human)] [J7183]
	Exception Criteria: Plan's Preferred Physician-Administered Drug(s) Exceptions Criteria	

[≈]subject 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.*

Clinical Indications

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 ALL of the following criteria:

1. The member meets ONE of the following criteria[s]:

a. Inadequate response or intolerance to ALL preferred products in the same class, when these are FDA, compendia, or evidence-based guideline-supported options*; or*
b. Hypersensitivity to specific excipients precluding the use of ALL preferred products*; or*
c. The member has a contraindication to ALL preferred products that would NOT exist or be reasonably expected to occur with the requested non-preferred product*; or*
d. The member is currently receiving treatment with the requested product and coverage is required to complete the current course of treatment, excluding when the requested product is obtained as samples or via assistance programs*; or*
e. There are no preferred products available in the same class*; or*
f. Drug shortage or unavailability of ALL of the preferred products*; or*
g. ALL preferred products have NOT received the requested FDA approval, is not supported by evidence-based guidelines, or is not clinically appropriate for the member's diagnosis*; or*
h. The required dosing or administration cannot be achieved using ALL preferred products*; or*
i. Documented facility or treatment requirements that cannot be met with ALL preferred products due to ONE of the following:
    i. Required volume or concentration specifications for route of administration*; or*
    ii. Specific preparation/stability requirements*; or*
    iii. Specific infusion time constraints*; or*
j. The request is for a therapy regimen where clinical evidence and/or current treatment guidelines (e.g., NCCN) support the preferential use of the requested product over ALL preferred products; *or*
k. The request is for cancer treatment in a state prohibiting prerequisite trials per regulations*; AND*

2. Clinical documentation is provided to support the exception request. Examples of supporting documentation include:
    a. The specific reason(s) why preferred products cannot be used (e.g. inadequate response, adverse event, contraindication, restrictions)*; 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*; and/or*
    d. Notification of drug shortage or unavailability.

<u>If the above prior authorization criteria are met, the requested product will be authorized for up to 12-months.</u>[s]

- <u>For drug transition (if criteria 1d is met above)</u>[s]:
    - <u>Initial approval - up to 3 months or other duration per provider clinical rationale.</u>
- <u>For drug shortage/unavailability</u>[s]:

- Initial approval - up to 3 months;
- May be extended based on continued documentation of shortage/unavailability.

  Note: If the shortage/unavailability resolves before the authorization period ends, the Plan may require transition to the preferred product at the next authorization period.

Experimental or Investigational / Not Medically Necessary[s]

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

Table 2	
Code	*Description*
ACTH and Analogs	
J0801	Acthar Gel Injection, corticotropin (acthar gel), up to 40 units
Agents for Amyloidosis-Associated Polyneuropathy	
J0225	Amvuttra Injection, vutrisiran, 1 mg
J0222	Onpattro Injection, patisiran, 0.1 mg
Agents for Opioid-Related Disorders	
J0577	Brixadi Injection, buprenorphine extended-release (brixadi), less than or equal to 7 days

Table 2	
Code	*Description*
	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

Table 2	
Code	*Description*
J9036	Belrapzo Apotex 505(b)(2) Baxter 505(b)(2) Injection, bendamustine hydrochloride, (belrapzo/bendamustine), 1 mg
J9056	Vivimusta Injection, bendamustine hydrochloride (vivimusta), 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-tnjn) Unclassified drugs or biologicals
J9999	Avzivi (bevacizumab-tnjn) Not otherwise classified, antineoplastic drugs
C9399	Jobevne (bevacizumab-nwgd) Unclassified drugs or biologicals
J9999	Jobevne (bevacizumab-nwgd) Not otherwise classified, antineoplastic drugs
Antineoplastics - Cyclophosphamide Products	
J9071	Injection, cyclophosphamide (auromedics), 5 mg
J9072	Injection, cyclophosphamide (avyxa), 5 mg
J9073	Injection, cyclophosphamide (Dr. Reddy's), 5 mg
J9075	Injection, cyclophosphamide, not otherwise specified, 5 mg
J9074	Injection, cyclophosphamide (sandoz), 5 mg
J9076	Injection, cyclophosphamide (baxter), 5 mg

Table 2	
Code	*Description*
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	Vabrinty 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
J1952	Camcevi Leuprolide injectable, camcevi, 1 mg
J1954	Lutrate Depot (leuprolide acetate) Injection, leuprolide acetate for depot suspension (lutrate depot), 7.5 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
J9201	Gemzar Injection, gemcitabine hydrochloride, not otherwise specified, 200 mg
C9399	Avgemsi Unclassified drugs or biologicals
J9999	Avgemsi Not otherwise classified, antineoplastic drugs
Antineoplastics - HER2-Targeted Agents	
J9306	Perjeta Injection, pertuzumab, 1 mg

Table 2	
Code	*Description*
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	
J9292	Axtle Injection, pemetrexed dipotassium, 10 mg
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 - Proteosome Inhibitors (i.e., bortezomib, carfilzomib)	
J9041	Velcade Injection, bortezomib, 0.1 mg

Table 2	
Code	*Description*
J9047	Kyprolis Injection, carfilzomib, 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
J9054	Boruzu Injection, bortezomib (boruzu), 0.1 mg
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
Q5146	Injection, trastuzumab-strf (hercessi), biosimilar, 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

Table 2	
Code	*Description*
J2267	Omvoh IV Injection, mirikizumab-mrkz, 1 mg
J2327	Skyrizi (intravenous) Injection, risankizumab-rzaa, intravenous, 1 mg
J3245	Ilumya Injection, tildrakizumab, 1 mg
J3247	Cosentyx IV Injection, secukinumab, intravenous, 1 mg
J3358	Stelara IV Ustekinumab, for intravenous injection, 1 mg
Q5098	Imuldosa IV Injection, ustekinumab-srlf (imuldosa), biosimilar, 1 mg
Q9998	Selarsdi IV Injection, ustekinumab-aekn (selarsdi), biosimilar, 1 mg
C9399	Starjemza IV Unclassified drugs or biologicals
J3590	Starjemza IV Unclassified biologics
Q5099	Steqeyma IV Injection, ustekinumab-stba (steqeyma), biosimilar, 1 mg
Q5100	Yesintek IV Injection, ustekinumab-kfce (yesintek), biosimilar, 1 mg
Q5138	Wezlana IV Injection, ustekinumab-auub (wezlana), biosimilar, intravenous, 1 mg
Q9997	Pyzchiva IV Injection, ustekinumab-ttwe (pyzchiva), intravenous, 1 mg
Q9999	Otulfi IV Injection, ustekinumab-aauz (otulfi), biosimilar, 1 mg
J3380	Entyvio IV Injection, vedolizumab, intravenous, 1 mg
Antineoplastic and Immunomodulating Agents - Infliximab Products	
J1745	Remicade Injection, infliximab, excludes biosimilar, 10 mg

Table 2	
Code	*Description*
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
Q5133	Tofidence IV Injection, tocilizumab-bavi (tofidence), biosimilar, 1 mg
Q5135	Tyenne IV Injection, tocilizumab-aazg (tyenne), biosimilar, 1 mg
Q5156	Avtozma IV Injection, tocilizumab-anoh (avtozma), biosimilar, 1 mg
Bacillus Calmette-Guérin (BCG)-unresponsive non-muscle invasive bladder cancer (NMIBC)	
J9028	Anktiva Injection, nogapendekin alfa inbakicept-pmln, for intravesical use, 1 microgram
J9029	Adstiladrin Intravesical instillation, nadofaragene firadenovec-vncg, per therapeutic dose

Table 2	
Code	*Description*
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) or Exdensur (depemokimab-ulaa) Unclassified drugs or biologicals
J3590	Dupixent (dupilumab) or Exdensur (depemokimab-ulaa) 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	
Q5152	Bkemv Injection, eculizumab-aeeb (bkemv), biosimilar, 2 mg
C9399	Empaveli Unclassified drugs or biologicals
J7799	Empaveli Noc drugs, other than inhalation drugs, administered through dme

Table 2	
Code	*Description*
Q5151	Epysqli Injection, eculizumab-aagh (epysqli), biosimilar, 2 mg
J1300	Soliris Injection, eculizumab, 10 mg
J1303	Ultomiris Injection, ravulizumab-cwvz, 10 mg
J1307	PiaSky Injection, crovalimab-akkz, 10 mg
Denosumab Biosimilars (Osteoporosis)	
J0897	Prolia Injection, denosumab, 1 mg
Q5136	Jubbonti Injection, denosumab-bbdz (jubbonti/wyost), biosimilar, 1 mg
Q5157	Stoboclo Injection, denosumab-bmwo (stoboclo/osenvelt), biosimilar, 1 mg
Q5158	Conexxence Injection, denosumab-bnht (bomyntra/conexxence), biosimilar, 1 mg
Q5159	Ospomyv Injection, denosumab-dssb (ospomyv/xbryk), biosimilar, 1 mg
C9399	unbranded denosumab-bnht, Bildyos (denosumab-nxxp), Bosaya (denosumab-kyqq), Enoby (denosumab-qbde) Unclassified drugs or biologicals
J3590	unbranded denosumab-bnht, Bildyos (denosumab-nxxp), Bosaya (denosumab-kyqq), Enoby (denosumab-qbde) Unclassified biologics
Denosumab Biosimilars (Antineoplastic)	
J0897	Xgeva Injection, denosumab, 1 mg
Q5136	Wyost Injection, denosumab-bbdz (jubbonti/wyost), biosimilar, 1 mg
Q5157	Osenvelt

Table 2	
Code	*Description*
	Injection, denosumab-bmwo (stoboclo/osenvelt), biosimilar, 1 mg
Q5158	Bomyntra Injection, denosumab-bnht (bomyntra/conexxence), biosimilar, 1 mg
Q5159	Xbryk Injection, denosumab-dssb (ospomyv/xbryk), biosimilar, 1 mg
C9399	unbranded denosumab-bnht, Aukelso (denosumab-kyqq), Bilprevda (denosumab-nxxp), Xtrenbo (denosumab-qbde) Unclassified drugs or biologicals
J3590	unbranded denosumab-bnht, Aukelso (denosumab-kyqq), Bilprevda (denosumab-nxxp), Xtrenbo (denosumab-qbde) Unclassified biologics
Docetaxel	
J9171	docetaxel (generic of Taxotere) Injection, docetaxel, 1 mg
J9172	Docivyx Injection, docetaxel (docivyx), 1 mg
J9174	Beizray Injection, docetaxel (beizray), 1 mg
Fertility Regulators - FSH	
S0126	Gonal-F Injection, follitropin alfa, 75 IU
S0128	Follistim AQ Injection, follitropin beta, 75 IU
Fulvestrant	
J9394	fulvestrant (Fresenius Kabi 505(b)(2)) Injection, fulvestrant (fresenius kabi) not therapeutically equivalent to J9395, 25 mg
J9395	Faslodex (fulvestrant) Injection, fulvestrant, 25 mg
Gene Therapy for Hemophilia A	

Table 2	
Code	*Description*
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

Table 2	
Code	*Description*
	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

Table 2	
Code	*Description*
Q5110	Nivestym Injection, filgrastim-aafi, biosimilar, (Nivestym), 1 mcg
Q5125	Releuko Injection, filgrastim-ayow, biosimilar, (Releuko), 1 mcg
Q5148	Nypozi Injection, filgrastim-txid (nypozi), biosimilar, 1 microgram
Hematological Agents, Other - Aminolevulinate 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

Table 2	
Code	*Description*
	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	Altuviiio Injection, factor viii/von willebrand factor complex, recombinant (altuviiio), 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
J1290	Kalbitor Injection, ecallantide, 1 mg
Immune globulin	
J1459	Privigen Injection, immune globulin (privigen), intravenous, non-lyophilized (e.g., liquid),

Table 2	
Code	*Description*
	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	Gammaplex Injection, immune globulin, (gammaplex), intravenous, non-lyophilized (e.g., liquid), 500 mg
J1558	Xembify Injection, immune globulin (xembify), 100 mg
J1559	Hizentra Injection, immune globulin (hizentra), 100 mg
J1560	GamaSTAN S/D Injection, gamma globulin, intramuscular, over 10 cc
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

Table 2	
Code	*Description*
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	Monoferric 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	Ferrlecit 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	
J3490	Miudella Unclassified drugs
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

Table 2	
Code	*Description*
J7300	Paragard Intrauterine copper contraceptive
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)	
J0202	Lemtrada Injection, alemtuzumab, 1 mg
J2323	Tysabri Injection, natalizumab, 1 mg
J2329	Briumvi Injection, ublituximab-xiiy, 1mg
J2350	Ocrevus Injection, ocrelizumab, 1 mg
J2351	Ocrevus Zunovo Injection, ocrelizumab, 1 mg and hyaluronidase-ocsq
Q5134	Injection, natalizumab-sztn (tyruko), biosimilar, 1 mg
Neonatal Fc Receptor Antagonist	
J9332	Vyvgart

Table 2	
Code	*Description*
	Injection, efgartigimod alfa-fcab, 2mg
J9334	Vyvgart Hytrulo Injection, efgartigimod alfa, 2 mg and hyaluronidase-qvfc
J9333	Rystiggo Injection, rozanolixizumab-noli, 1 mg
C9305	Imaavy Injection, nipocalimab-aahu, 3 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

Table 2	
Code	*Description*
	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	Synojoynt Hyaluronan or derivative, Synojoynt, 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
J7686	Tyvaso Treprostinil, inhalation solution, fda-approved final product, non-compounded, administered through dme, unit dose form, 1.74 mg
J8499	Yutrepia Prescription drug, oral, non chemotherapeutic, nos
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

Table 2	
Code	*Description*
	Injection, octreotide, non-depot form for subcutaneous or intravenous injection, 25 mcg
J2502	Signifor LAR Injection, pasireotide long acting, 1 mg
J3590	Somavert Unclassified biologics
Spinal Muscular Atrophy	
J3399	Zolgensma Injection, onasemnogene abeparvovec-xioi, per treatment, up to 5x10^15 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	Yesafili Unclassified drugs or biologicals
J0177	Eylea HD Injection, aflibercept hd, 1 mg
J0178	Eylea Injection, aflibercept, 1 mg
J0179	Beovu Injection, brolucizumab-dbll, 1 mg
J2777	Vabysmo Injection, faricimab-svoa, 0.1 mg
J2778	Lucentis Injection, ranibizumab, 0.1 mg
J2779	Susvimo

Table 2	
Code	*Description*
	Injection, ranibizumab, via intravitreal implant (susvimo), 0.1 mg
J3590	Yesafili 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
Q5147	Pavblu Injection, aflibercept-ayyh (pavblu), biosimilar, 1 mg
Q5149	Enzeevu Injection, aflibercept-abzv (enzeevu), biosimilar, 1 mg
Q5150	Ahzantive Injection, aflibercept-mrbb (ahzantive), biosimilar, 1 mg
Q5153	Opuviz Injection, aflibercept-yszy (opuviz), biosimilar, 1 mg
von Willebrand Disease	
J7183	Wilate Injection, von willebrand factor complex (human), wilate, 1 i.u. vwf:rco
J7186	Alphanate Injection, antihemophilic factor viii/von willebrand factor complex (human), per factor viii i.u.
J7187	Humate-P Injection, von willebrand factor complex (humate-p), per iu vwf:rco

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