Providence
Medicare Advantage Plans

PROVIDENCE MEDICARE ADVANTAGE PLANS

2023 STEP THERAPY CRITERIA FOR PART B DRUGS:

PHIP ALIGN GROUP PLAN + RX (HMO) AND FLEX GROUP PLAN + RX (HMO-POS) PLANS

Last Updated 11/30/2023

For more recent information or other questions, please contact Providence Health Assurance Customer Service at 503-574-8000 or 1-800-603-2340 or, for TTY users, 711, seven days a week, between 8 a.m. and 8 p.m. (Pacific Time), or visit ProvidenceHealthAssurance.com/PHIP.

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Medicare Part B Step Therapy

- Some medically administered Part B medications, like injectable drugs or biologics, may have special requirements or coverage limits, such as step therapy.
- Step therapy requires a trial of a preferred drug to treat a medical condition before covering a non-preferred drug.
- The step therapy requirement does not apply to members who have already received treatment with the non-preferred drug within the past 365 days.
- Both preferred and non-preferred drugs may still be subject to prior authorization or quantity limits.
- The step therapy criteria outlined in this document may also involve a combination of Part B and Part D drugs. For example, we may not cover a Part B drug unless you try a Part D drug first. Or we may not cover a Part D drug unless you try a Part B drug first. This is dependent on the therapy described to treat your medical condition. This document contains the Step Therapy protocols for Medicare Part B drugs that are associated with your plan.

How Step Therapy Works

In the list below, you'll see drugs labeled as either Step 1 (Preferred drug), Step 2 (Non-Preferred drug) or Step 3 (Non-Preferred drug). Step 2 and Step 3 drugs require step therapy.
For example: Before you can get a Step 3 drug, you have to first try a Step 1 and a Step 2 drug.

Step 1 drugs usually require prior authorization. That means before you can take this drug, your doctor has to send us information that explains why you need it. If a Step 1 drug doesn't require prior authorization, we tell you in the list below.

Step 2 drugs always require prior authorization. Your doctor also needs to let us know one of the following:

- Why the Step 1 drug didn't work for you or why you can't take the Step 1 drug
- Why the Step 2 drug is best for your needs
- Details from your doctor to show that you've taken the Step 2 drug in the past 365 days

Step 3 drugs always require prior authorization. Your doctor also needs to let us know one of the following:

- Why the Step 1 and Step 2 drugs didn't work for you or why you can't take them.
- Why the Step 3 drug is best for your needs
- Details from your doctor to show that you've taken the Step 1 and/or the Step 2 drug in the past 365 days

The drugs within this list may change at any time. You will receive notice when necessary.

Code	Non-Preferred Drug	Generic name	Prerequisite Drugs	Effective 1/1/2023 *unless otherwise noted*
Allergy And Asthma Agents				
J2356	TEZSPIRE	Tezepelumab-ekko	Documentation that, in the past three months, patient is adherent to treatment with maximally tolerated doses of both of the following, taken concurrently, unless patient has an intolerance to an inhaled steroid and a LABA, LTRA, or LAMA or has a contraindication to ALL therapies (This may be verified by pharmacy claims information): i. Inhaled corticosteroid, AND ii. One of the following: a) A long-acting inhaled beta 2-agonist (LABA), b) A leukotriene receptor antagonist (LTRA), c) A long-acting muscarinic antagonist (LAMA)	10/1/2023: Policy update
J2357	XOLAIR*	Omalizumab	**<u>For Asthma</u>** - **Step 1**: inhaled corticosteroids **AND Step 2**: One of the following: a. A long-acting inhaled beta 2-agonist (LABA) b. A leukotriene receptor antagonist (LTRA) c. A long-acting muscarinic antagonist (LAMA)	10/1/2023: Policy update
			<u>For chronic idiopathic urticaria</u>- Step 1: second-generation non-sedating H1 antihistamine (such as levocetirizine, loratadine, cetirizine, fexofenadine) **Step 2:** ONE additional medication from one of the following classes: 1. leukotriene receptor antagonists (such as montelukast), 2. first generation H1 antihistamine (such as diphenhydramine) or 3. histamine H2-receptor antagonist (such as famotidine, ranitidine)	10/1/2023: Policy update
			<u>For nasal polyps</u> - Step 1: inadequate response to intranasal corticosteroids (such as fluticasone). Intranasal corticosteroid therapy must be continued for those who tolerate.	10/1/2023: Policy update
Anti-Infective Agents				
J3490	PREVYMIS*	Letermovir	**Step 1:** Medical rationale for not using the oral formulation	
Central Nervous System Agents				

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G2082 G2083	SPRAVATO*	Esketamine nasal spray	**For treatment-resistant depression (TRD) – Step 1:** Inadequate response to at least three oral antidepressants in two different therapeutic classes for at least eight weeks of treatment at a therapeutic dose for major depressive disorder (MDD). **AND Step 2:** Inadequate response to augmentation therapy (i.e., two antidepressants with different mechanisms of action used concomitantly or an antidepressant and a second-generation antipsychotic, lithium, thyroid hormone, or anticonvulsant used concomitantly)	
Enzyme Replacement Therapy				
J3590	NEXVIAZYME*	Avalglucosidase alfa	**Step1:** Patients weighing less than 30 kg must have a documented trial, failure, intolerance or contraindication to alglucosidase alfa (LUMIZYME) *	3/1/2023
Hereditary Angioedema Agents				
J0597	BERINERT*	C1 esterase inhibitor	**Step 1:** generic icatibant*	
J0598	CINRYZE*	C1 esterase inhibitor	**For HAE with normal C1-INH or HAE Type III: Step 1:** HAEGARDA*	
J1290	KALBITOR*	Ecallantide	**Step 1:** generic icatibant*	
J0596	RUCONEST*	C1 esterase inhibitor, recombinant	**Step 1:** generic icatibant*	
Hormonal Agents				
J3145	AVEED*	Testosterone undecanoate	**Step 1:** Generic formulary topical testosterone (such as generic topical testosterone 1% or generic topical testosterone 1.62% pump) **AND** **Step 2:** generic injectable testosterone cypionate	
J3490	CETROTIDE*	Cetrorelix acetate	**For treatment of infertility - Step 1:** GANIRELIX*	
J3490	GONAL F*	Follitropin alfa	**For treatment of infertility - Step 1:** FOLLISTIM AQ*	
J0725	OVIDREL*	Chorionic gonadotropin	**For treatment of infertility - Step 1:** NOVAREL*, PREGNYL*OR generic chorionic gonadotropin*	
J2353	SANDOSTATIN LAR DEPOT*	Octreotide acetate, microspheres	**For Chemotherapy induced diarrhea – Step 1:** loperamide **AND Step 2:** Short-acting octreotide	
			For AIDS-related diarrhea – Step 1: loperamide and diphenoxylate/atropine (LOMOTIL) **AND Step 2:** Short-acting octreotide	

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J2502	SIGNIFOR LAR*	Pasireotide pamoate	**For Acromegaly - Step 1:** octreotide injection therapy OR lanreotide subcutaneous depot*	
J3490 J7999	TESTOPEL*	Testosterone (pellet)	**Step 1:** Generic formulary topical testosterone (such as generic topical testosterone 1% or generic topical testosterone 1.62% pump) **AND** Step 2: generic injectable testosterone cypionate	
IL-5 Inhibitors				
J2786	CINQAIR*	Reslizumab	**For eosinophilic asthma - Step 1:** medium to high-dose inhaled corticosteroid plus an additional asthma controller (e.g., long-acting inhaled beta2-agonist, leukotriene receptor antagonist)	Criteria for eosinophilic asthma thru 9/30/2023
			For eosinophilic asthma: Step 1: Trial and inadequate asthma control to at least the previous three months, treatment with maximally tolerated doses of both of the following, (unless patient has an intolerance or contraindication to all therapies) : 1) Inhaled corticosteroid, AND 2) A long-acting inhaled beta 2-agonist (LABA),OR A leukotriene receptor antagonist (LTRA), OR A long-acting muscarinic antagonist (LAMA)	10/1/2023: Eosinophilic asthma criteria changes
J0517	FASENRA*	Benralizumab	**For eosinophilic asthma - Step 1:** medium to high-dose inhaled corticosteroid plus an additional asthma controller (e.g., long-acting inhaled beta2-agonist, leukotriene receptor antagonist)	Criteria for eosinophilic asthma thru 9/30/2023
			For eosinophilic asthma - Step 1: Trial and inadequate asthma control to at least the previous three months, treatment with maximally tolerated doses of both of the following, (unless patient has an intolerance or contraindication to all therapies) : 1) Inhaled corticosteroid, AND 2) A long-acting inhaled beta 2-agonist (LABA),OR A leukotriene receptor antagonist (LTRA), OR A long-acting muscarinic antagonist (LAMA)	10/1/2023: Eosinophilic asthma criteria changes
J2182	NUCALA*	Mepolizumab	**For eosinophilic asthma - Step 1:** medium to high-dose inhaled corticosteroid plus an additional asthma controller (e.g., long-acting inhaled beta2-agonist, leukotriene receptor antagonist)	Criteria for eosinophilic asthma thru 9/30/2023

Code	Non-Preferred Drug	Generic name	Prerequisite Drugs	Effective 1/1/2023 *unless otherwise noted*
			For eosinophilic asthma: Step 1: Trial and inadequate asthma control to at least the previous three months, treatment with maximally tolerated doses of both of the following, (unless patient has an intolerance or contraindication to all therapies) : 1) Inhaled corticosteroid, AND 2) A long-acting inhaled beta 2-agonist (LABA),OR A leukotriene receptor antagonist (LTRA), OR A long-acting muscarinic antagonist (LAMA)	10/1/2023: Eosinophilic asthma criteria changes
			For EGPA - Step 1: relapse requiring an increase in glucocorticoid dose, initiation or increase in other immunosuppressive therapy, or hospitalization in previous two years while receiving at least 7.5mg/day prednisone (or equivalent) **OR Step2:** glucocorticoid in combination with an immunosuppressant such as cyclophosphamide, azathioprine, methotrexate or mycophenolate mofetil)	Criteria for EGPA thru 9/30/2023
			For EGPA -Confirmed diagnosis of EGPA with relapsing or refractory disease - Step 1: History of relapse requiring an increase in glucocorticoid dose, initiation or increase in other immunosuppressive therapy, or hospitalization in the previous two years while receiving at least 7.5 mg/day prednisone (or equivalent) **Step 2:** Failure to achieve remission following a standard treatment regimen administered for at least three months OR recurrence of symptoms of EGPA while tapering glucocorticoids. Standard treatment regimens include: prednisone [or equivalent] dosed at least 7.5 mg/day in combination with an immunosuppressant such as cyclophosphamide, azathioprine, methotrexate, or mycophenolate mofetil	10/1/2023: EGPA criteria changes
			For Hyperesosinophilic Syndrome (HES) - Step 1: one of the following: chronic or episodic oral corticosteroids, immunosuppressive therapy or, cytotoxic therapy	Criteria for HES thru 9/30/2023
			For Hyperesosinophilic Syndrome (HES) - Use of conventional HES therapy including **one** of the following in the past 12 months prior to initiation of therapy: 1) Chronic or episodic oral corticosteroids 2) Immunosuppressive therapy 3) Cytotoxic therapy	10/1/2023: HES criteria changes

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			For Chronic Rhinosinusitis with Nasal Polyp (CRSwNP): Step 1: inadequate response to 3-month trial of intranasal corticosteroid monotherapy (such as fluticasone) or intolerance or contraindication to ALL intranasal corticosteroids. **Note: Continuation of standard maintenance therapy (such as nasal saline irrigation, intranasal corticosteroids, etc) are required for approval of Nucala.**	
Immune Gamma Globulin (IGG)				
J1554, J1556, J1551, J1555, J1572, J1460, J1560, J1569, J1566, J1561, J1557, J1559, J1575, J1568, J1576, J1459, J1558	ASCENIV*, BIVIGAM*, CUTAQUIG*, CUVITRU*, FLEBOGAMMA DIF*, GAMASTAN S-D*, GAMMAGARD LIQUID*, GAMMAGARD SD*, GAMMAKED*, GAMMAPLEX*, GAMUNEX-C*, HIZENTRA*, HYQVIA*, OCTAGAM*, PANZYGA*, PRIVIGEN*, XEMBIFY*	Immune globulin (IM, IV, SQ)	**For Dermatomyositis and polymyositis: Step 1:** systemic corticosteroids (such as prednisone or methylprednisolone) **AND Step 2:** immunosuppressant therapy (e.g., methotrexate, azathioprine, cyclosporine, 6-mercaptopurine, chlorambucil, cyclophosphamide)	8/1/2023
			For Chronic inflammatory demyelinating polyneuropathy (CIDP): Step 1: systemic corticosteroids (such as prednisone or methylprednisolone)	8/1/2023
			For Autoimmune Hemolytic Anemia: Step 1: systemic corticosteroids (such as prednisone or methylprednisolone) **AND Step 2:** intolerance or contraindication to another conventional therapy for autoimmune hemolytic anemia (e.g., splenectomy, cyclophosphamide, azathioprine, cyclosporine)	8/1/2023
			Guillain-Barre Syndrome: Step 1: Documented trial, failure, intolerance or contraindication to plasma exchange	8/1/2023
			For Multiple Sclerosis: Step 1: Documented trial, failure, intolerance or contraindication to at least two conventional therapies (such as glatiramer, interferon beta, dimethyl fumarate)	8/1/2023
			For Myasthenia Gravis Refractory disease: Step 1: Documented trial, failure, intolerance or contraindication to at least two of the following conventional therapies: a. Acetylcholinesterase inhibitors (such as pyridostigmine), b. Corticosteroids (such as prednisone, methylprednisolone), c. Immunosuppressive agents (such as azathioprine, cyclosporine, mycophenolate), d. Plasma exchange	8/1/2023

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			Autoimmune mucocutaneous blistering disease: Step 1: One of the following: a. Documented trial, failure or contraindication to systemic corticosteroids with concurrent immunosuppressive treatment (such as azathioprine, cyclophosphamide, mycophenolate mofetil). **OR** Patient has rapidly progressive disease in whom a clinical response could not be affected quickly enough using conventional agents. In such situations documentation that IgG therapy will be given with conventional treatment(s) and only used until the conventional therapy can take effect is required.	8/1/2023
Migraine Agents				
J3032	VYEPTI*	Eptinezumab-jjmr	**ONE of the following: Step 1:** Trial and inadequate response to at least six weeks of at least one prophylactic medication from **one** of the following categories- 1. Anticonvulsants (specifically divalproex, valproate, topiramate), 2. Beta-blockers (specifically metoprolol, propranolol, timolol), 3. Antidepressants (specifically amitriptyline, venlafaxine) **OR** Documented intolerance or contraindication to an anticonvulsant, a beta blocker, **AND** an antidepressant listed above, **AND Step 2: Documented trial and failure, intolerance, or contraindication to TWO** preferred CGRP agents (AIMOVIG*, EMGALITY*, AJOVY*, NURTEC ODT* or QULIPTA*)	10/1/2023: Policy update
Miscellaneous Therapeutics				
J0879	KORSUVA*	Difelikefalin	**For moderate to severe Pruritis associated with chronic kidney disease- Step1**: optimized use of topical emollients **and Step 2:** inadequate response to at least two weeks trial of an oral antihistamine or intolerance/contraindication to antihistamine therapy **AND Step 3:** inadequate response to at least two weeks trial of pregabalin or gabapentin, or intolerance/contraindication to both pregabalin and gabapentin	
J9332	VYVGART*	Efgartigimod alfa - fcab	**For Generalized Myasthenia Gravis (gMG): Step 1:** at least two immunosuppressive agents (such as azathioprine, methotrexate, cyclosporine, mycophenolate, corticosteroids) or an intolerance or contraindication to these therapies	

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Neurologic Agents				
J0202	LEMTRADA*	Alemtuzumab	**Step 1:** OCREVUS **AND Step 2: One of the following**: Interferon-Beta 1a, Interferon-Beta 1b, Generic Dimethyl Fumarate, COPAXONE, TYSABRI, AUBAGIO, GILENYA, VUMERITY, ZEPOSIA, or MAYZENT	Criteria for Multiple Sclerosis thru 9/30/2023
			Step 1: Inadequate response (after at least six months of continuous therapy) to ocrelizumab (OCREVUS***) AND Step 2: One** of the following: a. Inadequate response (after at least six months of continuous therapy) or intolerance to one (1) of the following: generic dimethyl fumarate, generic glatiramer/Glatopa®, generic fingolimod, or generic teriflunomide b. FDA labeled contraindication to ALL the following: generic dimethyl fumarate, generic glatiramer/Glatopa®, generic fingolimod, or generic teriflunomide	10/1/2023: Multiple Sclerosis criteria changes
J2329	BRIUMVI*	Ublituximab	**Documentation of ONE of the following (a b, c, or d) for RRMS, SPMS, CIS:** a. Documentation the patient has highly active disease b. The patient has been treated with at least three multiple sclerosis agents from different drug classes c. Inadequate response (after at least six months of continuous therapy) or intolerance to one of the following: generic dimethyl fumarate, generic glatiramer/Glatopa®, generic fingolimod, or generic teriflunomide d. FDA labeled contraindication to ALL of the following: generic dimethyl fumarate, generic glatiramer/Glatopa®, generic fingolimod, and generic teriflunomide	11/1/2023: New Policy
J2350	OCREVUS*	Ocrelizumab	**Documentation of ONE of the following (a b, c, or d) for RRMS, SPMS, CIS:** a. Documentation the patient has highly active disease b. The patient has been treated with at least three multiple sclerosis agents from different drug classes c. Inadequate response (after at least six months of continuous therapy) or intolerance to one of the following: generic dimethyl fumarate, generic glatiramer/Glatopa®, generic fingolimod, or generic teriflunomide d. FDA labeled contraindication to ALL of the following: generic dimethyl fumarate, generic glatiramer/Glatopa®, generic fingolimod, and generic teriflunomide	11/1/2023: New Policy

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J1300	SOLIRIS*	Eculizumab	**For Paroxysmal Nocturnal Hemoglobinuria (PNH), Complement-Mediated Hemolytic Uremic Syndrome (HUS): Step 1:** Trial and failure, intolerance, or contraindication to ravulizumab-cwvz (ULTOMIRIS*)	8/1/2023: Policy update
			For gMG – Step 1: TWO immunosuppressive therapies (i.e., azathioprine, mycophenolate mofetil, cyclosporine and tacrolimus, corticosteroids) **OR** ONE immunosuppressive therapy of either IVIg* or plasma exchange **AND Step 2**: Trial and failure, intolerance, or contraindication to ravulizumab-cwvz (ULTOMIRIS*)	
			For NMOSD: Step 1: rituximab* **AND Step 2**: satralizumab (ENSPRINYNG*)	8/1/2023: Policy update
J2323	TYSABRI*	Natalizumab	**For Multiple Sclerosis - Step 1: ONE of the following:** Interferon-Beta 1a, Interferon-Beta 1b, Generic Dimethyl Fumarate, COPAXONE, AUBAGIO, GILENYA, ZEPOSIA, MAYZENT or OCREVUS	Criteria for Multiple Sclerosis thru 9/30/2023
			For Multiple Sclerosis - ONE of the following: a. The patient has been treated with at least three multiple sclerosis agents from different drug classes b. Inadequate response (after at least six months of continuous therapy) or intolerance to one (1) of the following: generic dimethyl fumarate, generic glatiramer acetate/GLATOPA®, generic fingolimod, or generic teriflunomide c. FDA labeled contraindication to ALL of the following: generic dimethyl fumarate, generic glatiramer/GLATOPA®, generic fingolimod, and generic teriflunomide	10/1/2023: Multiple Sclerosis criteria changes
			For moderate to severe Crohn's Disease – Step 1: documented trial and failure, intolerance or contraindication to a preferred infliximab product (RENFLEXIS*or INFLECTRA*) and/or adalimumab (HUMIRA*, HADLIMA*)	9/1/2023: Policy update preferred adalimumab products
J1303	ULTOMIRIS*	Ravulizumab-cwvz	**For gMG – Step 1:** Failed treatment for at least a year with ONE of the following: (A.) At least TWO immunosuppressive therapies (ie. azathioprine, mycophenolate mofetil, cyclosporine and tacrolimus, corticosteroids) **OR** (B.) ONE immunosuppressive therapy of either IVIg* or plasma exchange	
J1823	UPLIZNA*	Inebilizumab-cdon	**For NMOSD: Step 1:** Rituximab*	

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Oncology Agents				
Q5126	ALYMSYS*	Bevacizumab-maly	**Step 1:** ZIRABEV* and MVASI*	
J9035	AVASTIN*	Bevacizumab	**Step 1:** ZIRABEV*and MVASI*	
J9355	HERCEPTIN*	Trastuzumab	**Step 1:** KANJINTI*and OGIVRI*	
J9356	HERCEPTIN* HYLECTA	Trastuzumab and hyaluronidase-oysk	**Step 1:** KANJINTI* and OGIVRI*	
Q5113	HERZUMA*	Trastuzumab-pkrb	**Step 1:** KANJINTI* and OGIVRI*	
Q5112	ONTRUZANT*	Trastuzumab-dttb	**Step 1:** KANJINTI* and OGIVRI*	
Q5116	TRAZIMERA*	Trastuzumab-qyyp	**Step 1:** KANJINTI* and OGIVRI*	
Q5129	VEGZELMA*	Bevacizumab-adcd	**Step 1:** ZIRABEV* and MVASI*	4/1/2023
Ophthalmic Agents				
J0179	BEOVU*	Brolucizumab-dbll	**For Neovascular (wet) age-related macular degeneration (AMD), Diabetic macular edema or Diabetic retinopathy: Step 1:** Documentation that ALL the following agents have been ineffective, not tolerated, or contraindicated or rationale is provided why therapy is not appropriate for the patient: 1. bevacizumab, 2. aflibercept (EYLEA), 3. ranibizumab-nuna (BYOOVIZ) or ranibizumab-eqrn (CIMERLI)	8/1/2023: Policy update
Q5128	CIMERLI*	Ranibizumab-eqrn	**For Neovascular (wet) age-related macular degeneration (AMD), Diabetic macular edema, Diabetic retinopathy, or Macular edema following retinal vein occlusion: Step 1:** Bevacizumab (For Ophthalmology Use) **And Step 2:** EYLEA (aflibercept) **And Step 3:** BYOOVIZ (ranibizumab-nuna) **For Myopic Choroidal Neovascularization (mCNV): Step 1:** BYOOVIZ (ranibizumab-nuna) or ranibizumab-eqrn (CIMERLI)	2/1/2023: Update policy to include CIMERLI* 8/1/2023: CIMERLI is preferred, no prior authorization required

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J7351	DURYSTA*	Bimatoprost	Two ophthalmic products from TWO different pharmacological classes, one of which is an ophthalmic prostaglandin **Step 1 Drugs: Ophthalmic prostaglandins:** bimatoprost, latanoprost, travoprost, LUMIGAN, VYZULTA XELPROS **Step 2 Drugs: Ophthalmic beta-adrenergic blocking agents:** betaxolol, BETIMOL, carteolol, levobunolol, timolol maleate **Ophthalmic intraocular pressure lowering agents, other:** ALPHAGAN P, apraclonidine, brimonidine tartrate, brinzolamide, dorolamide, methazolamide, PHOSPHOLINE IODIDE, pilocarpine hcl, RHOPRESSA, SIMBRINZA	
J2778	LUCENTIS*	Ranibizumab	**For Neovascular (wet) age-related macular degeneration (AMD), Diabetic macular edema, Diabetic retinopathy, or Macular edema following retinal vein occlusion: Step 1:** Documentation that ALL the following agents have been ineffective, not tolerated, or contraindicated or rationale is provided why therapy is not appropriate for the patient: 1. bevacizumab, 2. aflibercept (EYLEA), 3. ranibizumab-nuna (BYOOVIZ) or ranibizumab-eqrn (CIMERLI)	8/1/2023: Policy update CIMERLI preferred
			For Myopic Choroidal Neovascularization (mCNV): Step 1: BYOOVIZ (ranibizumab-nuna) or ranibizumab-eqrn (CIMERLI)	8/1/2023: Policy update
J2779	SUSVIMO*	Ranibizumab	**For Neovascular (wet) age-related macular degeneration (AMD) Step 1:** Bevacizumab (For Ophthalmology Use) **AND Step 2:** EYLEA (aflibercept) **AND Step 3:** at least two intravitreal injections of LUCENTIS* (ranibizumab), CIMERLI (ranibizumab-eqrn) or BYOOVIZ (ranibizumab-nuna)	2/1/2023: Update policy to include CIMERLI* 8/1/2023: CIMERLI preferred
J2777	VABYSMO*	Faricimab	**For Neovascular (wet) age-related macular degeneration (AMD), Diabetic macular edema or Diabetic retinopathy: Step 1:** Documentation that ALL the following agents have been ineffective, not tolerated, or contraindicated or rationale is provided why therapy is not appropriate for the patient: 1. bevacizumab, 2. aflibercept (EYLEA), 3. ranibizumab-nuna (BYOOVIZ) or ranibizumab-eqrn (CIMERLI)	2/1/2023: Update policy to include CIMERLI* 8/1/2023: CIMERLI preferred
J3241	TEPEZZA*	Teprotumumab-trbw	**For moderate-to severe thyroid eye disease/Grave's Orbitopathy – Step 1:** Inadequate response to at least two weeks of therapy with high-dose intravenous (IV) glucocorticoid therapy (equivalent to methylprednisolone 0.5 g once weekly) *in combination with mycophenolate*	6/1/2023: Policy update removing mycophenolate prerequisite therapy

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Osteoanabolic Agents				
J3111	EVENITY*	Romosozumab-aqqg	**For treatment and prevention of osteoporosis:** Patient has a spine or hip BMD T-score less than or equal to -2.5 to - 3.0 **and one of the following:** i. Documented failure to anti-resorptive therapy (such as denosumab, bisphosphonates). Failure is defined as a new fracture or worsening BMD while adherent to therapy ii. Documented contraindication or intolerance to therapy with all the following: 1. denosumab, 2. oral bisphosphonate (such as alendronate), and 3. IV bisphosphonate therapy (such as zoledronic acid)	6/1/2023
Rare Disease Agents				
J0791	ADAKVEO*	Crizanlizumab-tmca	**Step 1:** Hydroxyurea	
J0224	OXLUMO*	Lumasiran sodium	**Step 1:** High fluid intake ≥3L/m^2 BSA AND pyridoxine	
Rituximab				
Q5123	RIABNI*	Rituximab-arrx	**For Oncology use - Step 1:** Documented trial and failure, intolerance, or contraindication to the use of both of the preferred biosimilar medications: RUXIENCE* and TRUXIMA*	
			For Rheumatology use - Step 1: ENBREL*, HUMIRA*, or a preferred infliximab product (RENFLEXIS*or INFLECTRA*) **AND Step 2:** Documentation that rituximab-arrx will be used concurrently with methotrexate. If intolerance or contraindication to methotrexate, then in combination with another disease-modifying antirheumatic drug (DMARD) (for example, leflunomide, sulfasalazine, hydroxychloroquine), unless medical rationale is provided to support monotherapy	
			For Immune Thrombocytopenia (ITP) – Step 1: systemic corticosteroids	
			For Refractory Myasthenia Gravis – Step 1: Documented trial, failure, intolerance, or contraindication to at least two of the following conventional therapies: (a) Acetylcholinesterase inhibitors (e.g., pyridostigmine), (b) Corticosteroids (e.g., prednisone, methylprednisolone), (c) Immunosuppressive agents (e.g., azathioprine, cyclosporine, mycophenolate), (d) Plasma exchange	
			For Autoimmune Warm Hemolytic Anemia (AIHA) – Step 1: systemic glucocorticoids	

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J9312	RITUXAN*	Rituximab	**For Oncology use - Step 1:** Documented trial and failure, intolerance, or contraindication to the use of both of the preferred biosimilar medications: RUXIENCE* and TRUXIMA*	
			For Rheumatology use - Step 1: ENBREL*, HUMIRA, or preferred infliximab product (RENFLEXIS*or INFLECTRA*) **AND Step 2:** Documentation that rituximab will be used concurrently with methotrexate. If intolerance or contraindication to methotrexate, then in combination with another disease-modifying antirheumatic drug (DMARD) (for example, leflunomide, sulfasalazine, hydroxychloroquine), unless medical rationale is provided to support monotherapy	
			For Immune Thrombocytopenia (ITP) – Step 1: systemic corticosteroids	
			For Refractory Myasthenia Gravis – Step 1: Documented trial, failure, intolerance, or contraindication to at least two of the following conventional therapies: (a) Acetylcholinesterase inhibitors (e.g., pyridostigmine), (b) Corticosteroids (e.g., prednisone, methylprednisolone), (c) Immunosuppressive agents (e.g., azathioprine, cyclosporine, mycophenolate), (d) Plasma exchange	
			For Autoimmune Warm Hemolytic Anemia (AIHA) – Step 1: systemic glucocorticoids	
J9311	RITUXAN HYCELA*	Rituximab/hyaluronidase, human recombinant	**For Oncology use - Step 1:** Documented trial and failure, intolerance, or contraindication to the use of both of the preferred biosimilar medications: RUXIENCE* and TRUXIMA*	
Q5119	RUXIENCE*	Rituximab-pvvr	**For Rheumatology use- Step 1:** Preferred infliximab product (RENFLEXIS*or INFLECTRA*) **AND Step 2:** Documentation that rituximab-pvvr will be used concurrently with methotrexate. If intolerance or contraindication to methotrexate, then in combination with another disease-modifying antirheumatic drug (DMARD) (for example, leflunomide, sulfasalazine, hydroxychloroquine), unless medical rationale is provided to support monotherapy	
			For Immune Thrombocytopenia (ITP) – Step 1: systemic corticosteroids	

Code	Non-Preferred Drug	Generic name	Prerequisite Drugs	Effective 1/1/2023 *unless otherwise noted*
			For Refractory Myasthenia Gravis – Step 1: Documented trial, failure, intolerance, or contraindication to at least two of the following conventional therapies: (a) Acetylcholinesterase inhibitors (e.g., pyridostigmine), (b) Corticosteroids (e.g., prednisone, methylprednisolone), (c) Immunosuppressive agents (e.g., azathioprine, cyclosporine, mycophenolate), (d) Plasma exchange	
			For Autoimmune Warm Hemolytic Anemia (AIHA) – Step 1: systemic glucocorticoids	
Q5115	TRUXIMA*	Rituximab-abbs	**For Rheumatology use- Step 1:** Preferred infliximab product (RENFLEXIS*or INFLECTRA*) **AND Step 2:** Documentation that rituximab-abbs will be used concurrently with methotrexate. If intolerance or contraindication to methotrexate, then in combination with another disease-modifying antirheumatic drug (DMARD) (for example, leflunomide, sulfasalazine, hydroxychloroquine), unless medical rationale is provided to support monotherapy	
			For Immune Thrombocytopenia (ITP) – Step 1: systemic corticosteroids	
			For Refractory Myasthenia Gravis – Step 1: Documented trial, failure, intolerance, or contraindication to at least two of the following conventional therapies: (a) Acetylcholinesterase inhibitors (e.g., pyridostigmine), (b) Corticosteroids (e.g., prednisone, methylprednisolone), (c) Immunosuppressive agents (e.g., azathioprine, cyclosporine, mycophenolate), (d) Plasma exchange	
			For Autoimmune Warm Hemolytic Anemia (AIHA) – Step 1: systemic glucocorticoids	
Therapeutic Immunomodulators				
J3262	ACTEMRA*	Tocilizumab	**For Rheumatoid Arthritis – Step 1:** At least one conventional therapy (e.g., methotrexate, leflunomide, hydroxychloroquine, sulfasalazine) **AND Step 2:** a preferred infliximab biosimilar (RENFLEXIS*or INFLECTRA*)	
			For Giant cell arteritis – Step 1: At least one conventional therapy (e.g., systemic corticosteroid therapy), **AND Step 2:** a preferred infliximab biosimilar (RENFLEXIS*or INFLECTRA*)	
			For Cytokine Release Syndrome – Step 1: a preferred infliximab biosimilar (RENFLEXIS*or INFLECTRA*)	

Code	Non-Preferred Drug	Generic name	Prerequisite Drugs	Effective 1/1/2023 *unless otherwise noted*
Q5121	AVSOLA*	Infliximab-axxq	**For Ulcerative Colitis and Crohn's Disease** - **Step 1:** documentation of failure, intolerance, or contraindication to both preferred infliximab products (INFLECTRA* **AND** RENFLEXIS*) (regardless of previous use of vedolizumab (ENTYVIO*).)	
			For Rheumatoid Arthritis and Psoriatic Arthritis – Step 1: At least one conventional therapy (e.g., methotrexate, leflunomide, hydroxychloroquine, sulfasalazine) **AND Step 2:** failure, intolerance, or contraindication to both preferred infliximab products (RENFLEXIS* **AND** INFLECTRA*)	
			For moderate to severe Plaque Psoriasis – Step 1: At least one conventional therapy (e.g., methotrexate, tazarotene, topical corticosteroids, calcitriol) **AND Step 2:** failure, intolerance, or contraindication to both preferred infliximab products (RENFLEXIS* **AND** INFLECTRA*)	
			For Immune Checkpoint Inhibitor Related Diarrhea/Colitis – Step 1 IV methylprednisolone, **AND Step 2:** failure, intolerance, or contraindication to both preferred infliximab products (RENFLEXIS* **AND** INFLECTRA*)	
			For all other FDA-Approved indications – Step 1: failure, intolerance, or contraindication to both preferred infliximab products (RENFLEXIS***AND** INFLECTRA*)	
J0717	CIMZIA* (IV)	Certolizumab	**For Crohn's disease – Step 1:** a preferred infliximab biosimilar (RENFLEXIS*or INFLECTRA*) or ENTYVIO*	
			For Rheumatoid Arthritis and Psoriatic Arthritis – Step 1: At least one conventional therapy (e.g., methotrexate, leflunomide, hydroxychloroquine, sulfasalazine) **AND Step 2:** a preferred infliximab biosimilar (RENFLEXIS*or INFLECTRA*)	
			For moderate to severe Plaque Psoriasis– Step 1: At least one conventional therapy (e.g., methotrexate, leflunomide, hydroxychloroquine, sulfasalazine) **AND Step 2:** a preferred infliximab biosimilar (RENFLEXIS*or INFLECTRA*)	
			For ankylosing spondylitis – Step 1: a preferred infliximab biosimilar (RENFLEXIS*or INFLECTRA*)	
			For NRAS (non-radiographic axial spondylarthritis- Step 1: a preferred infliximab biosimilar (RENFLEXIS*or INFLECTRA*)	

Code	Non-Preferred Drug	Generic name	Prerequisite Drugs	Effective 1/1/2023 *unless otherwise noted*
J0638	ILARIS*	Canakinumab/pf	**For SJIA and Adult-Onset Still's Disease: Step 1:** Documentation of trial and failure, intolerance or contraindication to non-steroidal anti-inflammatory drugs (NSAIDS).	
			For Familial Mediterranean Fever (FMF) – Step 1: Colchicine	
J3245	ILUMYA*	Tildrakizumab-asmn	**For moderate to severe Plaque Psoriasis – Step 1:** At least one conventional therapy (e.g., methotrexate tazarotene, topical corticosteroids, calcitriol) **AND Step 2:** a preferred infliximab biosimilar (RENFLEXIS*or INFLECTRA*)	
Q5103	INFLECTRA*	Infliximab-dyyb	**For Ulcerative Colitis and Crohn's Disease - Step 1:** Preferred infliximab products (INFLECTRA* or RENFLEXIS*) or vedolizumab (ENTYVIO*) may be covered.	
			For Rheumatoid Arthritis and Psoriatic Arthritis - Step 1: At least one conventional therapy (e.g., methotrexate, leflunomide, hydroxychloroquine, sulfasalazine)	
			For moderate to severe Plaque Psoriasis – Step 1: At least one conventional therapy (e.g., methotrexate, tazarotene, topical corticosteroids, calcitriol)	
			For immune checkpoint inhibitor related diarrhea/colitis – Step 1: IV methylprednisolone	
J0129	ORENCIA*	Abatacept/maltose	**For Rheumatoid Arthritis and Psoriatic Arthritis and Polyarticular Juvenile Idiopathic Arthritis – Step 1:** At least one conventional therapy (e.g., methotrexate, leflunomide, hydroxychloroquine, sulfasalazine) **AND Step 2:** a preferred infliximab biosimilar (RENFLEXIS*or INFLECTRA*)	
J1745	REMICADE*	Infliximab	**For Ulcerative Colitis and Crohn's Disease - Step 1:** documentation of failure, intolerance, or contraindication to both preferred infliximab products (INFLECTRA* **AND** RENFLEXIS*) (regardless of previous use of vedolizumab (ENTYVIO*)	
			For Rheumatoid Arthritis and Psoriatic Arthritis – Step 1: At least one conventional therapy (e.g., methotrexate, leflunomide, hydroxychloroquine, sulfasalazine) **AND Step 2:** failure, intolerance, or contraindication to both preferred infliximab products (RENFLEXIS* **AND** INFLECTRA*)	

Code	Non-Preferred Drug	Generic name	Prerequisite Drugs	Effective 1/1/2023 *unless otherwise noted*
			<u>For moderate to severe Plaque Psoriasis</u> – Step 1: At least one conventional therapy (e.g., methotrexate, tazarotene, topical corticosteroids, calcitriol) **AND Step 2:** failure, intolerance, or contraindication to both preferred infliximab products (RENFLEXIS* **AND** INFLECTRA*)	
			<u>For Immune Checkpoint Inhibitor Related Diarrhea/Colitis</u> – Step 1: IV methylprednisolone, **AND Step 2:** failure, intolerance, or contraindication to both preferred infliximab products (RENFLEXIS* **AND** INFLECTRA*)	
			<u>For all other FDA-Approved indications</u> – Step 1: failure, intolerance, or contraindication to both preferred infliximab products (RENFLEXIS***AND** INFLECTRA*)	
Q5104	RENFLEXIS*	Infliximab-abda	**<u>For Ulcerative Colitis and Crohn's Disease</u>** - **Step 1:** Preferred infliximab products (INFLECTRA* or RENFLEXIS*) or vedolizumab (ENTYVIO*) may be covered.	
			<u>For Rheumatoid Arthritis and Psoriatic</u> Arthritis – Step 1: At least one conventional therapy (e.g., methotrexate, leflunomide, hydroxychloroquine, sulfasalazine)	
			<u>For moderate to severe plaque psoriasis</u> – Step 1: At least one conventional therapy (e.g., methotrexate, tazarotene, topical corticosteroids, calcitriol)	
			<u>For immune checkpoint inhibitor related diarrhea/colitis</u> – Step 1: IV methylprednisolone	
J1602	SIMPONI ARIA*	Golimumab	**<u>For Rheumatoid Arthritis and Psoriatic Arthritis</u> – Step 1:** At least one conventional therapy (e.g., methotrexate, leflunomide, hydroxychloroquine, sulfasalazine) **AND Step 2:** a preferred infliximab biosimilar (RENFLEXIS*or INFLECTRA*)	
			<u>For ankylosing spondylitis</u> – Step 1: a preferred infliximab biosimilar (RENFLEXIS*or INFLECTRA*)	
J2327	SKYRIZI* (IV)	Risankizumab-rzaa	**<u>For Crohn's disease</u> – Step 1: a** preferred infliximab biosimilar (RENFLEXIS*or INFLECTRA*) or ENTYVIO*	
			Note: *Intravenous risankizumab-rzaa is indicated for three induction doses for Crohn's disease. Subcutaneous risankizumab-rzaa is eligible for coverage under Medicare Part D for self-administration for subsequent doses.*	

Code	Non-Preferred Drug	Generic name	Prerequisite Drugs	Effective 1/1/2023 *unless otherwise noted*
			For moderate to severe Plaque Psoriasis – Step 1: At least one conventional therapy (e.g., methotrexate, tazarotene, topical corticosteroids, calcitriol) **AND** **Step 2:** a preferred infliximab biosimilar (RENFLEXIS*or INFLECTRA*)	
			For Psoriatic Arthritis – Step 1: At least one conventional therapy (e.g., methotrexate, leflunomide, hydroxychloroquine, sulfasalazine) **AND Step 2:** a preferred infliximab biosimilar (RENFLEXIS*or INFLECTRA*)	
J3358	STELARA* (IV)	Ustekinumab	**For Crohn's disease and Ulcerative colitis – Step 1: a** preferred infliximab biosimilar (RENFLEXIS*or INFLECTRA*) or ENTYVIO*	
			Note: *Intravenous ustekinumab is indicated for a one-time induction dose for Crohn's disease and ulcerative colitis. Subcutaneous ustekinumab is eligible for coverage under Medicare Part D for self-administration for subsequent doses.*	
Thrombocytopenia Medications				
J2796	NPLATE*	Romiplostim	**For Immune Thrombocytopenia (ITP) – Pharmacologic Step 1:** systemic corticosteroids **or Step 2:** Immune globulin **or Step 3:** Rituximab*	

Diabetic Durable Medical Equipment (DME)

HCPCS CODE	Preferred Products	Non-Preferred Product Criteria	Effective 1/1/2023 *unless otherwise noted*
A4253	ONETOUCH BLOOD GLUCOSE TEST STRIPS – MANUFACURED BY LIFESCAN	1. Patient is using and insulin pump that requires a meter that synchronizes with their pump. **OR**	
	ACCU-CHEK BLOOD GLUCOSE TEST STRIPS - MANUFACTURED BY ROCHE	**2.** Physical or mental limitations that makes utilizing **BOTH** of the preferred products (manufactured by Roche and LifeScan) unsafe, inaccurate, or otherwise not feasible.	
E0607	ONETOUCH BLOOD GLUCOSE METERS – MANUFACURED BY LIFESCAN	1. Patient is using and insulin pump that requires a meter that synchronizes with their pump. **OR**	
	ACCU-CHEK BLOOD GLUCOSE METERS - MANUFACTURED BY ROCHE	**2.** Physical or mental limitations that makes utilizing **BOTH** of the preferred products (manufactured by Roche and LifeScan) unsafe, inaccurate, or otherwise not feasible.	