Policy Title:	Medically Administered Step Therapy Policy		
		Department:	PHA
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Purpose: To support the use of preferred products that are safe and effective.

Scope: Medicare

Policy Statement:

The Medically Administered Step Therapy Policy will provide coverage of preferred medications when it is determined to be medically necessary and is covered under the Medical Benefit when used within the following guidelines. Use outside of these guidelines may result in non-payment unless approved under an exception process.

Procedure:
Coverage of Medically administered drugs will be reviewed prospectively via the prior authorization process based on criteria below.
Medicare members who have previously received the requested medication within the past 365 days are not subject to Step Therapy Requirements.

Medications that Require Step Therapy	Preferred Medication(s)	Class of Medication
Aralast or Glassia	Emphysema due to alpha-1-antitrypsin (AAT) deficiency: Trial of Prolastin or Zemaira	Alpha-1-Proteinase Inhibitors
Duopa	Trial of all of the following - oral levodopa/carbidopa, a dopamine agonist, a catechol-O-methyl transferase (COMT) inhibitor OR a monoamine oxidase B (MAO)-B inhibitor	Anti- Parkinson Agent

Vyalev	Trial of at least two of the following from different drug classes: a dopamine agonist, a catechol-O-methyl transferase (COMT) inhibitor OR a monoamine oxidase B (MAO)-B inhibitor AND taking ≥400 mg of levodopa per day	Anti- Parkinson Agent
Linezolid: J2021	All indications: Trial and failure or contraindication to linezolid J2020	Antibiotic
Meropenem: J2184	All indications: Trial and failure or contraindication to meropenem J2183 and J2185	Antibiotic
Vancomycin: J3372	All indications: Trial and failure or contraindication to vancomycin J3371 and J3370	Antibiotic
Heparin: J1643	All indications: Trial and failure or contraindication to heparin J1644	Anticoagulant Agent
Alhemo	Hemophilia A without inhibitors: has had a trial of Hemlibra and had previous prophylaxis therapy with an antihemophilic Factor VIII agent product (e.g., Advate, Koate/Koate DVI, Hemofil, etc.) Hemophilia A with inhibitors: has had a trial of Hemlibra and has had previous prophylaxis therapy with an antihemophilic Factor VIII agent product (e.g., Advate, Koate/Koate DVI, Hemofil, etc. with bypassing agent [i.e., Novoseven, FEIBA, etc.]) Hemophilia B without inhibitors: has had a trial of Factor IX agent (e.g., Benefit, Alprolix, Idelvion, Rebinyn, etc.) prophylaxis Hemophilia B with inhibitors: has had a trial of Factor IX agent (e.g., Benefit, Alprolix, Idelvion, Rebinyn, etc. with bypassing agents, [i.e., Novoseven, FEIBA, etc.])	Antihemophilic Agent
Alphanate, Humate-P, Wilate	von Willebrand disease (mild or moderate): Trial of desmopressin	Antihemophilic Agent
Feiba	Hemophilia A: has had a trial of Hemlibra	Antihemophilic Agent

Hemlibra	Hemophilia A (congenital factor VIII deficiency) with inhibitors: trial of one of the following bypassing agents - NovoSeven, Feiba Hemophilia A (congenital factor VIII deficiency) without inhibitors: Member is not a suitable candidate for treatment with a shorter half-life Factor VIII products at a total weekly dose of 100 IU/kg or less	Antihemophilic Agent
Hympavzi	Hemophilia A (congenital factor VIII deficiency) without inhibitors: trial of a factor VIII product (e.g., Advate, Koate/Koate DVI, Hemofil, etc.) and Hemlibra Hemophilia A (congenital factor VIII deficiency) with inhibitors: trial of a Factor VIII agent product (e.g., Advate, Koate/Koate DVI, Hemofil, etc. with bypassing agent [i.e., Novoseven, FEIBA, etc.]) Hemophilia B (congenital factor IX deficiency) without inhibitors: trial of a factor IX product (e.g., Benefix, Rixubis, Alphanine, etc.) Hemophilia B with inhibitors: has had a trial of Factor IX agent (e.g., Benefit, Alprolix, Idelvion, Rebinyn, etc. with bypassing agents, [i.e., Novoseven, FEIBA, etc.])	Antihemophilic Agent
Novoseven RT	Hemophilia A: has had a trial of Hemlibra	Antihemophilic Agent
Qfitlia	Hemophilia A: has had a trial of at least one factor VIII product (e.g., Advate, Koate/Koate DVI, Hemofil, etc. with or without bypassing agent) AND Hemlibra AND one of the following: Alhemo, or Hympavzi Hemophilia B: has had a trial of at least one factor IX product (e.g., BeneFIX, Alprolix, Idelvion, Rebinyn, etc. with or without bypassing agent [i.e., Novoseven, FEIBA, etc.]) AND Alhemo	Antihemophilic Agent
Vonvendi	von Willebrand disease (mild or moderate): Trial of desmopressin	Antihemophilic Agent
Labetalol: J1921	All indications: Trial and failure or contraindication to labetalol J1920	Antihypertensive Agent

Vyepti	Chronic Migraines: 3-month trial of two oral medications from two different classes of drugs for the prevention of migraines AND trial of at least 12 weeks of one calcitonin gene-related peptide (CGRP) antagonist (e.g., erenumab, galcanezumab, fremanezumab, etc.) AND two quarterly injections of botulinum toxin Episodic migraines: 3-month trial of two oral medications from two different classes of drugs for the prevention of migraines AND trial of at least 12 weeks of one calcitonin gene-related peptide (CGRP) antagonist (e.g., erenumab, galcanezumab, fremanezumab, etc.)	Anti-migraine Agent
Bortezomib: J9048, J9046	All indications: Trial and failure or contraindication to bortezomib J9049, J9051, and J9041	Antineoplastic Agent
Carmustine: J9052	All indications: Trial and failure or contraindication to carmustine J9050	Antineoplastic Agent
Cyclophosphamide: J9074	All indications: Trial and failure or contraindication to cyclophosphamide J9073, J9071, and J9075	Antineoplastic Agent
Fulvestrant: J9394, J9393	All indications: Trial and failure or contraindication to fulvestrant J9395	Antineoplastic Agent
Paclitaxel: J9259	All indications: Trial and failure or contraindication to paclitaxel J9264	Antineoplastic Agent
Pemetrexed: J9304, J9324	All indications: Trial and failure or contraindication to pemetrexed J9296, J9294, J9297, J9314, J9323, and J9305	Antineoplastic Agent
Amvuttra	Cardiomyopathy of wild-type or hereditary transthyretin-mediated amyloidosis (ATTR-CM): Trial of a transthyretin (TTR) stabilizer (e.g., acoramidis (Attruby) or tafamidis (Vyndaqel/Vyndamax)	Anti-Transthyretin small interfering RNA (siRNA)
Onpattro	Cardiomyopathy of wild-type or hereditary transthyretin-mediated amyloidosis (ATTR-CM) and polyneuropathy of hereditary transthyretin-mediated amyloidosis (ATTR-PN) if Onpattro in used in in combination with a TTR-stabilizer: Trial of Amvuttra (vutrisiran)	Anti-Transthyretin small interfering RNA (siRNA)
Ganciclovir: J1574	All indications: Trial and failure or contraindication to ganciclovir J1570	Antiviral Agent
Sunlenca	Human immunodeficiency virus type 1 (HIV-1): Patient has heavily treated multi-drug resistant disease to at least two drugs in at least three classes, such as	Antiviral Agent

	Nucleoside reverse transcription inhibitor (NRTI): abacavir, emtricitabine, lamivudine, stavudine, tenofovir disoproxil fumarate, zidovudine; Non-nucleoside reverse transcription inhibitor (NNRTI): delaviridine, efavirenz, rilpivirine, nevirapine, etravirine, doravirine; Protease inhibitor (PI): atazanavir, darunavir, fosamprenavir, nelfinavir, ritonavir, tipranavir; CCR5 Antagonist: Maraviroc or Integrase strand transfer inhibitor (INSTI): raltegravir, dolutegravir, elvitegravir AND failing on their current anti-retroviral regimen for at least 2 months	
Actemra, Tofidence	All indications: trial of at least a 3-month trial of Tyenne (tocilizumab-aazg) Rheumatoid Arthritis: Trial of at least a 3-month trial of methotrexate or any other conventional disease-modifying antirheumatic drug (DMARD); AND at least a 3-month trial of adalimumab at maximum tolerated doses Systemic Juvenile Idiopathic Arthritis (sJIA) / Polyarticular Juvenile Idiopathic Arthritis (pJIA): 1 month trial of an NSAID OR an oral disease modifying anti-rheumatic drug (DMARD) such as methotrexate, leflunomide, sulfasalazine : AND at least a 3-month trial of adalimumab at maximum tolerated doses Management of Immune Checkpoint Inhibitor related Inflammatory Arthritis: Trial of corticosteroids Giant Cell Arteritis: Trial of glucocorticoid therapy	Autoimmune
Tyenne	Rheumatoid Arthritis: Trial of at least a 3-month trial of methotrexate or any other conventional disease-modifying antirheumatic drug (DMARD); AND at least a 3-month trial of adalimumab at maximum tolerated doses Systemic Juvenile Idiopathic Arthritis (sJIA)/ Polyarticular Juvenile Idiopathic Arthritis (pJIA): 1 month trial of an NSAID OR an oral disease modifying anti-rheumatic drug (DMARD)such as methotrexate, leflunomide, sulfasalazine AND at least a 3-month trial of adalimumab at maximum tolerated doses Management of Immune Checkpoint Inhibitor related Inflammatory Arthritis: Trial of corticosteroids	Autoimmune

	Giant Cell Arteritis: Trial of glucocorticoid therapy	
Cimzia	Rheumatoid Arthritis: Trial of at least a 3-month trial of methotrexate or any other conventional synthetic DMARD AND at least a 3-month trial of adalimumab at maximum tolerated doses Ankylosing spondylitis and non-radiographic axial spondyloarthritis: Trial of at least 2 non-steroidal anti-inflammatory drugs (NSAIDs) AND at least a 3-month trial of adalimumab at maximum tolerated doses Crohn's Disease: Trial of at least a 3-month trial of adalimumab or infliximab IV at maximum tolerated doses; AND at least a 6-month trial of ustekinumab at maximum tolerated doses. Plaque Psoriasis: Inadequate response to topical therapy (corticosteroids, calcineurin inhibitors (e.g., tacrolimus), vitamin D analogs (e.g., calcipotriene), retinoids (e.g., tazarotene) AND a trial of at least a 3-month trial of conventional agents(e.g., methotrexate, cyclosporine, or acitretin); OR at least a 3-month trial of phototherapy (e.g., UVB, PUVA) AND at least a 3-month trial of adalimumab at maximum tolerated doses AND at least a 6-month trial of ustekinumab at maximum tolerated doses. Psoriatic Arthritis: For mild to moderate disease: Trial of methotrexate or another conventional synthetic DMARD (e.g., leflunomide, sulfasalazine, etc.) AND at least a 3-month trial of adalimumab AND at least 6-month trial of ustekinumab at maximum tolerated doses For severe disease: Trial of at least a 3-month trial of adalimumab AND at least 6-month trial of ustekinumab at maximum tolerated doses	Autoimmune
Cosentyx	Psoriatic Arthritis: For mild to moderate disease: Trial of methotrexate or another conventional synthetic DMARD (e.g., leflunomide, sulfasalazine, etc.) AND at least a 3-month trial of adalimumab AND at least 6-month trial of ustekinumab at maximum tolerated doses	Autoimmune

	For severe disease: Trial of at least a 3-month trial of adalimumab AND at least 6-month trial of ustekinumab at maximum tolerated doses Ankylosing spondylitis and non-radiographic axial spondyloarthritis: Trial of at least 2 non-steroidal anti-inflammatory drugs (NSAIDs) AND at least a 3-month trial of adalimumab at maximum tolerated doses	
Entyvio	Crohn's Disease: Trial of at least a 3-month trial of adalimumab or infliximab IV at maximum tolerated doses AND at least a 6-month trial of ustekinumab at maximum tolerated doses. Ulcerative Colitis: Trial of at least a 3-month trial of infliximab IV at maximum tolerated doses AND at least a 6-month trial of ustekinumab at maximum tolerated doses Management of Immune Checkpoint Inhibitor related diarrhea/colitis: Trial of systemic corticosteroids or IV infliximab	Autoimmune
Ilaris	Still's Disease and Systemic Juvenile Idiopathic Arthritis: Trial of at least one month of one oral NSAID OR systemic glucocorticoid (e.g., prednisone, methylprednisolone) Familial Mediterranean Fever: colchicine Gout Flare: NSAID and colchicine	Autoimmune
Ilumya	Plaque psoriasis: Inadequate response to topical therapy (corticosteroids, calcineurin inhibitors (e.g., tacrolimus), vitamin D analogs (e.g., calcipotriene), retinoids (e.g., tazarotene) AND a trial of at least a 3-month trial of conventional agents (e.g., methotrexate, cyclosporine, or acitretin); OR at least a 3-month trial of phototherapy (e.g., UVB, PUVA); AND to at least a 3-month trial of adalimumab at maximum tolerated doses AND at least a 6-month trial of ustekinumab at maximum tolerated doses	Autoimmune
Omvoh	Ulcerative Colitis or Crohn's disease: Trial of at least a 3-month trial of infliximab IV or adalimumab at maximum tolerated AND at least a 6-month trial of ustekinumab at maximum tolerated doses	Autoimmune
Orencia	Rheumatoid Arthritis: 3-month trial of methotrexate or any other conventional disease-modifying antirheumatic drug (DMARD) AND at least a 3-month trial of adalimumab at maximum tolerated doses	Autoimmune

	Polyarticular juvenile idiopathic arthritis: 1-month Trial of oral non-steroidal anti-inflammatory drugs (NSAIDs) OR an oral disease-modifying anti-rheumatic agent (DMARD) (e.g., methotrexate, leflunomide, sulfasalazine, etc.) AND at least a 3-month trial of adalimumab at maximum tolerated doses Psoriatic Arthritis: For members with mild to moderate disease a trial of methotrexate, or another conventional synthetic DMARD (e.g., leflunomide, sulfasalazine, etc.) AND at least a 3-month trial of adalimumab at maximum tolerated doses AND at least a 6-month trial of ustekinumab at maximum tolerated doses Chronic Graft Versus Host Disease: Trial and failure of systemic corticosteroids Management of Immune Checkpoint Inhibitor Related Toxicity: Trial and failure of methylprednisolone	
Remicade or infliximab unbranded	All indications: Trial of Inflectra or Avsola, AND Renflexis	Autoimmune
Remicade or infliximab unbranded, Renflexis	Rheumatoid Arthritis: Trial of at least a 3-month trial of methotrexate or any other conventional synthetic DMARD AND used in combination with methotrexate Psoriatic Arthritis: For mild to moderate disease: Trial of methotrexate or another conventional synthetic DMARD (e.g., leflunomide, sulfasalazine, etc.) Ankylosing Spondylitis: Trial of two NSAIDs Plaque Psoriasis: Inadequate response to topical therapy (corticosteroids, calcineurin inhibitors (e.g., tacrolimus), vitamin D analogs (e.g., calcipotriene), retinoids (e.g., tazarotene) AND a trial of at least a 3-month trial of conventional agents(e.g., methotrexate, cyclosporine, or acitretin); OR at least a 3-month trial of phototherapy (e.g., UVB, PUVA); Management of Immune Checkpoint Inhibitor related diarrhea/colitis: Trial of systemic corticosteroids	Autoimmune
Renflexis	All indications: Trial of Inflectra or Avsola	Autoimmune

Infliximab SC products: Zymfentra	Crohn's Disease and Ulcerative Colitis: Trial of at least 10 weeks of IV infliximab therapy	Autoimmune
Golimumab Products: Simponi Aria and Biosimilars	Rheumatoid Arthritis: 3-month trial of methotrexate or any other conventional disease-modifying antirheumatic drug (DMARD); AND at least a 3-month trial of adalimumab at maximum tolerated doses Psoriatic Arthritis: Trial of methotrexate or another conventional synthetic DMARD (e.g., leflunomide, sulfasalazine, etc.) AND at least a 3-month trial of adalimumab at maximum tolerated doses AND at least a 6-month trial of ustekinumab at maximum tolerated doses for members 18 years of age and older OR for members 6 years of age and older but under 18 at least a 6-month trial of ustekinumab at maximum tolerated doses Ankylosing Spondylitis: Trial of two NSAIDs AND at least a 3-month trial of adalimumab at maximum tolerated doses Polyarticular Juvenile Idiopathic Arthritis (pJIA): 1-month trial of oral NSAIDs OR 1-month trial of an oral DMARD such as methotrexate, sulfasalazine, or leflunomide; AND at least a 3-month trial of adalimumab at maximum tolerated doses	Autoimmune
Skyrizi IV	Crohn's disease & Ulcerative Colitis: Trial of at least a 3-month trial of infliximab IV or adalimumab at maximum tolerated doses AND at least a 6-month trial of ustekinumab at maximum tolerated doses	Autoimmune
Ustekinumab IV preferred biosimilar products: Otulfi, Selarsdi, Steqeyma, & Yesintek	Crohn's Disease: Trial of at least a 3-month trial of infliximab IV or adalimumab at maximum tolerated doses(if over 6 years of age) Ulcerative Colitis: Trial of at least a 3-month trial of infliximab IV or adalimumab at maximum tolerated	Autoimmune
Stelara and non-preferred ustekinumab biosimilars (e.g., Imuldosa, Wezlana, Pyzchiva, Starjemza)	Crohn's Disease: Trial of at least a 3-month trial of infliximab IV or adalimumab at maximum tolerated doses (if over 6 years of age) AND at least a 6-month trial of one of the following: Otulfi, Selarsdi, Steqeyma, or Yesintek at maximum tolerated doses Ulcerative Colitis: Trial of at least a 3-month trial of infliximab IV or adalimumab at maximum tolerated AND at least a 6-month trial of one of the following: Otulfi, Selarsdi, Steqeyma, or Yesintek at maximum tolerated doses	Autoimmune

Tremfya IV	Ulcerative Colitis or Crohn's disease: Trial of at least a 3-month trial of infliximab IV or adalimumab at maximum tolerated AND at least a 6-month trial of ustekinumab biosimilar at maximum tolerated doses	Autoimmune
Rebyota	Prevention of recurrence of Clostridioides difficile infection (CDI): Member has at least one reoccurrence after a primary episode and has completed at least 1round of standard of care oral antibiotic therapy (e.g., metronidazole, fidaxomicin)	Biotherapeutic Agent
Evenity	Osteoporosis: 12-month trial of bisphosphonates (oral and/or IV) such as alendronate, risedronate, ibandronate, or zoledronic acid AND 12-month trial of RANKL-blocking agents such as denosumab	Bone Modifying Agent
Prolia and non-preferred denosumab biosimilars (e.g., Jubbonti, Bomyntra, Ospomyv; Aukelso)	Trial of Zometa/Reclast or Aredia AND a trial of Stoboclo or Bildyos.	Bone Modifying Agent
Xgeva and non-preferred denosumab biosimilars (e.g., Wyost, Conexxence, Xbryk, Bosaya)	Trial of Zometa/Reclast or Aredia AND a trial of Osenvelt or Bilprevda.	Bone Modifying Agent
Parsabiv	Hyperparathyroidism secondary to chronic kidney disease: Trial of Sensipar (cinacalcet) at maximum tolerated doses	Calcimimetic
Miacalcin	Hypercalcemic emergency: Trial of cinacalcet Paget's disease: trial of both of the following - alendronate and pamidronate Postmenopausal osteoporosis: Trial of two of the following - zoledronic acid, alendronate, teriparatide, denosumab biosimilar),	Calcitonin
Evkeeza	Homozygous Familial Hypercholesterolemia (HoFH): At least a 3-month trial of adherent therapy with: ezetimibe used in combination with the highest available dose of atorvastatin OR rosuvastatin and tried and failed at least a 3-month trial of adherent therapy with: combination therapy consisting of the highest available dose of atorvastatin OR rosuvastatin, ezetimibe, AND a PSCK9 inhibitor indicated for HoFH (e.g., evolocumab, alirocumab)	Cardiology

Leqvio	Atherosclerotic cardiovascular disease (ASCVD) and : Heterozygous Familial Hypercholesterolemia (HeFH): trial of highest available dose or maximally-tolerated dose***** of high intensity HMG-CoA reductase inhibitors (i.e., 'statin' therapy: atorvastatin 40 mg or 80 mg daily, rosuvastatin 20 mg or 40 mg daily, or simvastatin 80 mg daily); and has been adherent to ezetimibe used concomitantly with a statin at maximally tolerated dose for at least three months, and inadequate treatment response, intolerance or contraindication to treatment with PCSK9 inhibitor therapy for at least 3 months	Cardiology
Abecma	Relapsed/Refractory multiple myeloma: progressed on 4 or more lines of therapy AND refractory to an immunomodulatory agent (e.g., lenalidomide, thalidomide, pomalidomide), a proteasome inhibitor (e.g., bortezomib, carfilzomib, ixazomib), and an anti-CD38 monoclonal antibody (e.g., daratumumab, isatuximab).	CAR-T Immunotherapy
Kymriah	Pediatric and Young Adult Relapsed or Refractory (r/r) B-cell Acute Lymphoblastic Leukemia (ALL): Member has relapsed/refractory Philadelphia chromosome-negative B-ALL that has progressed after 2 cycles of a standard chemotherapy regimen for initial diagnosis OR after 1 cycle of standard chemotherapy for relapsed leukemia OR member with relapsed/refractory Philadelphia chromosome-positive B-ALL that has progressed after failure of 2 prior regimens, including a TKI-containing regimen Adult Relapsed or Refractory (r/r) Large B-cell Lymphoma: For diffuse large B-cell lymphoma arising from follicular lymphoma, high-grade B- cell lymphoma: Member has previously received at least 2 lines of therapy including rituximab and an anthracycline	CAR-T Immunotherapy
Yescarta	Non-Hodgkin Lymphomas (chemotherapy – refractory disease): trial and failure of two or more lines of systemic chemotherapy OR for DLBCL, failure of 2 or more lines of systemic chemotherapy, including rituximab and an anthracycline Follicular Lymphoma: trial of 2 or more lines of systemic therapies, including the combination of an anti-CD20 monoclonal antibody and an alkylating agent (e.g., R-bendamustine, R-CHOP, R-CVP)	CAR-T Immunotherapy
Empaveli	Complement 3 glomerulopathy (C3G) or primary immune-complex membranoproliferative glomerulonephritis (IC-MPGN): Stable dose of renin-	Complement Inhibitor

	angiotensin system (RAS) inhibitor therapy (e.g., angiotensin converting enzyme inhibitor [ACEI] or angiotensin II receptor blocker [ARB]) for at least 3 months prior to initiation of therapy	
Amondys 45	All indications: Trial of corticosteroids	Duchenne Muscular Dystrophy
Exondys 51	All indications: Trial of corticosteroids	Duchenne Muscular Dystrophy
Viltepso	All indications: Trial of corticosteroids	Duchenne Muscular Dystrophy
Vyondys 53	All indications: Trial of corticosteroids for at least 6 months and Viltepso	Duchenne Muscular Dystrophy
Elevidys	All Indications: Stable dose of a corticosteroid prior to the start of therapy	Duchenne Muscular Dystrophy
Nexviazyme	Trial of Lumizyme for members <30kg that require a dose of 40 mg/kg	Enzyme
Pombiliti and Opfolda	Trial of Lumizyme or Nexviazyme	Enzyme
Casgevy	Sickle Cell Disease: Trial of hydroxyurea and formulary add-on therapy (e.g., Adakveo)	Gene Therapy
Lyfgenia	Sickle Cell Disease: Trial of hydroxyurea and formulary add-on therapy (e.g., Adakveo) AND has a contraindication to or is not indicated for treatment with Casgevy (exagamglogene autotemcel)	Gene Therapy
Papzimeos	Recurrent respiratory papillomatosis (RRP): Required at least 3 interventions (e.g., surgery, systemic therapy [i.e., bevacizumab, cidofovir], etc.) in the previous 12 months	Gene Therapy
Krystexxa	All indications: At least a 3-month trial of Allopurinol or Probenecid	Gout
Aranesp	All indications: Trial of Retacrit or Procrit	Hematopoetic Agent
Long-Acting Colony Stimulating Factors – Non-Preferred: Fulphila, Nyvepria, Fylnetra, Rolvedon, Stimufend, Udenyca (Oncology and Non-Oncology)	All approved indications: Trial of Neulasta, Neulasta Onpro, or Ziextenzo	Hematopoetic Agent
Mircera	All indications: Trial of Retacrit or Procrit	Hematopoetic Agent
Epogen	All indications: Trial of Retacrit or Procrit	Hematopoetic Agent
Short Acting Colony Stimulating Factors: Nivestym, Neupogen, Nypozi,	All indications: Trail of Zarxio	Hematopoetic Agent

Granix, Releuko (Oncology and Non Oncology)		
Berinert	Trial of high dose antihistamine (e.g., cetirizine 40mg per day or the equivalent) for at least one month for members with normal C1 inhibitor levels and a family history of angioedema without genetic testing	Hereditary Angioedema
Cinryze	All indications: Trial of "on-demand" therapy (i.e., Ekterly, Kalbitor, icatibant, Ruconest, or Berinert) HAE with normal C1INH: trial of prophylactic therapy with an antifibrinolytic agent (e.g., tranexamic acid (TXA) or aminocaproic acid) and/or a 17α-alkylated androgen (e.g., danazol)	Hereditary Angioedema
Haegarda	All indications: Trial of "on-demand" therapy (i.e., Ekterly, Kalbitor, icatibant, Ruconest, or Berinert) Trial of high dose antihistamine (e.g., cetirizine 40mg per day or the equivalent) for at least one month for members with normal C1 inhibitor levels and a family history of angioedema without genetic testing	Hereditary Angioedema
Kalbitor	Trial of high dose antihistamine (e.g., cetirizine 40mg per day or the equivalent) for at least one month for members with normal C1 inhibitor levels and a family history of angioedema without genetic testing AND for members 18 years of age and older, a trail of icatibant	Hereditary Angioedema
Ruconest	Trial of high-dose antihistamine (e.g., cetirizine 40mg per day or the equivalent) for at least one month for members with normal C1 inhibitor levels and a family history of angioedema without genetic testing AND for members 18 years of age and older, a trail of icatibant	Hereditary Angioedema
Testopel	All indications: 3-month trial of one topical testosterone product (patch or gel) AND Trial of one injectable testosterone such as testosterone cypionate injection or testosterone enanthate injection	Hormone Replacement
Serostim	HIV wasting: Trial of at least three alternative therapies such as cyproheptadine, dronabinol, megestrol acetate or testosterone therapy if hypogonadal	Hormone Therapy
Fensolvi	Central Precocious Puberty: Trial of Lupron Depot-Ped AND either Triptodur or Supprelin LA	Hormone Therapy
Supprelin LA	Central Precocious Puberty: Trial of Lupron Depot-Ped	Hormone Therapy

Triptodur	Central Precocious Puberty: Trial of Trelstar Gender Dysphoria: Trial of Lupron Depot	Hormone Therapy
Euflexxa	All indications: 3-month trial of nonsteroidal anti-inflammatory drugs (NSAIDs), acetaminophen (up to 1 g 4 times/day) and/or topical capsaicin cream, and intra-articular steroids	Hyaluronic Acid
Durolane, Gel-One, Gelsyn, GenVisc 850, Hyalgan, Hymovis, Hymovis One, Monovisc, Orthovisc, Supartz/Supartz FX, Synojoynt, Synvisc, Synvisc-One, Triluron, Trivisc, &Visco-3	All indications: 3-month trial of nonsteroidal anti-inflammatory drugs (NSAIDs), acetaminophen (up to 1 g 4 times/day) and/or topical capsaicin cream, and intra-articular steroids and Euflexxa	Hyaluronic Acid
Crysvita	Adult members with X-linked hypophosphatemia: Trial of an oral phosphate and active vitamin D analogs (e.g., calcitriol, paricalcitol, doxercalciferol, calcifediol)	Hypophosphatemia
Subcutaneous Immune Globulins (IG) Cuvitru, Cutaquig, Xembify, Hizentra or Hyqvia	All indications: Trial of one of the following - Gammaked/Gamunex-C or Gammagard liquid ERC Chronic Inflammatory Demyelinating Polyneuropathy (CIDP): Re-initiation of maintenance therapy ONLY: trial of at least 3 months of corticosteroids	Immune Globulins
Intravenous Immune Globulins (IG): Asceniv, Alyglo, Bivigam, Gammagard S/D, Gammaplex, Privigen, Qivigy, Yimmugo or Panzyga	All indications: Gammaked/Gamunex-C, Gammagard liquid ERC, Flebogamma/Flebogamma DIF, or Octagam IgG Subclass Deficiency: member is receiving prophylactic antibiotic therapy Myasthenia Gravis: member is failing on conventional immunosuppressant therapy alone (e.g., corticosteroids, azathioprine, cyclosporine, mycophenolate, methotrexate, tacrolimus, cyclophosphamide, etc.) Dermatomyositis or Polymyositis: Trial of one corticosteroid AND one immunosuppressant (e.g., methotrexate, azathioprine) Chronic Inflammatory Demyelinating Polyneuropathy:	Immune Globulins

	Trial of one corticosteroid Stiff-Person syndrome: Trial of two of the following - benzodiazepines, baclofen, gabapentin, valproate, tiagabine, or levetiracetam Autoimmune Mucocutaneous Blistering Diseases: corticosteroids and concurrent immunosuppressive treatment (e.g., azathioprine, cyclophosphamide, mycophenolate mofetil, etc.)	
Monoferric	Trial of Injectafer or Feraheme	Iron Agent
Gazyva	Lupus Nephritis (LN): member is receiving in combination with standard immunosuppressive LN therapy (e.g., corticosteroids plus mycophenolate, azathioprine, or cyclophosphamide)	Lupus Nephritis
Benlysta	Systemic Lupus Erythematosus: Trial of two standard therapies such as antimalarials, corticosteroids, non-steroidal anti-inflammatory drugs, or immunosuppressives Lupus Nephritis: Trial of standard therapies including corticosteroids AND either cyclophosphamide or mycophenolate mofetil	Lupus
Saphnelo	Trial of two standard of care therapy such as antimalarials, corticosteroids, non-steroidal anti-inflammatory drugs, or immunosuppressives and trial of Benlysta	Lupus
Sublocade	All indications: initiated treatment with a single dose of transmucosal buprenorphine (4mg)	Medication Assisted Treatment
Brixadi	All indications: initiated therapy with transmucosal buprenorphine at a dose of at least 4mg or is transitioning from another buprenorphine-containing treatment	Medication Assisted Treatment
Cinqair	Asthma: Trial of Inhaled corticosteroid; AND an additional controller medication (long-acting beta 2-agonist, long-acting muscarinic antagonists, or leukotriene modifier,); AND Nucala or Fasenra	Monoclonal Antibody
Exdensur	Asthma: Trial of Inhaled corticosteroid; AND an additional controller medication (long-acting beta 2-agonist, long-acting muscarinic antagonists, or leukotriene modifier,); AND Nucala or Fasenra	Monoclonal Antibody
Fasenra	Asthma: Trial of Inhaled corticosteroid AND an additional controller medication (long-acting beta 2-agonist, long-acting muscarinic antagonists, or leukotriene modifier). Eosinophilic granulomatosis with polyangiitis (EGPA): Trial with oral corticosteroids with or without immunosuppressive therapy	Monoclonal Antibody

Niktimvo	Chronic graft verse host disease (cGVHD): Trial of two or more previous lines of systemic therapy for the treatment of cGVHD (e.g. methylprednisolone, cyclosporine, tacrolimus, sirolimus, mycophenolate mofetil, imatinib)	Monoclonal Antibody
Nucala	Asthma: Trial of a medium – high dose inhaled corticosteroid; AND an additional controller medication (long-acting beta 2-agonist, long-acting muscarinic antagonists, leukotriene modifier, etc.) Eosinophilic granulomatosis with polyangiitis: Trial of oral corticosteroids for at least 4 weeks Chronic Rhinosinusitis with Nasal Polyps: Trial of intranasal corticosteroid therapy for at least 8 weeks; AND Member has received ≥2 courses of systemic corticosteroids per year or > 3 months of low dose corticosteroids COPD: Member is currently receiving maintenance therapy with inhaled triple therapy OR LAMA + LABA and has a contraindication to treatment with an ICS	Monoclonal Antibody
Imaavy	Myasthenia Gravis: Trial of the following –at least one conventional agent used for the treatment of myasthenia gravis (i.e., corticosteroids, azathioprine, cyclosporine, mycophenolate mofetil, tacrolimus, methotrexate, cyclophosphamide) **OR** chronic intravenous immunoglobulin **OR** chronic plasmapheresis/plasma exchange. Adult members with anti-AChR Ab+ gMG: Trial of Uplizna and Vyvgart or Vyvgart Hytrulo. Adult members with anti-MUSK Ab+ gMG: Trial of Uplizna and Rystiggo Additionally, for members who require a maintenance dose requiring 2 vials (>1200mg): trial of Rystiggo or eculizumab	Monoclonal Antibody
Eculizumab Products: Soliris	Myasthenia Gravis: – Trial of the following – a 1-year total trial with at least (2) immunosuppressive therapies (e.g., azathioprine, cyclosporine, mycophenolate	Monoclonal Antibody

	mofetil, tacrolimus, methotrexate, cyclophosphamide; either in combination or monotherapy); **OR** a 1-year total trial with at least one immunosuppressive therapy (e.g., azathioprine, cyclosporine, mycophenolate mofetil, tacrolimus, methotrexate, cyclophosphamide) **AND** one of the following: chronic intravenous immunoglobulin (IVIG) (i.e., at least every 3 months over 12 months without symptom control); **OR** chronic plasmapheresis/plasma exchange (i.e., at least every 3 months over 12 months without symptom control). Additionally, the member must have an inadequate response or contraindication to eculizumab-aagh (Epysqli), Uplizna (inebilizumab) AND efgartigimod (Vyvgart IV or Vyvgart Hytrulo SC). Neuromyelitis optica spectrum disorder - (NMOSD): Trial of Ultorimis (ravulizumab) AND Uplizna (inebilizumab)	
Eculizumab Products: Bkemv	Myasthenia Gravis: – Trial of the following –one-year total trial with at least (2) immunosuppressive therapies (e.g., azathioprine, cyclosporine, mycophenolate mofetil, tacrolimus, methotrexate, cyclophosphamide; either in combination or monotherapy); **OR** a 1-year total trial with at least one immunosuppressive therapy (e.g., azathioprine, cyclosporine, mycophenolate mofetil, tacrolimus, methotrexate, cyclophosphamide) **AND** one of the following: chronic intravenous immunoglobulin (IVIG) (i.e., at least every 3 months over 12 months without symptom control); **OR** chronic plasmapheresis/plasma exchange (i.e., at least every 3 months over 12 months without symptom control). Additionally, the member must have an inadequate response or contraindication to eculizumab-aagh (Epysqli), Uplizna (inebilizumab AND efgartigimod (Vyvgart IV or Vyvgart Hytrulo SC).	Monoclonal Antibody

Eculizumab Products: Epysqli	Myasthenia Gravis: Trial of the following –one conventional agent used for the treatment of myasthenia gravis (i.e., corticosteroids, azathioprine, cyclosporine, mycophenolate mofetil, tacrolimus, methotrexate, cyclophosphamide) **OR** chronic intravenous immunoglobulin **OR** chronic plasmapheresis/plasma exchange	Monoclonal Antibody
Ryoncil	Acute graft verse host disease (aGVHD): Trial of Jakafi (for members 12-17 years of age)	Monoclonal Antibody
Rystiggo	Myasthenia Gravis: Trial of the following –one conventional agent used for the treatment of myasthenia gravis (i.e., corticosteroids, azathioprine, cyclosporine, mycophenolate mofetil, tacrolimus, methotrexate, cyclophosphamide) **OR** chronic intravenous immunoglobulin **OR** chronic plasmapheresis/plasma exchange and a trial of Uplizna	Monoclonal Antibody
Tezspire	Asthma: Trial of at least 3 months with or without oral corticosteroids with both of the following: high-dose inhaled corticosteroid; AND additional controller medication (e.g., long acting beta$_2$-agonist, long-acting muscarinic antagonist, leukotriene modifier); and If baseline blood eosinophil level is ≥150 cells/μL, trial with at least one biologic indicated for asthma (e.g., Cinqair, Dupixent, Exdensur, Fasenra, Nucala, Xolair) Chronic Rhinosinusitis with Nasal Polyps (CRSwNP): Trial of intranasal corticosteroid therapy for at least 8 weeks; AND prior trial of treatment with systemic corticosteroids within the last two years	Monoclonal Antibody
Omalizumab Products: Xolair	Asthma: Trial of Inhaled corticosteroid; AND an additional controller medication (long-acting beta 2-agonist, long-acting muscarinic antagonists or leukotriene modifier) Chronic spontaneous urticaria: inadequate response with: Up-dosing/dose advancement (up to 4-fold) of a second-generation H1 antihistamine (e.g., cetirizine, fexofenadine, levocetirizine, loratadine) for at least 2 weeks Chronic Rhinosinusitis with Nasal Polyps: Trial of intranasal corticosteroid therapy for at least 8 weeks; AND Member has received at least one course of treatment with a systemic corticosteroid for 5 days or more within the previous 2 years	Monoclonal Antibody

Ultomiris	Myasthenia Gravis: Trial of the following –one conventional agent used for the treatment of myasthenia gravis (i.e., corticosteroids, azathioprine, cyclosporine, mycophenolate mofetil, tacrolimus, methotrexate, cyclophosphamide) **OR** chronic intravenous immunoglobulin (IVIG) **OR** chronic plasmapheresis/plasma exchange. Additionally, the member must have an inadequate response or contraindication to efgartigimod (Vyvgart IV or Vyvgart Hytrulo SC) and Uplizna. Neuromyelitis optica spectrum disorder (NMOSD): Trial of Uplizna	Monoclonal Antibody
Uplizna	Immunoglobulin G4-Related Disease (IgG4-RD): Member has disease that is refractory to corticosteroids OR has a contraindication or intolerance to corticosteroid treatment Myasthenia Gravis: Trial of the following –one conventional agent used for the treatment of myasthenia gravis (i.e., corticosteroids, azathioprine, cyclosporine, mycophenolate mofetil, tacrolimus, methotrexate, cyclophosphamide) **OR** chronic intravenous immunoglobulin (IVIG) **OR** chronic plasmapheresis/plasma exchange	Monoclonal Antibody
Lemtrada	Multiple Sclerosis: Trial of Tysabri or Tyruko and Ocrevus or Briumvi	Multiple Sclerosis
Tysabri, Tyruko	Crohn's Disease: Trial of at least a 3-month trial of infliximab IV or adalimumab at maximum tolerated	Crohn's Disease Multiple Sclerosis
Vyvgart IV and Vyvgart Hytrulo vials	Myasthenia Gravis: Trial of the following –one conventional agent used for the treatment of myasthenia gravis (i.e., corticosteroids, azathioprine, cyclosporine, mycophenolate mofetil, tacrolimus, methotrexate, cyclophosphamide) **OR** chronic intravenous immunoglobulin (IVIG) **OR** chronic plasmapheresis/plasma exchange Vyvgart Hytrulo ONLY: Chronic Inflammatory Demyelinating polyneuropathy: Trial of at least 3-month trial of standard of care therapy (i.e., corticosteroids, immunoglobulin (IG) or plasma exchange therapy)	Myasthenia Gravis

Botox	Migraine: 8-week trial of two oral medications for the prevention of migraines, such as Antidepressants (e.g., amitriptyline, fluoxetine, nortriptyline, etc.) Beta blockers (e.g., propranolol, metoprolol, nadolol, timolol, atenolol, pindolol, etc.) Angiotensin converting enzyme inhibitors/angiotensin II receptor blockers (e.g., lisinopril, candesartan, etc.) Anti-epileptics (e.g., divalproex, valproate, topiramate, etc.) Calcium channels blockers (e.g., verapamil, etc.) Urinary incontinence and OAB: Trial of two medications from either the antimuscarinic or beta-adrenergic classes Chronic Anal Fissures: Trial of conventional pharmacologic therapy (e.g., nifedipine, diltiazem, and/or topical nitroglycerin, bethanechol, etc.)	Neuromuscular Blocker Agent
Dysport	Migraine: 8 week trial of two oral medications for the prevention of migraines, such as Antidepressants (e.g., amitriptyline, fluoxetine, nortriptyline, etc.) Beta blockers (e.g., propranolol, metoprolol, nadolol, timolol, atenolol, pindolol, etc.) Angiotensin converting enzyme inhibitors/angiotensin II receptor blockers (e.g., lisinopril, candesartan, etc.) Anti-epileptics (e.g., divalproex, valproate, topiramate, etc.) Calcium channels blockers (e.g., verapamil, etc.) Chronic Anal Fissures: at least 1-month trial of conventional pharmacologic therapy (e.g., nifedipine, diltiazem, and/or topical nitroglycerin, bethanechol, etc.) Incontinence due to neurogenic detrusor overactivity and OAB: 1-month trial of two medications from either the antimuscarinic or beta-adrenergic classes	Neuromuscular Blocker Agent
Myobloc	Migraine: 8 week trial of two oral medications for the prevention of migraines, such as Antidepressants (e.g., amitriptyline, fluoxetine, nortriptyline, etc.) Beta blockers (e.g., propranolol, metoprolol, nadolol, timolol, atenolol, pindolol, etc.) Angiotensin converting enzyme inhibitors/angiotensin II receptor blockers (e.g., lisinopril, candesartan, etc.) Anti-epileptics (e.g., divalproex, valproate, topiramate, etc.) Calcium channels blockers (e.g., verapamil, etc.)	Neuromuscular Blocker Agent

Xeomin	Migraine: two trials of at least 8 weeks of two oral medications for the prevention of migraines, such as Antidepressants (e.g., amitriptyline, fluoxetine, nortriptyline, etc.) Beta blockers (e.g., propranolol, metoprolol, nadolol, timolol, atenolol, pindolol, etc.) Angiotensin converting enzyme inhibitors/angiotensin II receptor blockers (e.g., lisinopril, candesartan, etc.) Anti-epileptics (e.g., divalproex, valproate, topiramate, etc.) Calcium channels blockers (e.g., verapamil, etc.) Incontinence due to neurogenic detrusor overactivity and OAB: 1-month trial of two medications from either the antimuscarinic or beta-adrenergic classes	Neuromuscular Blocker Agent
Avastin, Alymsys, Vegzelma	All Oncology Indications: Trial of Mvasi or Zirabev	Oncology
Herceptin and Biosimilars, Herceptin Hylecta	All indications: Ontruzant or Trazimera	Oncology
Khapzory/Fusilev	Osteosarcoma, Colorectal Cancer, and Treatment of a folate antagonist overdose: Trial of leucovorin	Oncology
Nipent	Chronic or acute graft verse host disease (GVHD): Trial of corticosteroids	Non-Oncology
Rituxan Hycela	All indications: Ruxience or Riabni	Oncology
Rituxan, Truxima	All indications: Ruxience or Riabni Rheumatoid Arthritis: 3-month trial of one oral disease modifying antirheumatic drug (DMARD) (e.g., methotrexate, azathioprine, hydroxychloroquine, sulfasalazine, leflunomide, etc.) AND at least one 3-month trial of a preferred tumor necrosis factor (TNF) antagonist (one must be self-injectable) Lupus Nephritis: Trial of standard first line therapy [e.g., mycophenolate mofetil, mycophenolic acid, cyclophosphamide, calcineurin inhibitors (e.g., tacrolimus)] Systemic Lupus Erythematosus (SLE): Trial of at least two standard therapies such as anti-malarials (i.e. hydroxychloroquine, chloroquine), corticosteroids, non-steroidal anti-inflammatory drugs (NSAIDs), aspirin, or immunosuppressives such as azathioprine, methotrexate, cyclosporine, oral cyclophosphamide, or mycophenolate.	Oncology

	Myasthenia Gravis: Trial of standard first line therapy (e.g., glucocorticoids, azathioprine, mycophenolate mofetil, etc.)	
Beovu	Neovascular (wet) age related macular degeneration (AMD): bevacizumab or ranibizumab (Byooviz) Diabetic Macular Edema (DME) with a baseline visual acuity of 20/50 or worse: bevacizumab or ranibizumab (Lucentis) DME and baseline visual acuity better than 20/50: bevacizumab	Ophthalmic Agent
Durysta	Open angle glaucoma or ocular hypertension: Trial of two ophthalmic prostaglandin analogs (e.g., latanoprost) and at least one other IOP reducing ophthalmic product from a different medication class, such as beta-blockers, alpha-agonists, and carbonic anhydrase inhibitors (combination therapy should be used if warranted)	Ophthalmic Agent
iDose TR	Open angle glaucoma or ocular hypertension: Trial of two ophthalmic prostaglandin analogs (e.g., latanoprost) and at least one other IOP reducing ophthalmic product from a different medication class, such as beta-blockers, alpha-agonists, and carbonic anhydrase inhibitors (combination therapy should be used if warranted)	Ophthalmic Agent
Eylea or Pavblu	Diabetic Macular Edema (DME) with a baseline visual acuity of 20/50 or worse: bevacizumab or ranibizumab (Lucentis) DME and baseline visual acuity better than 20/50: bevacizumab Diabetic retinopathy (DR) or Retinopathy of Prematurity (ROP): bevacizumab Neovascular (Wet) Age Related Macular Degeneration (AMD), Macular Edema Following Retinal Vein Occlusion(RVO): bevacizumab or ranibizumab (Byooviz)	Ophthalmic Agent
Eylea HD	Diabetic Macular Edema (DME) with a baseline visual acuity of 20/50 or worse: bevacizumab or ranibizumab (Lucentis) DME and baseline visual acuity better than 20/50: bevacizumab Diabetic retinopathy (DR): bevacizumab	Ophthalmic Agent

	Neovascular (Wet) Age Related Macular Degeneration (AMD), Macular Edema Following Retinal Vein Occlusion(RVO): bevacizumab or ranibizumab (Byooviz) All indications: Trial of Pavblu or Eylea	
Cimerli	Diabetic macular edema and Diabetic retinopathy: bevacizumab Neovascular (wet) age related macular degeneration, Macular edema due to retinal vein occlusion, or Myopic Choroidal Neovascularization: bevacizumab and Byooviz or Lucentis	Ophthalmic Agent
Byooviz, Lucentis	All indications: Bevacizumab	Ophthalmic Agent
Susvimo	Neovascular (wet) age related macular degeneration(AMD): responded to at least two intravitreal injections of a VEGF inhibitor medication (e.g., aflibercept, bevacizumab, brolucizumab, ranibizumab); and had an inadequate treatment response with bevacizumab, AND Lucentis (ranibizumab) or Byooviz (ranibizumab) AND Eylea (aflibercept) Diabetic Macular Edema (DME) or Diabetic Retinopathy (DR): responded to at least two intravitreal injections of a VEGF inhibitor medication (e.g., aflibercept, bevacizumab, brolucizumab, ranibizumab); and bevacizumab, AND Lucentis (ranibizumab) AND Eylea (aflibercept)	Ophthalmic Agent
Vabysmo	Neovascular (wet) age related macular degeneration (AMD) or Macular edema due to retinal vein occlusion (RVO): bevacizumab and Byooviz (ranibizumab) or Lucentis (ranibizumab) Diabetic Macular Edema (DME) and baseline visual acuity of 20/50 or worse: bevacizumab or ranibizumab (Lucentis) DME and baseline visual acuity better than 20/50: bevacizumab	Ophthalmic Agent
Tepezza	Active Thyroid Eye Disease: Intravenous glucocorticoids	Ophthalmic Agent
Oxlumo	Trial of at least 3 months of pyridoxine	Primary Hyperoxaluria
Signifor LAR	Acromegaly: Trial of Sandostatin LAR (octreotide) or Somatuline Depot (lanreotide)	Somatostatin Analog

Per §§ 42 CFR 422.101, this clinical medical policy only applies to Medicare in the absence of National Coverage Determination (NCD) or Local Coverage Determination (LCD).

Investigational use: All therapies are considered investigational when used at a dose or for a condition other than those that are recognized as medically accepted indications as defined in any one of the following standard reference compendia: American Hospital Formulary Service Drug information (AHFS-DI), Thomson Micromedex DrugDex, Clinical Pharmacology, Wolters Kluwer Lexi-Drugs, or Peer-reviewed published medical literature indicating that sufficient evidence exists to support use. Neighborhood does not provide coverage for drugs when used for investigational purposes.

For additional information on the step therapy process, please call member services at 1-844-812-6896 for Medicare members.

Policy Rationale: These products were reviewed by the Neighborhood Health Plan of Rhode Island Pharmacy & Therapeutics (P&T) Committee. Neighborhood adopted the following clinical coverage criteria to ensure that its members use them according to Food and Drug Administration (FDA) approved labeling and/or relevant clinical literature. Neighborhood worked with network prescribers and pharmacists to draft these criteria. These criteria will help ensure its members are using this drug for a medically accepted indication, while minimizing the risk for adverse effects and ensuring more cost-effective options are used first, if applicable and appropriate. For Medicare members, these coverage criteria will only apply in the absence of National Coverage Determination (NCD) or Local Coverage Determination (LCD) criteria. Neighborhood will give individual consideration to each request it reviews based on the information submitted by the prescriber and other information available to the plan.