

<b>Policy Title:</b>	Medically Administered Step Therapy Policy		
		<b>Department:</b>	PHA
<b>Effective Date:</b>	10/01/2020		
<b>Review Date:</b>	1/1/2020, 9/21/2020, 11/23/2020, 12/28/2020, 1/28/2021, 2/25/2021, 3/25/21, 4/29/2021, 5/27/2021, 6/24/2021, 7/29/2021, 9/28/2021, 10/28/2021, 12/30/2021, 1/27/2022, 2/25/2022, 3/24/2022, 4/28/2022, 5/26/2022, 6/30/2022, 7/22/2022, 8/25/2022, 9/29/2022, 10/20/2022, 12/15/2022, 1/26/2023, 2/16/2023, 3/24/2023, 4/27/2023, 5/19/2023, 5/31/2023, 7/6/2023, 7/27/2023, 8/10/2023, 9/14/2023, 9/28/2023, 10/19/2023, 11/30/2023, 12/27/2023, 5/8/2024, 5/29/2024, 6/26/2024, 7/26/2024, 8/28/2024, 10/23/2024, 11/15/2024, 12/18/2024, 01/08/2025, 02/15/2025, 03/19/2025, 04/18/2025		

**Purpose:** To support the use of preferred products that are safe and effective.

**Scope:** Medicare-Medicaid Plan (MMP)

**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.

MMP patients 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: Documented failure, intolerance, or contraindication to 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
Xenleta	Trial of alternative antibiotic to which the organism is susceptible (i.e., moxifloxacin, levofloxacin, beta-lactam + macrolide, beta-lactam + doxycycline, etc.)	Antibiotic

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
Adynovate, Esperoct	Hemophilia A: Trial of one of the following - Advate, Afstyl, Hemofil M, Koate DVI, Kogenate FS, Kovaltry, Novoeight, Nuwiq, Obizur, Recombinate, Xyntha/Xyntha Solofuse	Antihemophilic Agent
Alphanate, Humate-P, Wilate	von Willebrand disease (mild or moderate): Trial of desmopressin	Antihemophilic Agent
Idelvion, Rebinyn	All indications: Trial of one of the following - Alphanine SD, BeneFIX, Ixinity, Mononine, Profilnine, and Rixubis	Antihemophilic Agent
Feiba NF/ Feiba VF	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: Patient 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
Hypavzi	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 B (congenital factor IX deficiency) without inhibitors: trial of a factor IX product (e.g., Benefix, Rixubis, Alphanine, etc.)	Antihemophilic Agent
Novoseven RT	Hemophilia A: has had a trial of Hemlibra	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	<p>Chronic Migraines: 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</p> <p>Episodic migraines: 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.)</p>	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
Ganciclovir: J1574	All indications: Trial and failure or contraindication to ganciclovir J1570	Antiviral Agent
Actemra, Tofidence	<p>Rheumatoid Arthritis: Trial of one oral DMARD such as methotrexate, azathioprine, hydroxychloroquine, penicillamine, sulfasalazine, leflunomide, etc.; AND at least a 3-month trial of adalimumab at maximum tolerated doses</p> <p>Juvenile Idiopathic Arthritis: Trial of one NSAID or systemic glucocorticoid (e.g., prednisone, methylprednisolone) AND at least a 3-month trial of adalimumab at maximum tolerated doses</p> <p>Management of Immune Checkpoint Inhibitor related Inflammatory Arthritis: Trial of corticosteroids</p> <p>Giant Cell Arteritis: Trial of glucocorticoid therapy</p> <p>All indications: trial of at least a 3-month trial of Tynne (tocilizumab-aazg)</p>	Autoimmune

Tyenne	<p>Rheumatoid Arthritis: Trial of one oral DMARD such as methotrexate, azathioprine, hydroxychloroquine, penicillamine, sulfasalazine, leflunomide, etc.; AND at least a 3-month trial of adalimumab at maximum tolerated doses</p> <p>Juvenile Idiopathic Arthritis: Trial of one NSAID or systemic glucocorticoid (e.g., prednisone, methylprednisolone) AND at least a 3-month trial of adalimumab at maximum tolerated doses</p> <p>Management of Immune Checkpoint Inhibitor related Inflammatory Arthritis: Trial of corticosteroids</p> <p>Giant Cell Arteritis: Trial of glucocorticoid therapy</p>	Autoimmune
Cimzia	<p>Rheumatoid Arthritis: Trial of one oral DMARD such as methotrexate, azathioprine, hydroxychloroquine, sulfasalazine, leflunomide, etc. AND at least a 3-month trial of adalimumab at maximum tolerated doses</p> <p>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</p> <p>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.</p> <p>Plaque Psoriasis: Inadequate response to topical agents, inadequate response to at least one non-biologic systemic agent 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.</p> <p>Psoriatic Arthritis:</p> <ul style="list-style-type: none"> <li>- Predominantly axial disease: trial and failure of an NSAID</li> <li>- Peripheral arthritis or active enthesitis disease: trial of an oral DMARD such as methotrexate, azathioprine, sulfasalazine, hydroxychloroquine, etc</li> <li>- At least a 3-month trial of adalimumab at maximum tolerated doses</li> <li>- At least a 6-month trial of ustekinumab at maximum tolerated doses.</li> </ul>	Autoimmune

Cosentyx	<p>Psoriatic Arthritis:</p> <ul style="list-style-type: none"> <li>- Predominantly axial disease: trial and failure of an NSAID</li> <li>- Peripheral arthritis, dactylitis or active enthesitis disease: trial of an oral DMARD such as methotrexate, azathioprine, sulfasalazine, hydroxychloroquine, etc</li> <li>- At least a 3-month trial of adalimumab at maximum tolerated doses</li> <li>- At least a 6-month trial of ustekinumab at maximum tolerated doses.</li> </ul> <p>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</p>	Autoimmune
Entyvio	<p>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.</p> <p>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 for biologic experienced patients</p>	Autoimmune
Ilaris	<p>Still's Disease and Systemic Juvenile Idiopathic Arthritis: Trial of one oral NSAID OR systemic glucocorticoid (e.g., prednisone, methylprednisolone)</p> <p>Familial Mediterranean Fever: colchicine</p> <p>Gout Flare: NSAID and colchicine</p>	Autoimmune
Ilumya	<p>Plaque psoriasis: Trial of one of the following - methotrexate, cyclosporine, or acitretin 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</p>	Autoimmune
Omvo	<p>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 ustekinumab at maximum tolerated doses</p>	Autoimmune
Orencia	<p>Rheumatoid Arthritis: Trial of one oral disease modifying anti-rheumatic agent (DMARD) such as methotrexate, azathioprine, hydroxychloroquine, sulfasalazine, or leflunomide AND at least a 3-month trial of adalimumab at maximum tolerated doses</p> <p>Polyarticular juvenile idiopathic arthritis: 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</p> <p>Psoriatic Arthritis: For patients with predominantly axial disease OR active enthesitis and/or dactylitis, an adequate</p>	Autoimmune

	<p>trial and failure of at least two non-steroidal anti-inflammatory agents (NSAIDs); OR for patients with peripheral arthritis, a trial and failure of at least a 3 month trial of one oral disease-modifying anti-rheumatic drug (DMARD) such as methotrexate, azathioprine, sulfasalazine, or hydroxychloroquine 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</p> <p>Chronic Graft Versus Host Disease: Trial and failure of systemic corticosteroids</p> <p>Management of Immune Checkpoint Inhibitor Related Toxicity: Trial and failure of methylprednisolone</p>	
Remicade or infliximab unbranded	All indications: Trial of Inflectra or Avsola, AND Renflexis	Autoimmune
Remicade or infliximab unbranded, Renflexis	<p>Rheumatoid Arthritis: Trial of one oral disease modifying anti-rheumatic agent (DMARD) ) such as methotrexate, azathioprine, hydroxychloroquine, sulfasalazine, leflunomide, etc; AND used in combination with methotrexate</p> <p>Psoriatic Arthritis: Trial of one NSAID OR Trial of one oral DMARD such as methotrexate, azathioprine hydroxychloroquine, sulfasalazine, etc;</p> <p>Ankylosing Spondylitis: Trial of two NSAIDs</p> <p>Plaque Psoriasis: Trial of one of the following systemic products - immunosuppressives, retinoic acid derivatives, and/or methotrexate</p>	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
Simponi Aria	<p>Rheumatoid Arthritis: Trial of one oral disease modifying anti-rheumatic agent (DMARD) such as methotrexate, azathioprine, hydroxychloroquine, sulfasalazine, or leflunomide; AND at least a 3-month trial of adalimumab at maximum tolerated doses</p> <p>Psoriatic Arthritis: Trial of one NSAID OR Trial of one oral DMARD such as methotrexate, azathioprine, hydroxychloroquine, sulfasalazine, or leflunomide; 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</p> <p>Ankylosing Spondylitis: Trial of two NSAIDs AND at least</p>	Autoimmune

	a 3-month trial of adalimumab at maximum tolerated doses  Polyarticular Juvenile Idiopathic Arthritis (pJIA): Trial of oral NSAIDs OR Trial of an oral DMARD such as methotrexate, sulfasalazine, or leflunomide; AND at least a 3-month trial of adalimumab at maximum tolerated doses	
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 products: ustekinumab biosimilars	Crohn's Disease: Trial of at least a 3-month trial of infliximab IV or adalimumab 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 ustekinumab at maximum tolerated doses	Autoimmune
Stelara	All indications: At least a 6-month trial of ustekinumab at maximum tolerated doses	Autoimmune
Tremfya IV	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 ustekinumab at maximum tolerated doses	Autoimmune
Evenity	Osteoporosis: bisphosphonates (oral and/or IV) such as alendronate, risedronate, ibandronate, or zoledronic acid AND RANKL-blocking agents such as denosumab	Bone Modifying Agent
Prolia	Trial of Zometa/Reclast or Aredia	Bone Modifying Agent
Xgeva	Trial of Zometa/Reclast or Aredia	Bone Modifying Agent
Parsabiv	Hyperparathyroidism secondary to chronic kidney disease: Trial of cinacalcet	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, Prolia (denosumab), Xgeva (denosumab)	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	CAR-T Immunotherapy



	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)	
Prevymis IV	Prevymis Oral Tablet	CMV Prophylaxis
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 and Viltepso	Duchenne Muscular Dystrophy
Elevidys	All Indications: Stable dose of a corticosteroid prior to the start of therapy	Duchenne Muscular Dystrophy
VPRIV, Elelyso	All indications: Trial of Cerezyme	Enzyme Replacement
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)  Patient has a contraindication to or is not indicated for treatment with Casgevy (exagamglogene autotemcel)	Gene Therapy
Krystexxa	All indications: Trial of Allopurinol or Probenecid	Gout
Aranesp	All indications: Trial of Retacrit	Hematopoietic Agent
Long-Acting Colony Stimulating Factors – Non-Preferred: Fulphila, Nyvepria, Ziextenzo, Fylmetra, Rolvedon, Stimufend (Oncology and Non-Oncology)	All approved indications: Trial of Neulasta, Neulasta Onpro, or Udenyca	Hematopoietic Agent
Mircera	All indications: Trial of Retacrit	Hematopoietic Agent
Nplate	Chronic immune (idiopathic) thrombocytopenia: Trial of one of the following – corticosteroids (e.g., prednisone, methylprednisolone) and/or immunoglobulins and/or rituximab	Hematopoietic Agent
Procrit, Epogen	All indications: Trial of Retacrit	Hematopoietic Agent

Short Acting Colony Stimulating Factors: Nivestym, Neupogen, Granix, Releuko (Oncology and Non Oncology)	All indications: Trial of Zarxio	Hematopoetic Agent
Berinert	Trial of high dose antihistamine (e.g., cetirizine) 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., Kalbitor, Firazyr, 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 17 $\alpha$ -alkylated androgen (e.g., danazol)	Hereditary Angioedema
Haegarda	Trial of high dose antihistamine (e.g., cetirizine) 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) for members with normal C1 inhibitor levels and a family history of angioedema without genetic testing	Hereditary Angioedema
Ruconest	Trial of high-dose antihistamine (e.g., cetirizine) for members with normal C1 inhibitor levels and a family history of angioedema without genetic testing	Hereditary Angioedema
Testopel	All indications: 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: 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
Triptodur	Central Precocious Puberty: Trial of Trelstar  Gender Dysphoria: Trial of Lupron Depot	Hormone Therapy
Trogarzo	Patient has heavily treated multi-drug resistant disease, confirmed by resistance testing, to at least one drug in at least three classes (NRTI, NNRTI, PI)	Human Immunodeficiency Virus
Euflexxa	All indications: 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, Monovisc, Orthovisc, Supartz/Supartz FX, Synjoynt, Synvisc, Synvisc-One, Triluron, Trivisc, &Visco-3	All indications: 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 patients with X-linked hypophosphatemia: Trial of an oral phosphate and active vitamin D analogs (e.g., calcitriol, paricalcitol, doxercalciferol, calcifediol)	Hypophosphatemia
Cuvitru, Cutaquig, Xembify, Hizentra or Hyqvia (Subcutaneous IG)	All indications: Trial of one of the following - Gammaked/Gamunex-C or Gammagard liquid	Immune Globulins
Intravenous Immune Globulins: Asceniv, Alyglo,Bivigam, Gammagard S/D, Gammaplex, Privigen or Panzyga	All indications: Gammaked/Gamunex-C, Gammagard liquid, Flebogamma/Flebogamma DIF, or Octagam  IgG Subclass Deficiency: patient is receiving prophylactic antibiotic therapy  Myasthenia Gravis: patient 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: 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.)	Immune Globulins
Monoferic	Trial of Injectafer or Feraheem	Iron Agent
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
Probuphine	All indications: Trial of one of the following - Buprenorphine/naloxone, buprenorphine	Medication Assisted Treatment
Sublocade	All indications: Trial of one of the following - Buprenorphine/naloxone, buprenorphine	Medication Assisted Treatment
Brixadi	All indications: initiated therapy with transmucosal buprenorphine or is transitioning from another buprenorphine-containing treatment	Medication Assisted Treatment
Rebyota	Trial of Zinplava or fecal microbiota transplantation (FMT) from a reputable source	Microbiota
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
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
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  Hypereosinophilic Syndrome (HES): trial of at least one other HES therapy, such as oral corticosteroids, immunosuppressive agents, cytotoxic therapy, etc.  Chronic Rhinosinusitis with Nasal Polyps: Trial of intranasal corticosteroid therapy for at least 8 weeks; AND Patient has received $\geq 2$ courses of systemic corticosteroids per year or $> 3$ months of low dose corticosteroids	Monoclonal Antibody
Soliris	Myasthenia Gravis: – Trial of the following –minimum one-year trial of concurrent use with two (2) or more immunosuppressive therapies (e.g., corticosteroids plus an immunosuppressant such as azathioprine, methotrexate, cyclosporine, mycophenylate, etc.) OR Patient has required at least one acute or chronic treatment with plasmapheresis or plasma exchange (PE) or intravenous immunoglobulin (IVIG) in addition to immunosuppressant therapy. Additionally, the patient must have an inadequate response or contraindication to both ravulizumab (Ultomiris) AND	Monoclonal Antibody

	efgartigimod IV (Vyvgart IV).  Neuromyelitis optica spectrum disorder (NMOSD): Trial of Ultomiris and Uplizna	
Rystiggo	Myasthenia Gravis: Trial of one of the following based on their antibodies: <ul style="list-style-type: none"> <li>• <u>AChR+ disease</u>: a minimum one-year trial of concurrent use with two (2) or more immunosuppressive therapies (e.g., corticosteroids plus an immunosuppressant such as azathioprine, cyclosporine, mycophenolate, etc.); <b>OR</b></li> <li>• <u>MuSK+ disease</u>: a minimum one-year trial with immunosuppressive therapy (e.g., corticosteroids, azathioprine, or mycophenolate) and rituximab; <b>OR</b></li> </ul> Patient required at least one acute or chronic treatment with plasmapheresis or plasma exchange (PE) or intravenous immunoglobulin (IVIG) in addition to immunosuppressant therapy	Monoclonal Antibody
Xolair	Chronic idiopathic urticaria: scheduled dosing of a second-generation H1 antihistamine for at least one month; AND inadequate response with scheduled dosing of one of the following: Updosing/dose advancement (up to 4-fold) of a second-generation H1 antihistamine, add-on therapy with a leukotriene antagonist (e.g., montelukast), add-on therapy with another H1 antihistamine or add-on therapy with a H2-antagonist.  Asthma: Trial of Inhaled corticosteroid; AND an additional controller medication (long acting beta 2-agonist, long-acting muscarinic antagonists or leukotriene modifier)  Chronic Rhinosinusitis with Nasal Polyps : Trial of intranasal corticosteroid therapy for at least 8 weeks; AND Patient 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 – minimum one-year trial of concurrent use with two (2) or more immunosuppressive therapies (e.g., corticosteroids plus an immunosuppressant such as azathioprine, methotrexate, cyclosporine, mycophenolate, etc.) OR Patient has required at least one acute or chronic treatment with plasmapheresis or plasma exchange (PE) or intravenous immunoglobulin (IVIG) in addition to immunosuppressant therapy. Additionally, the patient must have an inadequate response or contraindication to efgartigimod IV (Vyvgart IV).	Monoclonal Antibody

	<p>Neuromyelitis optica spectrum disorder (NMOSD): Trial of Enspryng*, AND Uplizna</p> <p>*This requirement ONLY applies to Medicaid members</p>	
Briumvi	Multiple Sclerosis: Trial of Tysabri and Ocrevus	Multiple Sclerosis
Lemtrada	Multiple Sclerosis: Trial of Tysabri and Ocrevus	Multiple Sclerosis
Tysabri	Crohn's Disease: Trial of 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	Crohn's
Vyvgart IV and Vyvgart Hytrulo	<p>Myasthenia Gravis: Trial of the following – minimum six month trial of concurrent use with two (2) or more immunosuppressive therapies (e.g., corticosteroids plus an immunosuppressant such as azathioprine, methotrexate, cyclosporine, mycophenolate, etc.) OR Patient has required at least one acute or chronic treatment with plasmapheresis or plasma exchange (PE) or intravenous immunoglobulin (IVIG) in addition to immunosuppressant therapy</p> <p>Vyvgart Hytrulo ONLY:</p> <p>Chronic Inflammatory Demyelinating polyneuropathy: Trial of at least 3-month trial of immunoglobulin (IG) or plasma exchange therapy</p>	Myasthenia Gravis
Botox	<p>Migraine: 8-week trial of two oral medications for the prevention of migraines, such as</p> <p>Antidepressants (e.g., amitriptyline, fluoxetine, nortriptyline, etc.)</p> <p>Beta blockers (e.g., propranolol, metoprolol, nadolol, timolol, atenolol, pindolol, etc.)</p> <p>Angiotensin converting enzyme inhibitors/angiotensin II receptor blockers (e.g., lisinopril, candesartan, etc.)</p> <p>Anti-epileptics (e.g., divalproex, valproate, topiramate, etc.)</p> <p>Calcium channels blockers (e.g., verapamil, etc.)</p> <p>Urinary incontinence and OAB: Trial of two medications from either the antimuscarinic or beta-adrenergic classes</p> <p>Chronic Anal Fissures: Trial of conventional pharmacologic therapy (e.g., nifedipine, diltiazem, and/or topical nitroglycerin, bethanechol, etc.)</p>	Neuromuscular Blocker Agent

Dysport	<p>Migraine: 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.)</p> <p>Chronic Anal Fissures: Trial of conventional pharmacologic therapy (e.g., nifedipine, diltiazem, and/or topical nitroglycerin, bethanechol, etc.)</p> <p>Incontinence due to neurogenic detrusor overactivity and OAB: Trial of two medications from either the antimuscarinic or beta-adrenergic classes</p>	Neuromuscular Blocker Agent
Myobloc	<p>Migraine: 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.)</p>	Neuromuscular Blocker Agent
Xeomin	<p>Migraine: 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.)</p> <p>Incontinence due to neurogenic detrusor overactivity and OAB: Trial of two medications from either the antimuscarinic or beta-adrenergic classes</p>	Neuromuscular Blocker Agent
Avastin, Alysmsys, Vegzelma	All Oncology Indications: Trial of Mvasi or Zirabev	Oncology
Herceptin and Biosimilars, Herceptin Hylecta	All indications: Kanjinti or Trazimera	Oncology
Khazory/Fusilev	Osteosarcoma, Colorectal Cancer, and Treatment of a folate antagonist overdose: Trial of leucovorin	Oncology
Nipent	Chronic or acute graft versus host disease (GVHD): Trial of corticosteroids	Oncology



Rituxan Hycela	All indications: Ruxience or Truxima	Oncology
Rituxan, Riabni	<p>All indications: Ruxience or Truxima</p> <p>Rheumatoid Arthritis: one oral disease modifying antirheumatic drug (DMARD) (e.g., methotrexate, azathioprine, hydroxychloroquine, sulfasalazine, leflunomide, etc.) AND at least one preferred tumor necrosis factor (TNF) antagonist (one must be self-injectable)</p> <p>Lupus Nephritis: Trial of standard first line therapy [e.g., mycophenolate mofetil, mycophenolic acid, cyclophosphamide, calcineurin inhibitors (e.g., tacrolimus)]</p> <p>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.</p> <p>Myasthenia Gravis: Trial of standard first line therapy (e.g., glucocorticoids, azathioprine, mycophenolate mofetil, etc.)</p>	Oncology
Beovu	<p>Neovascular (wet) age related macular degeneration (AMD): bevacizumab or ranibizumab (Byooviz)</p> <p>Diabetic Macular Edema (DME) with a baseline visual acuity of 20/50 or worse: bevacizumab or ranibizumab (Lucentis)</p> <p>DME and baseline visual acuity better than 20/50: bevacizumab Diabetic Retinopathy: bevacizumab</p>	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	<p>Diabetic Macular Edema (DME) with a baseline visual acuity of 20/50 or worse: bevacizumab or ranibizumab (Lucentis)</p> <p>DME and baseline visual acuity better than 20/50: bevacizumab Diabetic Retinopathy: bevacizumab</p>	Ophthalmic Agent



	<p>Diabetic retinopathy (DR) or Retinopathy of Prematurity (ROP): bevacizumab</p> <p>Neovascular (Wet) Age Related Macular Degeneration (AMD), Macular Edema Following Retinal Vein Occlusion(RVO): bevacizumab or ranibizumab (Byooviz)</p>	
Eylea HD	<p>Diabetic Macular Edema (DME) with a baseline visual acuity of 20/50 or worse: bevacizumab or ranibizumab (Lucentis)</p> <p>DME and baseline visual acuity better than 20/50: bevacizumab Diabetic Retinopathy: bevacizumab</p> <p>Diabetic retinopathy (DR): bevacizumab</p> <p>Neovascular (Wet) Age Related Macular Degeneration (AMD): bevacizumab or ranibizumab (Byooviz)</p> <p>All indications: Trial of Eylea</p>	Ophthalmic Agent
Cimerli	<p>Diabetic macular edema and Diabetic retinopathy: bevacizumab</p> <p>Neovascular (wet) age related macular degeneration, Macular edema due to retinal vein occlusion, or Myopic Choroidal Neovascularization: bevacizumab and Byooviz or Lucentis</p>	Ophthalmic Agent
Byooviz, Lucentis	All indications: Bevacizumab	Ophthalmic Agent
Susvimo	Neovascular (wet) age related macular degeneration: 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, Byooviz (ranibizumab) AND Eylea (aflibercept)	Ophthalmic Agent
Vabysmo	<p>Neovascular (wet) age related macular degeneration (AMD) or Macular edema due to retinal vein occlusion (RVO): bevacizumab and Byooviz (ranibizumab)</p> <p>Diabetic Macular Edema (DME) and baseline visual acuity of 20/50 or worse: bevacizumab or ranibizumab (Lucentis)</p> <p>DME and baseline visual acuity better than 20/50: bevacizumab</p>	Ophthalmic Agent
Tepezza	Active Thyroid Eye Disease: Intravenous glucocorticoids	Ophthalmic Agent
Oxlumo	Trial of at least 3 months of pyridoxine	Primary Hyperoxaluria
Synagis	Contraindication to Beyfortus	Respiratory Syncytial Virus

Signifor LAR	Acromegaly: Trial of Sandostatin LAR (octreotide) or Somatuline Depot (lanreotide)	Somatostatin Analog
Somatuline Depot	Acromegaly: Trial of lanreotide.	Somatostatin Analog

Per §§ 42 CFR 422.101, this clinical medical policy only applies to INTEGRITY 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 INTEGRITY (Medicare Medicaid Plan) 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 INTEGRITY (Medicare-Medicaid Plan) 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.