

Policy Title:	Medically Administered Step Therapy Policy		
		Department:	PHA
Effective Date:	10/01/2020		
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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)
Avastin	All Oncology Indications: Trial of Bevacizumab biosimilar product, such as Mvasi or Zirabev
Herceptin and Biosimilars, Herceptin Hylecta	All indications: Kanjinti or Trazimera
	All indications: Ruxience or Truxima
	Rheumatoid Arthritis: one oral disease modifying antirheumatic drug (DMARD) AND at least one preferred tumor necrosis factor (TNF) antagonist (must be self-injectable)
Rituxan, Riabni	Pemphigus Vulgaris: corticosteroids and/or azathioprine
Rituxan Hycela	All indications: Rituximab biosimilar, such as Ruxience or Truxima
Elelyso, VPRIV	All indications: Trial of Cerezyme
Procrit, Epogen	All indications: Trial of Retacrit
Aranesp	All indications: Trial of Retacrit
Mircera	All indications: Trial of Retacrit

Short Acting Colony Stimulating Factors: Nivestym, Neupogen, Granix (Oncology)	All indications: Zarxio
Long Acting Colony Stimulating Factors: Fulphila, Nyvepria, Ziextenzo (Oncology)	All indications: Trial of either Neulasta or Udenyca
Short Acting Colony Stimulating Factors: Nivestym, Neupogen, Granix (Non-Oncology)	All indications: Zarxio
Long Acting Colony Stimulating Factors: Fulphila, Nyvepria, Ziextenzo (Non-Oncology)	All indications: Trial of either Neulasta or Udenyca
Eylea	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, Neovascular (Wet) Age Related Macular Degeneration, Macular Edema Following Retinal Vein Occlusion, and Diabetic Retinopathy: bevacizumab
Lucentis	All indications: bevacizumab
Beovu	Neovascular (wet) age related macular degeneration (AMD): bevacizumab
H.P. Acthar	Multiple Sclerosis: Trial of one of the following - IV methylprednisolone, or IV dexamethasone Rheumatic Disorders, Collagen Diseases, Dermatologic Disorders, Allergic States, Ophthalmic Diseases, Respiratory Disease, and Edematous States: Trial of two IV corticosteroids Nephrotic syndrome without uremia of the idiopathic type or lupus erythematosus: Trial of two IV corticosteroids and Trial of one of the following - cyclophosphamide, cyclosporine, mycophenolate OR using diuretics, Angiotensin-Converting Enzyme (ACE) inhibitors, Angiotensin Receptor Blockers (ARBs), or albumin
Hyalgan, Durolane, Monovisc, Orthovisc, Supartz, Synvisc, Synvisc-One, Genvisc, Visco-3, Hymovis, Gel-one, Gelysn, Synjoyn, Triluron, Trivisc	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
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
Cimzia	Rheumatoid Arthritis: Trial of methotrexate Ankylosing spondylitis and axial spondyloarthritis: Trial of at least 2 non-steroidal anti-inflammatory drugs (NSAIDs) Crohn's Disease: Trial of one of the following - budesonide, metronidazole, ciprofloxacin, Xifaxan, azathioprine, mercaptopurine, methotrexate, sulfasalazine, prednisone, methylprednisolone, or tacrolimus Plaque Psoriasis: Trial of one of the following - methotrexate, cyclosporine, or acitretin

Entyvio	Crohn's Disease: Trial of one of the following - corticosteroids, 6-mercaptopurine, methotrexate, or azathioprine AND Trial of one TNF modifier (e.g., Humira, Remicade, Renflexis, Inflectra, or Avsola)
	Ulcerative Colitis: Trial of one of the following - corticosteroids, 6-mercaptopurine, methotrexate or azathioprine AND Trial of one TNF modifier (e.g., Humira, Remicade, Renflexis, Inflectra, or Avsola)
	Immune Checkpoint Inhibitor related Diarrhea/Colitis: Refractory to Infliximab products
Ilumya	Plaque psoriasis: Trial of one of the following - methotrexate, cyclosporine, or acitretin
Remicade, Renflexis, Inflectra, Avsola	Crohn's Disease and Ulcerative Colitis: Trial of one of the following - corticosteroids, 6-mercaptopurine, methotrexate, or azathioprine
	Rheumatoid Arthritis: Trial of one oral disease modifying anti-rheumatic agent (DMARD) AND used in combination with methotrexate
	Psoriatic Arthritis: Trial of two NSAIDs OR Trial of one oral DMARD
	Ankylosing Spondylitis: Trial of two NSAIDs
	Plaque Psoriasis: Trial of one of the following systemic products - immunosuppressives, retinoic acid derivatives, and/or methotrexate
Remicade	All indications: Trial of Inflectra, Avsola, AND Renflexis
Renflexis or Avsola	All indications: Trial of Inflectra
Orencia	Rheumatoid Arthritis: Trial of one oral disease modifying anti-rheumatic agent (DMARD) such as methotrexate, azathioprine, hydroxychloroquine, penicillamine, sulfasalazine, or leflunomide
	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.)
	Psoriatic Arthritis: For patients with predominantly axial disease OR active enthesitis and/or dactylitis, an adequate 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
	Chronic Graft Versus Host Disease: Trial and failure of systemic corticosteroids
Stelara	Management of Immune Checkpoint Inhibitor Related Toxicity: Trial and failure of methylprednisolone
	Crohn's Disease: Trial of one of the following - corticosteroids or immunomodulators, (e.g., 6-mercaptopurine, methotrexate, azathioprine) AND Trial of one TNF modifier

	Ulcerative Colitis: Trial of one of the following – mesalamine, corticosteroids, 6-mercaptopurine, or azathioprine AND Trial of one TNF modifier (e.g., Humira, Simponi, Inflectra, Renflexis, Avsola, or Remicade)
Simponi Aria	Rheumatoid Arthritis: Trial of one oral disease modifying anti-rheumatic agent (DMARD)
	Psoriatic Arthritis: Trial of two NSAIDs OR Trial of one oral DMARD
	Ankylosing Spondylitis: Trial of two NSAIDs
	Polyarticular Juvenile Idiopathic Arthritis (pJIA): Trial of oral NSAIDs OR Trial of an oral DMARD
Actemra	Rheumatoid Arthritis: Trial of one oral DMARD AND Trial of two or more TNF inhibitors (e.g., Humira)
	Juvenile Idiopathic Arthritis: Trial of one NSAID or systemic glucocorticoid (e.g., prednisone, methylprednisolone) AND Trial of Humira
	Management of Immune Checkpoint Inhibitor related Inflammatory Arthritis: Trial of corticosteroids
Tremfya	Plaque psoriasis: Trial of one of the following - methotrexate, cyclosporine, or acitretin
Ilaris	Still's Disease and Systemic Juvenile Idiopathic Arthritis: Trial of one oral NSAID OR systemic glucocorticoid (e.g., prednisone, methylprednisolone)
	Familial Mediterranean Fever: colchicine
Intravenous Immune Globulins: Asceniv, Bivigam, Gammagard S/D, Gammaplex, Privigen or Panzyga	All indications: Gammaked/Gamunex-C, Gammagard liquid, Flebogamma/Flebogamma DIF, or Octagam
	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
	Management of Immune-Checkpoint-Inhibitor Related Toxicity: Trial of high dose corticosteroids or methylprednisolone
	Autoimmune Mucocutaneous Blistering Diseases: corticosteroids and concurrent immunosuppressive treatment (e.g., azathioprine, cyclophosphamide, mycophenolate mofetil, etc.)
Cuvitru, Cutaquig, Xembify, Hizentra or Hyqvia (Subcutaneous IG)	All indications: Trial of one of the following - Gammaked/Gamunex-C or Gammagard liquid
Krystexxa	All indications: Trial of all of the following -Allopurinol, Probenecid

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
Lemtrada	Multiple Sclerosis(MS): Trial of two drugs indicated for MS AND trial and failure of Tysabri
Ocrevus	Multiple Sclerosis: Trial of a disease modifying agent if the patient is not newly diagnosed with relapsing MS
Tysabri	Multiple Sclerosis: Trial of two drugs indicated for the treatment of relapsing MS Crohn's Disease: Trial of two oral immunosuppressive therapies, such as corticosteroids, 6-mercaptopurine, methotrexate, and/or azathioprine AND Trial of one TNF-inhibitor
Soliris	Myasthenia Gravis: Trial of two of the following -azathioprine, cyclosporine, mycophenolate mofetil, tacrolimus, methotrexate, cyclophosphamide AND Trial of a chronic IVIG
	Neuromyelitis optica spectrum disorder (NMOSD): Trial of Uplizna
	Paroxysmal nocturnal hemoglobinuria (PNH): Trial of Ultomiris
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
Crysvita	Adult patients with X-linked hypophosphatemia: Trial of an oral phosphate and active vitamin D analogs
Triptodur	Central Precocious Puberty : Trial of Trelstar
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
Probuphine	All indications: Trial of one of the following - Buprenorphine/naloxone, buprenorphine
Sublocade	All indications: Trial of one of the following - Buprenorphine/naloxone, buprenorphine
Botox	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.)
	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.)
Dysport	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.) Chronic Anal Fissures: Trial of conventional pharmacologic therapy (e.g., nifedipine, diltiazem, and/or topical nitroglycerin, bethanechol, etc.) Incontinence due to neurogenic detrusor overactivity and OAB: Trial of two medications from either the antimuscarinic or beta-adrenergic classes
Myobloc	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.)
Xeomin	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.) Incontinence due to neurogenic detrusor overactivity and OAB: Trial of two medications from either the antimuscarinic or beta-adrenergic classes

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
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 α -alkylated androgen (e.g., danazol)
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
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
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
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
Nplate	Chronic immune (idiopathic) thrombocytopenia: Trial of one of the following – corticosteroids (e.g., prednisone, methylprednisolone) and/or immunoglobulins and/or rituximab
Parsabiv	Hyperparathyroidism secondary to chronic kidney disease: Trial of Cinacalcet
Hemlibra	Hemophilia A (congenital factor VIII deficiency) with inhibitors: Trial of one of the following bypassing agents - NovoSeven, FEIBA
Vonvendi	von Willebrand disease (mild or moderate): Trial of desmopressin
Alphanate, Humate-P, Wilate	von Willebrand disease (mild or moderate): Trial of desmopressin
Novoseven RT	Hemophilia A: has had a trial of Hemlibra
Feiba NF/ Feiba VF	Hemophilia A: has had a trial of Hemlibra
Adynovate, Eloctate, Jivi, 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
Alprolix, Idelvion, Rebinyn	All indications: Trial of one of the following - Alphanine SD, Bebulin, BeneFIX, Ixinity, Mononine, Profilnine, and Rixubis
Amondys 45	All indications: Trial of corticosteroids for at least 6 months
Exondys 51	All indications: Trial of corticosteroids for at least 6 months
Vyondys 53	All indications: Trial of corticosteroids for at least 6 months and Vilepso
Evenity	Osteoporosis: bisphosphonates (oral and/or IV) such as alendronate, risedronate, ibandronate, or zoledronic acid AND RANKL-blocking agents such as denosumab
Tepezza	Thyroid Eye Disease: Intravenous glucocorticoids
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, leukotriene modifier, or sustained-release theophylline)
	Nasal Polyps: Trial of intranasal corticosteroid therapy
Vyepti	Chronic Migraines: 8-week trial of two oral medications from two different classes of drugs for the prevention of migraines AND two triptan medications AND 12-week trial of one calcitonin gene-related peptide (CGRP) antagonists (e.g., erenumab, galcanezumab, fremanezumab, etc.) AND two doses of a botulinum toxin for members with chronic migraine
Prolia	Episodic migraines: 8-week trial of two oral medications from two different classes of drugs for the prevention of migraines AND two triptan medications AND 12-week trial of one calcitonin gene-related peptide (CGRP) antagonists (e.g., erenumab, galcanezumab, fremanezumab, etc.)
Xgeva	Trial of Zometa/Reclast or Aredia
Cinqair	Trial of Zometa/Reclast or Aredia
Fasenra	Asthma: Trial of Inhaled corticosteroid; AND an additional controller medication (long acting beta 2-agonist, leukotriene modifier, or sustained-release theophylline)
Nucala	Asthma: Trial of a medium – high dose inhaled corticosteroid; AND an additional controller medication (long acting beta 2-agonist, leukotriene modifier, or sustained-release theophylline)
Khapzory/Fusilev	Eosinophilic granulomatosis with polyangiitis: Trial of oral corticosteroids for at least 4 weeks
Xenleta	Osteosarcoma, Colorectal Cancer, and Treatment of a folate antagonist overdose: Trial of leucovorin
Oxlumo	Trial of alternative antibiotic to which the organism is susceptible (i.e., moxifloxacin, levofloxacin, beta-lactam + macrolide, beta-lactam + doxycycline, etc.)
Durysta	Trial of at least 3 months of pyridoxine
	Trial of at least two trials of IOP reducing eye drop agents (combination therapy should be used if warranted) from two different

	medication classes. For one trial, the member must have been treated with a prostaglandin analog (e.g., latanoprost)
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)
Serostim	HIV wasting: at least three alternative therapies such as cyproheptadine, dronabinol, megestrol acetate or testosterone therapy if hypogonadal
Somatuline Depot or Bynfezia pen	All Indications: trial of Sandostatin IV/SQ or LAR Depot
Yescarta	Non-Hodgkin Lymphomas(chemotherapy – refractory disease): trial and failure of two or more lines of systemic chemotherapy OR for DLBL, 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)
Viltepso	All indications: trial of corticosteroids for at least 3 months
Nipent	Chronic or acute graft verse host disease (GVHD): Trial of corticosteroids
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).
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 PCSK9 inhibitor indicated for HoFH (e.g., evolocumab, alirocumab)

*** Requests will also be reviewed to National Coverage Determination (NCD) and Local Coverage Determinations (LCDs) if applicable.***

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 reach out to member services at Neighborhood Health Plan of RI at 800-459-6019 for Medicaid members, 844-812-6896 for MMP members and 855-321-9244 for Exchange members.