Policy Title:	Medically Administered Step Therapy Policy		
		Department:	PHA
Effective Date:	1/1/2020, 10/01/2020		
Review Date:	1/1/2020, 9/21/2020		
Revision Date:	9/21/2020		

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

Scope: Medicaid, Commercial, and 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
Rituxan	All indications: Rituximab biosimilar, such as Ruxience or Truxima
	Rheumatoid Arthritis: one oral disease modifying antirheumatic drug (DMARD) AND at least one preferred tumor necrosis factor (TNF) antagonist (one must be self-injectable)
	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	All indications: Zarxio
Long Acting Colony Stimulating Factors: Fulphila, Nyvepria, Ziextenzo	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, Synojoynt, 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 - mesalamine, 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 - mesalamine, 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, auranofin, 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 (2) non-steroidal anti-inflammatory agents (NSAIDs), unless use is contraindicated; 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 Management of Immune Checkpoint Inhibitor Related Toxicity: Trial and failure of methylprednisolone
Stelara	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
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 and anti-inflammatory agents
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
	Auto-immune Mucocutaneous Blistering Diseases: corticosteroids and concurrent immunosuppressive treatment (e.g., azathioprine, cyclophosphamide, mycophenolate mofetil, etc.)
Cuvitru, Cutaquiq, Xembify, Hizentra or Hyqvia (Subcutaneous IG)	Trial of one of the following - Gammaked/Gamunex-C or Gammagard liquid Chronic Inflammatory Demyelinating Polyneuropathy: Treatment and with a preferred IVIG agent
Krystexxa	All indications: Trial of all of the following -Allopurinol, Febuxostat, Probenecid

Kymriah	Pediatric and Young Adult Relapsed or Refractory (r/r) B-cell Acute Lymphoblastic Leukemia (ALL): Member has Philadelphia chromosome-positive disease and failed at least two tyrosine kinase inhibitors (TKI) (e.g., imatinib, dasatinib, nilotinib, bosutinib, ponatinib) OR 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 Adult Relapsed or Refractory (r/r) Large B-cell Lymphoma: For diffuse large B-cell lymphoma arising from follicular lymphoma, Relapsed/refractory DLBCL- Diffuse Large B-Cell Lymphoma AND member has experienced disease progression after two or more lines of systemic therapy (if tisagenlecleucel or axicabtagene ciloleucel not previously given).
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 and rituximab/biosimilar of rituximab Paroxysmal nocturnal hemoglobinuria (PNH) and Atypical hemolytic uremic syndrome (aHUS): 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
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 (ex. 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. oral/topical nifedipine, diltiazem, and/or topical nitroglycerin, bethanecol, etc)
	Severe Primary Axillary Hyperhidrosis and Severe Palmar Hyperhidrosis:: Trial of topical agents
	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 (ex. 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. oral/topical nifedipine, diltiazem, and/or topical nitroglycerin, bethanecol, etc)
	Incontinence due to neurogenic detrustor overactivity and OAB: Trial of two medications from either the antimuscarinic or beta-adrenergic classes
Dysport	Severe Primary Axillary Hyperhidrosis: Trial of topical agents
	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 (ex. lisinopril, candesartan, etc.) • Anti-epileptics (e.g., divalproex, valproate, topiramate, etc) • Calcium channels blockers (e.g., verapamil, etc)
Myobloc	Severe Primary Axillary Hyperhidrosis: Trial of topical agents
	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 (ex. lisinopril, candesartan, etc.)
Xeomin	

	• Anti-epileptics (e.g., divalproex, valproate, topiramate, etc) • Calcium channels blockers (e.g., verapamil, etc)
	Incontinence due to neurogenic detrustor overactivity and OAB: Trial of two medications from either the antimuscarinic or beta-adrenergic classes
	Severe Primary Axillary Hyperhidrosis: Trial of topical agents
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	Trial of high dose antihistamine (e.g., cetirizine) for members with normal C1 inhibitor levels and a family history of angioedema without genetic testing
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) or immunoglobulins
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 - 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, Sevenfact	Hemophilia A: Have one of these in the members possession - Advate, Afstyla, Hemofil M, Koate DVI, Kogenate FS, Kovaltry, Monoclate-P, Novoeight, Nuwiq, Obizur, Recombinate, Xyntha, Esperoct AND has had a trial of Hemlibra
	Hemophilia B: Have one of these in the members possession - Alphanine SD, Alprolix, Bebulin, BeneFIX, Idelvion, Ixinity, Mononine, Profilnine, Rebinyn, and Rixubis
Feiba NF/ Feiba VF	Hemophilia A: Have one of these in the members possession - Advate, Afstyla, Hemofil M, Koate DVI, Kogenate FS, Kovaltry, Monoclate-P, Novoeight, Nuwiq, Obizur, Recombinate, Xyntha, Esperoct AND has had a trial of Hemlibra
	Hemophilia B: Have one of these in the members possession - Alphanine SD, Alprolix, Bebulin, BeneFIX, Idelvion, Ixinity, Mononine, Profilnine, Rebinyn, and Rixubis

Adynovate, Eloctate, Jivi	All indications: Trial of one of the following - Advate, Afstyla, Hemofil M, Koate DVI, Kogenate FS, Kovaltry, Monoclate-P, Novoeight, Nuwiq, Obizur, Recombinate, Xyntha, Esperoct
Alprolix, Idelvion, Rebinyn	All indications: Trial of one of the following - Alphanine SD, Bebulin, BeneFIX, Ixinity, Mononine, Profilnine, and Rixubis
Exondys 51	All indications: Trial of corticosteroids for at least 6 months
Vyondys 53	All indications: Trial of corticosteroids for at least 6 months
Evenity	Osteoporosis: bisphosphonates (oral 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)
Vyepti	Chronic Migraines: 8-week trial of two oral medications from two different classes of drugs for the prevention of migraines AND an inadequate response to two triptan medications AND 12-week trial of two calcitonin gene-related peptide (CGRP) antagonists (e.g., erenumab, galcanezumab, fremanezumab, etc.) AND two doses of a botulinum toxin for members Episodic migraines: 8-week trial of two oral medications from two different classes of drugs for the prevention of migraines AND an inadequate response to two triptan medications AND 12-week trial of two calcitonin gene-related peptide (CGRP) antagonists (e.g., erenumab, galcanezumab, fremanezumab, etc.)
Prolia	Trial of Zometa/Reclast or Aredia
Xgeva	Trial of Zometa/Reclast or Aredia
Cinqair	Asthma: Trial of Inhaled corticosteroid; AND an additional controller medication (long acting beta 2-agonist, leukotriene modifier, or sustained-release theophylline)
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 Inhaled corticosteroid; AND an additional controller medication (long acting beta 2-agonist, leukotriene modifier, or sustained-release theophylline) Eosinophilic granulomatosis with polyangiitis: Trial of oral corticosteroids
Preyymis	Trial of Prevymis tablets

Yescarta	Non-Hodgkin Lymphomas (NHL): Trial of anti-CD20 monoclonal antibody (i.e. rituximab or obinutuzumab) AND an anthracycline (i.e. CHOP) containing chemotherapy regimen.
Khapzory/Fusilev	Osteosarcoma, Colorectal Cancer, and Treatment of a folate antagonist overdose: : Trial of leucovorin
Xenleta	Trial of alternative antibiotic to which the organism is susceptible (i.e., moxifloxacin, levofloxacin, beta-lactam + macrolide, beta-lactam + doxycycline, etc.)

*** 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.