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| Policy Title: | Medically Administered Step Therapy Policy | | |
| | | Department: | PHA |
| Effective Date: | 10/01/2020 | | |
| Review Date: | 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, 11/10/2022, 1/3/2023, 1/27/2023, 2/16/23, 3/23/2023, 4/27/2023, 5/19/2023, 5/31/2023, 7/6/2023, 7/27/2023,8/10/2023, 9/14/2023, 9/28/23, 10/19/2023, 11/30/23,12/27/2023, 5/08/2024, 05/29/2024, 6/26/2024, 7/26/2024, 8/28/2024 | | |

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

Scope: Medicaid and Commercial

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.

| Medications that Require Step Therapy | Preferred Medication(s) | Class of Medication |
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| Acthar Gel | Infantile Spasms (West Syndrome); Trial of Cortrophin Gel | Adrenocorticotropin Stimulating Hormone |
| Aralast, Glassia, Zemaira | Emphysema due to alpha-1-antitrypsin (AAT) deficiency: <i>For Commercial patients ONLY:</i> Documented failure, intolerance, or contraindication to Prolastin | Alpha-1-Proteinase Inhibitors |
| Zulresso | Trial of 4 weeks of a formulary oral selective serotonin reuptake inhibitor (SSRI) or serotonin-norepinephrine reuptake inhibitor (SNRI) | Antidepressant |
| 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 |

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| Xenleta | Trial of alternative antibiotic to which the organism is susceptible (i.e., moxifloxacin, levofloxacin, beta-lactam + macrolide, beta-lactam + doxycycline, etc.) | Antibiotic |
| Adynovate, Esperoct, | Hemophilia A: Trial of one of the following - Advate, Afstyla, 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, Bebulin, 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 (recombinant) products at a total weekly dose of 100 IU/kg or less | 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 |
| Roctavian | Hemophilia A: Patient is on a stable dose of regularly administered exogenous factor VIII | Antihemophilic Agent |
| Vyepti | Chronic Migraines: Trial of two oral medications from two different classes of drugs for the prevention of migraines AND two triptan medications AND trial of two calcitonin gene-related peptide (CGRP) antagonists (e.g., erenumab, galcanezumab, fremanezumab, etc.) AND botulinum toxin Episodic migraines: Trial of two oral medications from two different classes of drugs for the prevention of migraines AND two triptan medications AND trial of two calcitonin gene-related peptide (CGRP) antagonists (e.g., erenumab, galcanezumab, fremanezumab, etc.) | Anti-migraine Agent |
| Bortezomib: J9046, J9049, J9048, J9051 | All indications: Trial of bortezomib, 0.1 mg (J9041) | Antineoplastic Agent |

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| Fulvestrant: J9395, J9393 | All indications: Trial of fulvestrant (fresenius kabi) not therapeutically equivalent to J9395, 25 mg (J9394) | Antineoplastic Agent |
| Pemetrexed: J9305, J9314, J9304, J9294, J9323, J9322, J9296 | All indications: Trial of pemetrexed (sandoz), not therapeutically equivalent to J9305, 10mg (J9297) | Antineoplastic Agent |
| Actemra | <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>Juvenile Idiopathic Arthritis: Trial of an oral 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 (GCA): Trial of glucocorticoid therapy</p> <p>Polymyalgia rheumatica: Trial of Prednisone</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 corticosteroids or immunomodulators (e.g., azathioprine, 6-mercaptopurine, or methotrexate); AND at least a 3-month trial of adalimumab at</p> | Autoimmune |

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| | <p>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</p> <p>Psoriatic Arthritis:</p> <ul style="list-style-type: none"> - Predominantly axial disease: trial and failure of an NSAID - Peripheral arthritis or active enthesitis disease: trial of oral DMARD, such as methotrexate, azathioprine, sulfasalazine, hydroxychloroquine, etc. - at least a 3-month trial of adalimumab at maximum tolerated doses | |
| Cosentyx | <p>Psoriatic Arthritis:</p> <ul style="list-style-type: none"> - Predominantly axial disease: trial and failure of an NSAID - Peripheral arthritis, dactylitis or active enthesitis disease: trial of an oral DMARD such as methotrexate, azathioprine, sulfasalazine, hydroxychloroquine, etc - At least a 3-month trial of adalimumab at maximum tolerated doses <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 one of the following for Medicaid members only - corticosteroids, 6-mercaptopurine, methotrexate, or azathioprine AND at least a 3-month trial of adalimumab at maximum tolerated doses</p> <p>Trial of one of the following for Commercial members only - corticosteroids, 6-mercaptopurine, methotrexate, or azathioprine OR at least a 3-month trial of a TNF modifier, such as adalimumab, certolizumab, or infliximab at maximum tolerated doses for Commercial members</p> <p>Ulcerative Colitis: Trial of one of the following - corticosteroids, 6-mercaptopurine, methotrexate or azathioprine</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 |

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| Ilumya | Plaque psoriasis: Trial of one of the following - methotrexate, cyclosporine, or acitretin; AND at least a 3-month trial of adalimumab at maximum tolerated doses | Autoimmune |
| OmvoH | Ulcerative Colitis: Trial of one of the following – mesalamine, corticosteroids, 6-mercaptopurine, or azathioprine AND at least a 3-month trial of adalimumab at maximum tolerated AND at least a 3-month trial of Entyvio, except if the member has failed to respond to infliximab | 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 trial and failure of at least one 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</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> | Autoimmune |
| Remicade or infliximab unbranded | All indications: Trial of ALL Infliximab Biosimilars (Example: Inflectra or Avsola, AND Renflexis) | Autoimmune |
| Remicade or infliximab unbranded, Renflexis, Avsola | <p>Crohn's Disease and Ulcerative Colitis: Trial of one of the following -corticosteroids, 6-mercaptopurine, methotrexate, or azathioprine</p> <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 formulary 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 |

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| Renflexis | All indications: Trial of Inflectra or Avsola | 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 formulary DMARD such as methotrexate, azathioprine, hydroxychloroquine, sulfasalazine, or leflunomide; AND at least a 3-month trial of adalimumab at maximum tolerated doses</p> <p>Ankylosing Spondylitis: Trial of two NSAIDs AND at least a 3-month trial of adalimumab at maximum tolerated doses</p> <p>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</p> | Autoimmune |
| Skyrizi | Crohn's disease: Trial of corticosteroids or immunomodulators (e.g., 6-mercaptopurine, methotrexate, azathioprine) AND at least a 3-month trial of adalimumab at maximum tolerated doses | Autoimmune |
| Stelara | <p>For Medicaid members:</p> <p>Crohn's Disease: Trial of one of the following - corticosteroids or immunomodulators, (e.g., 6-mercaptopurine, methotrexate, azathioprine) AND at least a 3-month trial of adalimumab at maximum tolerated doses AND Skyrizi AND Entyvio (except for if they have moderate to severe luminizing Crohn's Disease)</p> <p>Ulcerative Colitis: Trial of one of the following – mesalamine, corticosteroids, 6-mercaptopurine, or azathioprine AND at least a 3-month trial of adalimumab at maximum tolerated doses AND Entyvio (except for if the member failed to respond to infliximab)</p> <p>For Commercial members:</p> <p>Crohn's Disease: Trial of one of the following - corticosteroids or immunomodulators, (e.g., 6-mercaptopurine, methotrexate, azathioprine) AND at least a 3-month trial of adalimumab at maximum tolerated doses AND Entyvio (except for if they have moderate to severe luminizing Crohn's Disease)</p> <p>Ulcerative Colitis: Trial of one of the following – mesalamine, corticosteroids, 6-mercaptopurine, or azathioprine AND at least a 3-month trial of adalimumab at maximum tolerated doses AND Entyvio (except for if the member failed to respond to infliximab)</p> | Autoimmune |

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| 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 (zoledronic acid) or Aredia (pamidronate) | Bone Modifying Agent |
| Xgeva | Trial of Zometa/Reclast or Aredia for all indications except Giant Cell Tumor of Bone | 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 PCSK9 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 |

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| Kymriah | <p>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</p> <p>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</p> | CAR-T Immunotherapy |
| Yescarta | <p>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</p> <p>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)</p> | CAR-T Immunotherapy |
| 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 |
| Viltepsso | All Indications: Trial of corticosteroids | Duchenne Muscular Dystrophy |
| Vyondys 53 | All Indications: Trial of corticosteroids and Viltepsso | Duchenne Muscular Dystrophy |
| Elevidys | All Indications: Stable dose of a corticosteroid prior to the start of therapy | Duchenne Muscular Dystrophy |
| Elelyso, VPRIV | For Medicaid members ONLY All indications: Trial of Cerezyme | Enzyme Replacement |
| Cerezyme, VPRIV | For Commercial Members ONLY: All indications: Trial of Elelyso | Enzyme Replacement |
| Nexviazyme | Commercial members ONLY: Trial of Lumizyme for members <30kg that require a dose of 40 mg/kg | Enzyme |
| Pombiliti and Opfolda | Trial of Lumizyme or Nexviazyme | Enzyme |
| Fabrazyme & Elfabrio | Failure, intolerance, or contraindication to Galafold (migalastat) | Fabry Disease (alpha-galactosidase A deficiency) |
| Casgevy | Sickle Cell Disease: Trial of hydroxyurea and formulary add-on therapy (e.g., Adakveo, Oxbryta*) *Only applies to Medicaid Members | Gene Therapy |

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| Lyfgenia | Sickle Cell Disease: Trial of hydroxyurea and formulary add-on therapy (e.g., Adakveo, Oxbrytra*) Patient has a contraindication to or is not indicated for treatment with Casgevy™ (exagamglogene autotemcel) *Only applies to Medicaid Members | Gene Therapy |
| Krystexxa | All indications: Trial of Allopurinol or Probenecid | Gout |
| Aranesp | All indications: Trial of Retacrit | Hematopoetic 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 | Hematopoetic Agent |
| Mircera | All indications: Trial of Retacrit | Hematopoetic Agent |
| Nplate | Chronic immune (idiopathic) thrombocytopenia: Trial of one of the following – corticosteroids (e.g., prednisone, methylprednisolone) and/or immunoglobulins and/or rituximab | Hematopoetic Agent |
| Procrit, Epogen | All indications: Trial of Retacrit | Hematopoetic 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 <i>Commercial patients only: trial of Ruconest</i> | 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 α -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 |
| Apretude | PrEP: Trial of emtricitabine/tenofovir disoproxil fumarate (generic Truvada) | HIV |

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| 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) | HIV |
| 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 |
| Triptodur | Central Precocious Puberty: Trial of Trelstar Gender Dysphoria: Trial of Lupron Depot | Hormone Therapy |
| 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 |
| Hyalgan, Durolane, Monovisc, Orthovisc, Supartz, Synvisc, Synvisc-One, Genvisc, Visco-3, Hymovis, Gel-one, Gelysn, Synjoynnt, 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 | 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, 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: | Immune Globulins |

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| | Corticosteroids and concurrent immunosuppressive treatment (e.g., azathioprine, cyclophosphamide, mycophenolate mofetil, etc.) | |
| Monoferric | Trial of Injectafer or Feraheme | 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 therapies 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 Fasentra, Nucala, and Xolair | Monoclonal Antibody |
| Fasentra | Asthma: Trial of Inhaled corticosteroid; AND an additional controller medication (long-acting beta 2-agonist, long-acting muscarinic antagonists, or leukotriene modifier) | 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, or leukotriene modifier) 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 ≥ 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, mycophenolate, etc.) OR Patient has required at least one acute or chronic treatment with plasmapheresis or plasma exchange (PE) | Monoclonal Antibody |

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| | <p>or intravenous immunoglobulin (IVIG) in addition to immunosuppressant therapy.</p> <p>Additionally, the patient must have an inadequate response or contraindication to both ravulizumab (Ultomiris) AND efgartigimod IV (Vyvgart IV).</p> <p>Neuromyelitis optica spectrum disorder (NMOSD): Trial of Enspryng*, Ultomiris, AND Uplizna</p> <p>* This requirement ONLY applies to Medicaid Members</p> | |
| Tezspire | <p>Severe 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 beta₂-agonist, long-acting muscarinic antagonist, leukotriene modifier); and</p> <p>If baseline blood eosinophil level is ≥ 150 cells/μL, trial with at least one biologic indicated for asthma (e.g., Cinqair, Dupixent, Fasenra, Nucala, Xolair)</p> | Monoclonal Antibody |
| Rystiggo | <p>Myasthenia Gravis:</p> <p>Trial of one of the following based on their antibodies:</p> <ul style="list-style-type: none"> • <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.); OR • <u>MuSK+ disease</u>: a minimum one-year trial with immunosuppressive therapy (e.g., corticosteroids, azathioprine, or mycophenolate) and rituximab; OR <p>Patient required at least one acute or chronic treatment with plasmapheresis or plasma exchange (PE) or intravenous immunoglobulin (IVIG) in addition to immunosuppressant therapy</p> | Monoclonal Antibody |
| Ultomiris | <p>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).</p> <p>Neuromyelitis optica spectrum disorder (NMOSD): Trial of Enspryng*, AND Uplizna</p> | Monoclonal Antibody |

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| | *This requirement ONLY applies to Medicaid members | |
| Uplizna | Neuromyelitis optica spectrum disorder (NMOSD): Trial of Enspryng* * This requirement ONLY applies to Medicaid Members | 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: Up-dosing/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 |
| Briumvi | Multiple Sclerosis: Trial of Tysabri and Ocrevus (Commercial ONLY) Trial of Tysabri (Medicaid ONLY) | Multiple Sclerosis |
| Lemtrada | Multiple Sclerosis: Trial of Tysabri and Ocrevus (Commercial ONLY) Trial of Tysabri and one other drug indicated for MS (Medicaid ONLY) | Multiple Sclerosis |
| Tysabri | Crohn's Disease: Trial of two oral immunosuppressive therapies, such as corticosteroids, 6-mercaptopurine, methotrexate, and/or azathioprine AND 3-month trial of one TNF-inhibitor | Crohn's Disease |
| Vyvgart IV and Vyvgart Hytrulo | 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 AND for Medicaid members only who request Vyvgart IV at a weekly dose requiring 3 vials (>800mg to 1200mg), documentation that patient is unable to tolerate Vyvgart Hytrulo Vyvgart Hytrulo ONLY: Chronic Inflammatory Demyelinating polyneuropathy: Trial of at least 3-month trial of immunoglobulin (IG) or plasma exchange therapy | Myasthenia Gravis |

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| <p>Botox</p> | <p>Severe Primary Axillary Hyperhidrosis: Trial and failure of ≥ 1 month of a tropical agent e.g., aluminum chloride, glycopyrronium, etc.</p> <p>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.)</p> <p>Urinary incontinence and OAB: Trial of two medications from either the antimuscarinic or beta-adrenergic classes</p> <p>Severe Palmar Hyperhidrosis: Trial and failure of ≥ 1 month of a tropical agent e.g., aluminum chloride, etc.</p> <p>Chronic Anal Fissures: Trial conventional pharmacologic therapy (e.g., nifedipine, diltiazem, and/or topical nitroglycerin, bethanechol, etc.)</p> | <p>Neuromuscular Blocker Agent</p> |
| <p>Dysport</p> | <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> <p>Severe Primary Axillary Hyperhidrosis: Trial and failure of ≥ 1 month of a tropical agent e.g., aluminum chloride, glycopyrronium, etc.</p> | <p>Neuromuscular Blocker Agent</p> |

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| 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> <p>Severe Primary Axillary Hyperhidrosis: Trial and failure of ≥ 1 month of a tropical agent e.g., aluminum chloride, glycopyrronium, 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> <p>Severe Primary Axillary Hyperhidrosis: Trial and failure of ≥ 1 month of a tropical agent e.g., aluminum chloride, glycopyrronium, etc.</p> | Neuromuscular Blocker Agent |
| Nipent | Chronic or acute graft versus host disease (GVHD): Trial of corticosteroids | Non-Oncology |
| Rituxan, Riabni | <p>All indications: Ruxience or Truxima</p> <p>Rheumatoid Arthritis: One oral disease modifying antirheumatic drug (DMARD) AND at least one preferred tumor necrosis factor (TNF) antagonist (one must be self-injectable) trialed for at least 3 months</p> <p>Lupus Nephritis: Patient has disease that is non-responsive or refractory to standard first line therapy [e.g., mycophenolate mofetil, mycophenolic acid, cyclophosphamide, calcineurin inhibitors (e.g., tacrolimus)]</p> <p>Myasthenia Gravis: Patient is refractory to standard first-line therapy (e.g., glucocorticoids, azathioprine, mycophenolate mofetil, etc.)</p> <p>Systemic Lupus Erythematosus (SLE): Trial of at least two standard therapies such as anti-malarials (i.e. hydroxychloroquine, chloroquine), corticosteroids, non-</p> | Non-Oncology |

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| | steroidal anti-inflammatory drugs (NSAIDs), aspirin, or immunosuppressives such as azathioprine, methotrexate, cyclosporine, oral cyclophosphamide, or mycophenolate. | |
| Avastin Alymsys, Vegzelma | All Oncology Indications: Trial of Mvasi or Zirabev | Oncology |
| Herceptin and Biosimilars, Herceptin Hylecta | All indications: Kanjinti or Trazimera | Oncology |
| Khapzory/Fusilev | Osteosarcoma, Colorectal Cancer, and Treatment of a folate antagonist overdose: Trial of leucovorin | Oncology |
| Rituxan, Rituxan Hycela, Riabni | All indications: Truxima or Ruxience | Oncology |
| 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 Diabetic Retinopathy: bevacizumab | Ophthalmic Agent |
| Byooviz | All indications: Bevacizumab | Ophthalmic Agent |
| Durysta | Open angle glaucoma or ocular hypertension: Trial of two ophthalmic prostaglandin analogs (e.g., latanoprost, travoprost, tafluprost) 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, travoprost, tafluprost) 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 | 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: 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 |

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| 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 |
| Lucentis 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 ranibizumab (Byooviz)</p> | Ophthalmic Agent |
| Susvimo | <p>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, Lucentis (ranibizumab) AND Eylea (aflibercept)</p> | Ophthalmic Agent |
| Vabysmo | <p>Neovascular (wet) age related macular degeneration (AMD) or Macular edema due to retinal vein occlusion (RVO): bevacizumab and Byooviz</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 |
| Oxlumo | Trial of at least 3 months of pyridoxine | Primary Hyperoxaluria |
| Synagis | Contraindication to Beyfortus | Respiratory Syncytial Virus |
| Signifor LAR | <p>Acromegaly: Trial of Sandostatin LAR (octreotide) or Somatuline Depot (lanreotide)*</p> <p>*For Medicaid members: Trial of Somatuline Depot (lanreotide) only</p> | Somatostatin Analog |
| Tepezza | <p>Active Thyroid Eye Disease: Intravenous glucocorticoids*</p> <ul style="list-style-type: none"> • For commercial members ONLY | Ophthalmic Agent |

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.

Please call the Pharmacy Help Desk at 1-401-459-6020 for pharmacy authorization requests or for further information on the Neighborhood Medicaid formulary.

Please call Member Services at 1-855-321-9244 for pharmacy authorization requests or for further information on the Neighborhood Commercial formulary.