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| <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 |                    |     |

**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                     |
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| H.P. Acthar                           | <p>Multiple Sclerosis: Trial of one of the following - IV methylprednisolone, or IV dexamethasone</p> <p>Rheumatic Disorders, Collagen Diseases, Dermatologic Disorders, Allergic States, Ophthalmic Diseases, Respiratory Disease, and Edematous States: Trial of two IV corticosteroids</p> <p>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</p> | Adrenocorticotropin Stimulating Hormone |

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| 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            |
| Adynovate, Elocate, 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                                                                                                                                                                                                                                                                                                                                                                                                             | Antihemophilic Agent  |
| Alphanate, Humate-P, Wilate        | von Willebrand disease (mild or moderate): Trial of desmopressin                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | Antihemophilic Agent  |
| Alprolix, 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<br><br>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  |
| Novoseven RT                       | Hemophilia A: has had a trial of Hemlibra                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | Antihemophilic Agent  |
| Vonvendi                           | von Willebrand disease (mild or moderate): Trial of desmopressin                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | Antihemophilic Agent  |
| Vyepiti                            | 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 one calcitonin gene-related peptide (CGRP) antagonist (e.g., erenumab, galcanezumab, fremanezumab, etc.) AND botulinum toxin for members<br><br>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 one calcitonin gene-related peptide (CGRP) antagonist (e.g., erenumab, galcanezumab, fremanezumab, etc.) | Anti-migraine Agent   |

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| Actemra | <p>Rheumatoid Arthritis: Trial of one oral DMARD AND Trial of two or more TNF inhibitors (e.g., Humira)</p> <p>Juvenile Idiopathic Arthritis: Trial of one NSAID or systemic glucocorticoid (e.g., prednisone, methylprednisolone) AND Trial of Humira</p> <p>Management of Immune Checkpoint Inhibitor related Inflammatory Arthritis: Trial of corticosteroids</p>                                                                                                                                                                                                                                                                                                                                                                                                      | Autoimmune |
| Cimzia  | <p>Rheumatoid Arthritis: Trial of one oral DMARD</p> <p>Ankylosing spondylitis and axial spondyloarthritis: Trial of at least 2 non-steroidal anti-inflammatory drugs (NSAIDs)</p> <p>Crohn's Disease: Trial of corticosteroids or immunomodulators</p> <p>Plaque Psoriasis:</p> <ul style="list-style-type: none"> <li>- Inadequate response to topical agents</li> <li>- Inadequate response to at least one non-biologic systemic agent</li> </ul> <p>Psoriatic Arthritis:</p> <ul style="list-style-type: none"> <li>- Predominantly axial disease or active enthesitis: trial and failure of an NSAID</li> <li>- Peripheral arthritis or dactylitis: trial of an oral DMARD</li> </ul> <p>Non-radiographic Axial Spondyloarthritis: Trial of at least two NSAIDs</p> | Autoimmune |
| Entyvio | <p>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)</p> <p>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)</p> <p>Immune Checkpoint Inhibitor related Diarrhea/Colitis: Refractory to Infliximab products</p>                                                                                                                                                                                                                                        | Autoimmune |

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| 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>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | Autoimmune |
| Ilumya                                                         | Plaque psoriasis: Trial of one of the following - methotrexate, cyclosporine, or acitretin                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | Autoimmune |
| Orencia                                                        | <p>Rheumatoid Arthritis: Trial of one oral disease modifying anti-rheumatic agent (DMARD) such as methotrexate, azathioprine, hydroxychloroquine, penicillamine, sulfasalazine, or leflunomide</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.)</p> <p>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</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, Avsola, AND Renflexis)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | Autoimmune |
| Remicade or infliximab unbranded, Renflexis, Inflectra, 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) AND used in combination with methotrexate</p> <p>Psoriatic Arthritis: Trial of one NSAID OR Trial of one oral DMARD</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 or Avsola | All indications: Trial of Inflectra                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | Autoimmune           |
| Simponi Aria        | <p>Rheumatoid Arthritis: Trial of one oral disease modifying anti-rheumatic agent (DMARD)</p> <p>Psoriatic Arthritis: Trial of one NSAID OR Trial of one oral DMARD</p> <p>Ankylosing Spondylitis: Trial of two NSAIDs</p> <p>Polyarticular Juvenile Idiopathic Arthritis (pJIA): Trial of oral NSAIDs OR Trial of an oral DMARD</p>                                                                                                                                                                                                                                  | Autoimmune           |
| Stelara             | <p>Crohn's Disease: Trial of one of the following - corticosteroids or immunomodulators, (e.g., 6-mercaptopurine, methotrexate, azathioprine) AND Trial of one TNF modifier 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 Trial of one TNF modifier (e.g., Humira, Simponi, Inflectra, Renflexis, Avsola, or Remicade) AND Entyvio (except for if the member failed to respond to infliximab)</p> | Autoimmune           |
| Tremfya             | <p>Plaque psoriasis: Trial of one of the following - methotrexate, cyclosporine, or acitretin</p> <p>Active Psoriatic Arthritis: Trial of at least two NSAIDs OR Trial of one DMARD</p>                                                                                                                                                                                                                                                                                                                                                                               | 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           | <p>Hypercalcemic emergency: Trial of cinacalcet</p> <p>Paget's disease: trial of both of the following - alendronate and pamidronate</p> <p>Postmenopausal osteoporosis: Trial of two of the following - zoledronic acid, alendronate, teriparatide, Prolia (denosumab), Xgeva (denosumab)</p>                                                                                                                                                                                                                                                                        | Calcitonin           |

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| 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                  |
| 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<br><br>Adult Relapsed or Refractory (r/r) Large B-cell Lymphoma: For diffuse large B-cell lymphoma arising from follicular lymphoma, high-grade B- cell lymphoma: Member has previously received at least 2 lines of therapy including rituximab and an anthracycline | CAR-T Immunotherapy         |
| Yescarta    | Non-Hodgkin Lymphomas (chemotherapy – refractory disease): trial and failure of two or more lines of systemic chemotherapy OR for DLBCL, failure of 2 or more lines of systemic chemotherapy, including rituximab and an anthracycline<br><br>Follicular Lymphoma: trial of 2 or more lines of systemic therapies, including the combination of an anti-CD20 monoclonal antibody and an alkylating agent (e.g., R-bendamustine, R-CHOP, R-CVP)                                                                                                                                                                                                                                                                                                                                | CAR-T Immunotherapy         |
| 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 |

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| Viltepso                                                                                                        | All indications: trial of corticosteroids                                                                                                                                                                                                                                                             | Duchenne Muscular Dystrophy |
| Vyondys 53                                                                                                      | All indications: Trial of corticosteroids and Viltepso                                                                                                                                                                                                                                                | Duchenne Muscular Dystrophy |
| Elelyso, VPRIV                                                                                                  | All indications: Trial of Cerezyme                                                                                                                                                                                                                                                                    | Enzyme Replacement          |
| Nexviazyme                                                                                                      | Trial of Lumizyme                                                                                                                                                                                                                                                                                     | Enzyme                      |
| Krystexxa                                                                                                       | All indications: Trial of all of the following -Allopurinol, Probenecid                                                                                                                                                                                                                               | Gout                        |
| Aranesp                                                                                                         | All indications: Trial of Retacrit                                                                                                                                                                                                                                                                    | Hematopoetic Agent          |
| Long Acting Colony Stimulating Factors – Preferred: Neulasta Onpro and Ziextenzo                                | All approved indications: Trial of Zarxio                                                                                                                                                                                                                                                             | Hematopoetic Agent          |
| Long Acting Colony Stimulating Factors – Non Preferred: Fulphila, Nyvepria, Udenyca (Oncology and Non Oncology) | All approved indications: Trial of Zarxio AND either Neulasta Onpro or Ziextenzo                                                                                                                                                                                                                      | 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 (Oncology and Non Oncology)                 | All indications: 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)<br><br>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       |

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| 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       |
| Somatuline Depot or Bynfezia pen                                                                                                                                       | All Indications: trial of Sandostatin IV/SQ or LAR Depot                                                                                                                                        | Hormone Therapy       |
| Triptodur                                                                                                                                                              | Central Precocious Puberty : Trial of Trelstar                                                                                                                                                  | 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, sodium hyaluronate 1% | 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                                                                                          | 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      |

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| Intravenous Immune Globulins: Asceniv, Bivigam, Gammagard S/D, Gammalex, Privigen or Panzyga | <p>All indications: Gammaked/Gamunex-C, Gammagard liquid, Flebogamma/Flebogamma DIF, or Octagam</p> <p>Myasthenia Gravis: patient is failing on conventional immunosuppressant therapy alone (e.g., corticosteroids, azathioprine, cyclosporine, mycophenolate, methotrexate, tacrolimus, cyclophosphamide, etc.)</p> <p>Dermatomyositis or Polymyositis: Trial of one corticosteroid AND one immunosuppressant (e.g., methotrexate, azathioprine)</p> <p>Chronic Inflammatory Demyelinating Polyneuropathy: Trial of one corticosteroid</p> <p>Stiff-Person syndrome: Trial of two of the following - benzodiazepines, baclofen, gabapentin, valproate, tiagabine, or levetiracetam</p> <p>Management of Immune-Checkpoint-Inhibitor Related Toxicity: Trial of high dose corticosteroids or methylprednisolone</p> <p>Autoimmune Mucocutaneous Blistering Diseases: corticosteroids and concurrent immunosuppressive treatment (e.g., azathioprine, cyclophosphamide, mycophenolate mofetil, etc.)</p> | Immune Globulins              |
| Monoferic                                                                                    | Trial of Injectafer or Feraheme                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | Iron Agent                    |
| Benlysta                                                                                     | <p>Systemic Lupus Erythematosus: Trial of two standard therapies such as antimalarials, corticosteroids, non-steroidal anti-inflammatory drugs, or immunosuppressives</p> <p>Lupus Nephritis: Trial of standard therapies including corticosteroids AND either cyclophosphamide or mycophenolate mofetil</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | Lupus                         |
| Saphnelo                                                                                     | Trial of one standard of care therapy (e.g., prednisone, hydroxychloroquine, azathioprine, mycophenolate mofetil, methotrexate) 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 |
| Cinqair                                                                                      | Asthma: Trial of Inhaled corticosteroid; AND an additional controller medication (long acting beta 2-agonist, leukotriene modifier, or sustained-release theophylline); AND Fasenra, Nucala, and Xolair                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | Monoclonal Antibody           |

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| Fasenra  | Asthma: Trial of Inhaled corticosteroid AND an additional controller medication (long acting beta 2-agonist, leukotriene modifier, or sustained-release theophylline)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | Monoclonal Antibody |
| Nucala   | <p>Asthma: Trial of a medium – high dose inhaled corticosteroid; AND an additional controller medication (long acting beta 2-agonist, leukotriene modifier, etc.)</p> <p>Eosinophilic granulomatosis with polyangiitis: Trial of oral corticosteroids for at least 4 weeks</p> <p>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</p>                                                                                                                                                                                                                                                                                                                                       | Monoclonal Antibody |
| Soliris  | <p>Myasthenia Gravis: Trial of two of the following - azathioprine, cyclosporine, mycophenolate mofetil, methotrexate, OR one immunosuppressive therapy and required chronic treatment with plasmapheresis or plasma exchanges or IVIG</p> <p>Neuromyelitis optica spectrum disorder (NMOSD): Trial of Uplizna</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | Monoclonal Antibody |
| Xolair   | <p>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.</p> <p>Asthma: Trial of Inhaled corticosteroid; AND an additional controller medication (long acting beta 2-agonist, leukotriene modifier, or sustained-release theophylline)</p> <p>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</p> | Monoclonal Antibody |
| Lemtrada | Multiple Sclerosis: Trial of two drugs indicated for Multiple Sclerosis AND trial and failure of Tysabri                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | Multiple Sclerosis  |

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| Ocrevus | Multiple Sclerosis: Trial of a disease modifying agent if the patient is not newly diagnosed with relapsing Multiple Sclerosis                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | Multiple Sclerosis          |
| Tysabri | Multiple Sclerosis: Trial of two drugs indicated for the treatment of relapsing MS<br><br>Crohn's Disease: Trial of two oral immunosuppressive therapies, such as corticosteroids, 6-mercaptopurine, methotrexate, and/or azathioprine AND Trial of one TNF-inhibitor                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | Multiple Sclerosis/Crohn's  |
| Vyvgart | Trial of two (2) or more immunosuppressive therapies (e.g., corticosteroids plus an immunosuppressant such as azathioprine, cyclosporine, mycophenolate, etc.); OR<br>Trial of chronic treatment with plasmapheresis or plasma exchange (PE) or intravenous immunoglobulin (IVIG) in addition to immunosuppressant therapy                                                                                                                                                                                                                                                                                                                                                                                                                                                 | Myasthenia Gravis           |
| Botox   | Migraine: two oral medications for the prevention of migraines, such as<br>Antidepressants (e.g., amitriptyline, fluoxetine, nortriptyline, etc.)<br>Beta blockers (e.g., propranolol, metoprolol, nadolol, timolol, atenolol, pindolol, etc.)<br>Angiotensin converting enzyme inhibitors/angiotensin II receptor blockers (e.g., lisinopril, candesartan, etc.)<br>Anti-epileptics (e.g., divalproex, valproate, topiramate, etc.)<br>Calcium channels blockers (e.g., verapamil, etc.)<br><br>Urinary incontinence and OAB: Trial of two medications from either the antimuscarinic or beta-adrenergic classes<br><br>Chronic Anal Fissures: Trial of conventional pharmacologic therapy (e.g., nifedipine, diltiazem, and/or topical nitroglycerin, bethanechol, etc.) | Neuromuscular Blocker Agent |

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|----------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------|
| Dysport                                      | <p>Migraine: 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>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</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>                                                                                                                                                                                                                                                                                                                  | Neuromuscular Blocker Agent |
| Xeomin                                       | <p>Migraine: 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>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                                      | All Oncology Indications: Trial of Bevacizumab biosimilar product, such as 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                    |

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| Nipent          | Chronic or acute graft versus host disease (GVHD): Trial of corticosteroids                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | Oncology              |
| Rituxan Hycela  | All indications: Ruxience or Truxima                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | Oncology              |
| Rituxan, Riabni | All indications: Ruxience or Truxima<br><br>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)<br><br>Lupus Nephritis: Trial of standard first line therapy [e.g., mycophenolate mofetil, mycophenolic acid, cyclophosphamide, calcineurin inhibitors (e.g., tacrolimus)]<br><br>Myasthenia Gravis: Trial of standard first line therapy (e.g., glucocorticoids, azathioprine, mycophenolate mofetil, etc.) | Oncology              |
| Beovu           | Neovascular (wet) age related macular degeneration (AMD): bevacizumab                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | Ophthalmic Agent      |
| Durysta         | 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)                                                                                                                                                                                                                                                                                                                                                                        | Ophthalmic Agent      |
| Eylea           | Diabetic Macular Edema (DME) with a baseline visual acuity of 20/50 or worse: bevacizumab or ranibizumab (Lucentis)<br><br>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                                                                                                                                                                                                                                                                                                        | Ophthalmic Agent      |
| Lucentis        | All indications: bevacizumab                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | Ophthalmic Agent      |
| Tepezza         | Thyroid Eye Disease: Intravenous glucocorticoids                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | Ophthalmic Agent      |
| Oxumo           | Trial of at least 3 months of pyridoxine                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | Primary Hyperoxaluria |
| Signifor LAR    | Acromegaly: Trial of Sandostatin LAR (octreotide) or Somatuline Depot (lanreotide)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | Somatostatin Analog   |

\*\*\* 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 call member services at 1-844-812-6896 for INTEGRITY (Medicare Medicaid Plan) members.**