Clinical Policy: Step Therapy

Reference Number: WCG.MCPB.ST.00
Effective Date: 01.01.21
Last Review Date: 12.20
Line of Business: Medicare Part B for Legacy Wellcare

See Important Reminder at the end of this policy for important regulatory and legal information.

Description

This policy provides a list of drugs that require step therapy. Step therapy is when we require the trial of a preferred therapeutic alternative prior to coverage of a non-preferred drug for a specific indication.

FDA Approved Indication(s)

Various.

Policy/Criteria

This policy does not replace existing Medicare rules and regulations for the applicable agent(s).

The following drugs are **medically necessary** when the member meets the criteria below based on MCPB step therapy requirement, FDA indication and/or CMS approved pharmacy compendia:

I. Approval Criteria (NEW STARTS ONLY – member has not received the drug for the past 365 days)

A. Step Therapy:

Drug Name	Part B Required Step-Through Agents* By Indication **The Regimen May require prior authorization*
Abatacept (Orencia®)	• **Polyarticular juvenile idiopathic arthritis**: a tumor necrosis factor (TNF) inhibitor*
Aflibercept (Eylea®)	• **Neovascular (wet) age-related macular degeneration (AMD), macular edema following retinal vein occlusion (RVO), diabetic macular edema (DME), or diabetic retinopathy (DR)**: intravitreal bevacizumab solution
Atezolizumab (Tecentriq®)	• **Urothelial carcinoma, non-small cell lung cancer**: prior platinum-containing chemotherapy* (*note some IV chemo may not require prior authorization*)
Axicabtagene ciloleucel (Yescarta®)	• **Large B-cell lymphoma**: 2 lines of systemic therapy that includes rituximab* and one anthracycline-containing regimen (e.g., doxorubicin) *Only for initial treatment dose; subsequent doses will not be covered*
Bevacizumab (Avastin®, Mvasi®, Zirabev™)	• **Oncology indications**, if request is for Avastin: Mvasi* or Zirabev*

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Drug Name	Part B Required Step-Through Agents* By Indication **The Regimen May require prior authorization*
Brexucabtagene autoleucel (Tecartus™)	• **Mantle cell lymphoma**: 2 to 5 prior regimens that included all of the following: anthracycline (e.g., doxorubicin*) or bendamustine*-containing chemotherapy; anti-CD20 monoclonal antibody therapy (e.g., rituximab*) *Only for initial treatment dose; subsequent doses will not be covered*
Brolucizumab-dbll (Beovu®)	• **Neovascular (wet) AMD**: intravitreal bevacizumab solution
Certolizumab (Cimzia®)	• **Crohn's disease**: a different TNF inhibitor* • **Ankylosing spondylitis**: a different TNF inhibitor*
Corticosteroid intravitreal implants: dexamethasone (Ozurdex®), fluocionolone acetonide (Iluvien®, Retisert®, Yutiq™)	• **Macular edema following branch or central RVO (*Ozurdex only*)**: intravitreal bevacizumab solution • **Non-infectious uveitis affecting the posterior segment of the eye (*Ozurdex, Retisert, or Yutiq*)**: intravitreal bevacizumab solution • **DME (*Ozurdex or Iluvien*)**: intravitreal bevacizumab solution
Corticotropin (H.P. Acthar®)	• **Multiple sclerosis**: corticosteroid and multiple sclerosis treatment (e.g., Avonex*, Betaseron*, Plegridy*, glatiramer*, Copaxone*, Glatopa*, Rebif*)
Daratumumab (Darzalex®)	• **Multiple myeloma, systemic light chain amyloidosis**: 1 prior systemic therapy (e.g., bortezomib*, carfilzomib*) (*note some IV chemo may not require prior authorization*)
Denosumab (Xgeva®)	• **Systemic mastocytosis**: zoledronic acid* or pamidronate* • **Hypercalcemia of malignancy**: zoledronic acid* or pamidronate*
Durvalumab (Imfinzi®)	• **Urothelial carcinoma**: platinum-containing chemotherapy* (*note some IV chemo may not require prior authorization*)
Eculizumab (Soliris®)	• **Neuromyelitis optica spectrum disorder**: rituximab*
Elotuzumab (Empliciti®)	• **Multiple myeloma**: prior line of systemic therapy (e.g., bortezomib*) (*note some IV chemo may not require prior authorization*)
Emapalumab-lzsg (Gamifant™)	• **Primary hemophagocytic lymphohistiocytosis (HLH)**: conventional HLH therapy that includes an etoposide-* and dexamethasone-based regimen* (*note some IV chemo may not require prior authorization*)

Drug Name	Part B Required Step-Through Agents* By Indication **The Regimen May require prior authorization*
Enfortumab vedotin-ejfv (Padcev™)	• **Urothelial carcinoma**: a PD-1 or PD-L1 inhibitor, and a platinum-containing chemotherapy* (*note some IV chemo may not require prior authorization*)
Filgrastim (Neupogen®, Zarxio®, Nivestym™, Granix®)	• **All indications**, if request is for an agent other than Zarxio: Zarxio*
Golimumab (Simponi®, Simponi Aria®)	• **Ankylosing spondylitis**: a different TNF inhibitor*
Hyaluronate derivatives: sodium hyaluronate (Euflexxa®, Gelsyn-3™, GenVisc®850, Hyalgan®, Supartz™, Supartz FX™, Synojoynt™, Triluron™, TriVisc™, VISCO-3™), hyaluronic acid (Durolane®), cross-linked hyaluronate (Gel-One®), hyaluronan (Hymovis®, Orthovisc®, Monovisc®), hylan polymers A and B (Synvisc®, Synvisc One®)	• **Osteoarthritis of the knee**: intra-articular glucocorticoid injection, and: ○ If request is for a product other than Synvisc/Synvisc One or Euflexxa: Synvisc*/Synvisc One* or Euflexxa*
Immune globulins (Asceniv™, Bivigam®, Carimune® NF, Cutaquig®, Cuvitru™, Flebogamma® DIF, GamaSTAN®, GamaSTAN® S/D, Gammagard® liquid, Gammagard® S/D, Gammaked™, Gammaplex®, Gamunex®-C, Hizentra®, HyQvia®, Octagam®, Panzyga®, Privigen®, Xembify®)	• **<u>ALL INDICATIONS</u> except viral prophylaxis for hepatitis A, measles, varicella, or rubella viruses**, if request is for an agent other than Gammagard: Gammagard* <u>IN ADDITION:</u> • **Chronic idiopathic demyelinating polyneuropathy**: a systemic corticosteroid (e.g., prednisone) • **Dermatomyositis**: rituximab* • **Idiopathic thrombocytopenic purpura**: Rho(D) immune globulin* • **Opsoclonus-myoclonus syndrome**: one systemic corticosteroid • **Pemphigus vulgaris, pemphigus foliaceus, bullous pemphigoid, mucous membrane pemphigoid (a.k.a. cicatricial pemphigoid), or epidermolysis bullosa acquisita**: one corticosteroid and rituximab*

Drug Name	Part B Required Step-Through Agents* By Indication **The Regimen May require prior authorization*
	• **Adenosine deaminase (ADA)-severe combined immunodeficiency disorders (SCID)**: Adagen* or Revcovi*
Infliximab (Remicade®, Renflexis™, Inflectra®, Avsola ™)	• **All Indications:** if request is for Remicade: Inflectra* and Renflexis*
Natalizumab (Tysabri®)	• **Crohn's disease**: infliximab*
OnabotulinumtoxinA (Botox®)	• **Upper limb spasticity, Cervical Dystonia, Blepharospasm**: Xeomin*
Pegaptanib (Macugen®)	• **Neovascular (wet) AMD**: intravitreal bevacizumab solution
Pegfilgrastim (Neulasta®, Fulphila™, Nyvepria™, Udenyca™, Ziextenzo™)	• **All indications**: Zarxio*, unless member requires ≥ 10 doses of Zarxio, member is unable to self-administer Zarxio due to lack of caregiver or support system for assistance with administration and inadequate access to healthcare facility or home care interventions ○ If unable to use Zarxio for any of the reasons listed above and request is for an agent other than Ziextenzo: Ziextenzo*
Ramucirumab (Cyramza®)	• **Esophageal, esophagogastric junction, and gastric cancer**: prior lines of systemic therapy* (*note some IV chemo may not require prior authorization*)
Ranibizumab (Lucentis®)	• **Neovascular (wet) AMD, macular edema following RVO, DME, DR, or myopic choroidal neovascularization (mCNV)**: intravitreal bevacizumab solution
Rituximab (Rituxan®, Riabni™, Truxima®, Ruxience™), rituximab/ hyaluronidase (Rituxan Hycela™)	• **All indications**, if request is for an agent other than Ruxience: Ruxience* (*credit may be given for other rituximab products if Rituxan Hycela is requested*) IN ADDTION: • **Rheumatoid arthritis**, if request is for Rituxan or Truxima: infliximab*
Romiplostim (Nplate®)	• **Immune thrombocytopenia:** if intolerant or contraindicated to systemic corticosteroids, then immune globulin* • **Myelodysplastic syndrome**: hypomethylating agent (e.g., azacitadine*, decitabine*) or immunosuppressive therapy (e.g., Atgam*, cyclosporine)
Romosuzumab-aqqg (Evenity™)	• **Postmenopausal osteoporosis**: bisphosphonate (e.g., zoledronic acid*), unless member is very high risk for fracture (BMD T-score at hip or spine ≤ -3.5, OR BMD

Drug Name	Part B Required Step-Through Agents* By Indication **The Regimen May require prior authorization*
	T-score at hip or spine ≤ -2.5 and major osteoporotic fracture [i.e., hip, spine, forearm, wrist, humerus])
Sargramostim (Leukine®)	• **All indications**: Zarxio*
Sipuleucel-T (Provenge®)	• **Prostate cancer**: androgen deprivation therapy (e.g., Zoladex*, Vantas*, leuprolide*, Trelstar*, Firmagon*)
Teprotumumab (Tepezza™)	• **Thyroid eye disease**: a systemic corticosteroid
Tisagenlecleucel (Kymriah®)	• **B-cell precursor acute lymphoblastic leukemia**: at least two prior systemic therapy* *Only for initial treatment dose; subsequent doses will not be covered* • **Large B-cell lymphoma**: 2 lines of systemic therapy that includes rituximab and one anthracycline*-containing regimen (e.g., doxorubicin*) *Only for initial treatment dose; subsequent doses will not be covered*
Tocilizumab (Actemra®)	• **Polyarticular juvenile idiopathic arthritis**: a TNF inhibitor*
Trastuzumab (Herceptin®, Ontruzant®, Herzuma®, Ogivri™, Trazimera™, Kanjinti™), trastuzumab/hyaluronidase (Herceptin Hylecta™)	• **All indications**, if request is for an agent other than Ogivri or Trazimera: Ogivri* or Trazimera*
Triamcinolone ER injection (Zilretta®)	• **Osteoarthritis of the knee**: intra-articular glucocorticoid injection*
Ustekinumab (Stelara®)	• **Crohn's disease**: a TNF inhibitor*
Vedolizumab (Entyvio®)	• **Ulcerative colitis**: infliximab*/infliximab biosimilar* • **Crohn's disease**: infliximab*/infliximab biosimilar*
Verteporfin (Visudyne®)	**Classic subfoveal CNV due to AMD, pathologic myopia, or presumed ocular histoplasmosis**: intravitreal bevacizumab solution

For questions, please reach out to your provider relations.

Important Reminder
This clinical policy has been developed by appropriately experienced and licensed health care professionals based on FDA recommendation(s), peer-reviewed medical literature and evidence-based clinical practice guidelines.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan or responsible business unit. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

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