Clinical Policy: Step Therapy

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Line of Business: Medicare Part B

Coding Implications
Revision Log

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.

FDA Approved Indication(s)
Various.

Policy/Criteria
This policy does not replace existing Medicare rules and regulations for the applicable agent(s). Relevant National Coverage Determination (NCD) and Local Coverage Determination (LCD) documents must be reviewed and applied for all coverage determinations (visit www.CMS.gov); if there are no applicable NCD or LCD documents, CMS approved pharmacy compendia (see Appendix B) must be reviewed. Thereafter the step therapy requirement(s) in this policy should be applied. Step therapy requirement(s) should not be applied if the request is not supported by NCD/LCD documents or CMS approved pharmacy compendia. All requests necessitating a denial based on this policy or requests for which no NCD/LCD document or compendia support exists must be directed to an Envolve Medical Director or Pharmacist for further review and final determination of medical necessity.

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 (see Appendix B):

I. Approval Criteria (NEW STARTS ONLY – member has not received the drug for the past 365 days)
Step therapy requirement(s) below should be applied in addition to any NCD/LCD documents if NCD/LCD is silent on the step therapy requirement. Step therapy requirements do not apply if request is for treatment associated with Stage IV or metastatic cancer for a State with regulations against step therapy in advanced oncology settings (see Appendix C)

A. Step Therapy:
Drugs listed in the table below may be approved for the duration of request or through the end of the contract year, whichever is less, for members who have had a previous trial of or who have contraindications to required step-through agents.

Drug Name	Part B Required Step-Through Agents*† By Indication **May require prior authorization* *†Exceptions for stage IV/metastatic cancer may apply; see Appendix C*
Abatacept (Orencia®)	PART B STEP: • **All indications**: a tumor necrosis factor (TNF) inhibitor (e.g., infliximab)* (*note credit may be given if another TNF inhibitor was tried*)
Ado-trastuzumab emtansine (Kadcyla®)	PART B STEP: • **Breast cancer**: trastuzumab-based therapy* and a taxane* (*note some IV chemo may not require prior authorization*)
Aflibercept (Eylea®)	PART B STEP: • **Neovascular (wet) age-related macular degeneration (AMD), macular edema following retinal vein occlusion (RVO), diabetic macular edema (DME), or diabetic retinopathy (DR)**: bevacizumab intravitreal solution

Drug Name	Part B Required Step-Through Agents*† By Indication **May require prior authorization* *†Exceptions for stage IV/metastatic cancer may apply; see Appendix C*
Atezolizumab (Tecentriq®)	PART B STEP: • **Urothelial carcinoma**: member is ineligible for platinum-containing chemotherapy as first-line systemic therapy* (*note some IV chemo may not require prior authorization*) • **Non-small cell lung cancer that is anaplastic lymphoma kinase (ALK) or epidermal growth factor receptor (EGFR) mutation negative or unknown**: prior platinum-containing chemotherapy* (*note some IV chemo may not require prior authorization*), UNLESS one of the following is met: ○ Request is for use as a single agent as first-line therapy for tumors that have high programmed death-ligand 1 (PD-L1) expression, defined as PD-L1 ≥ 50% (tumor cells [TC] ≥ 50%) or tumor-infiltrating immune cells (IC) covering ≥ 10% of the tumor area [IC ≥ 10%] ○ Disease is non-squamous, and Tecentriq is prescribed as combination therapy ○ No prior progression on a programmed death receptor-1 (PD-1) or PD-L1 inhibitor (e.g., Tecentriq, nivolumab, pembrolizumab, durvalumab), and Tecentriq is prescribed as single agent as subsequent therapy
Axicabtagene ciloleucel (Yescarta®)	PART B STEP: • **Large B-cell lymphoma**: 2 lines of systemic therapy that includes rituximab* and one anthracycline-containing regimen (e.g., doxorubicin) • **Relapsed or refractory follicular lymphoma (FL):** 2 lines of systemic therapy that includes a combination of an anti-CD20 monoclonal antibody* (e.g., rituximab or Gazyva) and an alkylating agent (e.g., bendamustine, cyclophosphamide, chlorambucil) *Only for initial treatment dose; subsequent doses will not be covered*
Bevacizumab (Avastin®, Mvasi®, Zirabev™)	PART B STEP: • **Oncology indications**, if request is for Avastin: Mvasi† and Zirabev†
Brexucabtagene autoleucel (Tecartus™)	PART B STEP: • **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) • **B-cell precursor acute lymphoblastic leukemia**: at least two prior systemic therapies* *Only for initial treatment dose; subsequent doses will not be covered*
Brolucizumab-dbll (Beovu®)	PART B STEP: • **Neovascular (wet) AMD**: bevacizumab intravitreal solution
Cemiplimab-rwlc (Libtayo®)	PART B STEP: • **Cutaneous squamous cell carcinoma**: cisplatin*, unless curative radiation therapy or surgery is not feasible
Certolizumab (Cimzia®)	PART B STEP: • **All indications**: a different TNF inhibitor (e.g., infliximab)* (*note credit may be given if another TNF inhibitor was tried*)

Drug Name	Part B Required Step-Through Agents*† By Indication **May require prior authorization* *†Exceptions for stage IV/metastatic cancer may apply; see Appendix C*
Corticosteroid intravitreal implants: dexamethasone (Ozurdex®), fluocionolone acetonide (Iluvien®, Retisert®, Yutiq™)	PART B STEP: • **Macular edema following branch or central RVO (*Ozurdex only*)**: bevacizumab intravitreal solution • **DME (*Ozurdex or Iluvien*)**: bevacizumab intravitreal solution
Corticotropin (H.P. Acthar®)	PART B STEP: • **Multiple sclerosis**: corticosteroid
Daratumumab (Darzalex®), daratumumab/ hyaluronidase-fihj (Darzalex Faspro™)	PART B STEP: • **Multiple myeloma**: 1 prior systemic therapy* (e.g., ixazomib, bortezomib, carfilzomib) (*note some IV chemo may not require prior authorization*) if prescribed in combination with dexamethasone and either lenalidomide, bortezomib, or carfilzomib; OR 2 prior systemic therapies* (e.g., ixazomib, bortezomib, carfilzomib) if prescribed as monotherapy or in combination with pomalidomide and dexamethasone; UNLESS the requested agent is prescribed as primary therapy in one of the following ways: ○ In combination with lenalidomide and dexamethasone or bortezomib, melphalan, and prednisone, and member is ineligible for autologous stem cell transplant (ASCT); or ○ In combination with bortezomib, thalidomide, and dexamethasone, and member is eligible for ASCT • **Systemic light chain amyloidosis (*Darzalex only*)**: 1 prior systemic therapy* (e.g., bortezomib) (*note some IV chemo may not require prior authorization*)
Darbepoetin alfa (Aranesp®)	PART B STEP: • **All indications**: Retacrit†
Denosumab (Xgeva®)	PART B STEP: • **Hypercalcemia of malignancy, systemic mastocytosis**: zoledronic acid (Zometa)† or pamidronate†
Durvalumab (Imfinzi®)	PART B STEP: • **Non-small cell lung cancer**: chemotherapy (e.g., platinum-containing chemotherapy)* (*note some IV chemo may not require prior authorization*)
Eculizumab (Soliris®)	PART B STEP: • **Neuromyelitis optica spectrum disorder**: rituximab*
Elotuzumab (Empliciti®)	PART B STEP: • **Multiple myeloma**: prior line of systemic therapy* (e.g., bortezomib) (*note some IV chemo may not require prior authorization*)
Emapalumab-lzsg (Gamifant™)	PART B STEP: • **Primary hemophagocytic lymphohistiocytosis (HLH)**: conventional HLH therapy that includes an etoposide- and dexamethasone-based regimen* (*note some IV chemo may not require prior authorization*)
Epoetin alfa (Epogen®, Procrit®)	PART B STEP: • **All indications**: Retacrit†
Filgrastim (Neupogen®, Zarxio®, Nivestym™, Granix®)	PART B STEP: • **All indications**, if request is for an agent other than Zarxio: Zarxio†

Drug Name	Part B Required Step-Through Agents*† By Indication **May require prior authorization* *†Exceptions for stage IV/metastatic cancer may apply; see Appendix C*
	○ If unable to use Zarxio and request is for Neupogen: biosimilar filgrastim product (e.g., Nivestym, Granix)†
Golimumab (Simponi®, Simponi Aria®)	PART B STEP: • **All indications**: a different TNF inhibitor (e.g., infliximab)* (*note credit may be given if another TNF inhibitor was tried*)
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®)	PART B STEP: • **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®)	PART B STEP: • **<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, polymyositis, myasthenia gravis/Lambert Eaton myasthenic syndrome, opsoclonus-myoclonus syndrome**: a systemic corticosteroid • **Dermatomyositis**: rituximab* • **Idiopathic thrombocytopenic purpura**: a systemic corticosteroid or Rho(D) immune globulin* • **Pemphigus vulgaris, pemphigus foliaceus, bullous pemphigoid, mucous membrane pemphigoid (a.k.a. cicatricial pemphigoid), or epidermolysis bullosa acquisita**: one corticosteroid and rituximab* • **Adenosine deaminase (ADA)-severe combined immunodeficiency disorders (SCID)**: Adagen or Revcovi
Infliximab (Remicade®, Avsola™, Inflectra®, Renflexis™)	PART B STEP: • **All indications,** if request is for Remicade: Avsola†, Inflectra†, and Renflexis†
Lisocabtagene maraleucel (Breyanzi®)	PART B STEP: • **Large B-cell lymphoma**: 2 lines of systemic therapy that includes an anti-CD20 therapy (e.g., rituximab)* and one anthracycline-containing regimen (e.g., doxorubicin) *Only for initial treatment dose; subsequent doses will not be covered*
Lurbinectedin (Zepzelca™)	PART B STEP: • **Small cell lung cancer**: platinum-containing regimen (e.g., cisplatin, carboplatin)* (*note some IV chemo may not require prior authorization*)
Luspatercept-aamt (Reblozyl®)	PART B STEP:

Drug Name	Part B Required Step-Through Agents*† By Indication **May require prior authorization* *†Exceptions for stage IV/metastatic cancer may apply; see Appendix C*
	• **Myelodysplastic syndrome:** erythropoiesis-stimulating agent used in combination with a granulocyte colony stimulating factor, unless current serum erythropoietin is greater than 500 mU/mL
Lutetium Lu 177 dotatate (Lutathera®)	PART B STEP: • **Neuroendocrine tumor**: somatostatin analog (e.g., octreotide, lanreotide)
Natalizumab (Tysabri®)	PART B STEP: • **Crohn's disease**: a TNF inhibitor (e.g., infliximab)* (*note credit may be given if another TNF inhibitor was tried*)

Nivolumab (Opdivo®)	PART B STEP:
	• **Non-small cell lung cancer**: prior systemic therapy*, UNLESS one of the following is met:
	  ○ Tumor is positive for the tumor mutation burden (TMB) biomarker, or
	  ○ Prescribed in combination with Yervoy for disease with RET rearrangement or unknown/negative mutation status for EGFR, ALK, ROS1, BRAF, MET exon 14 skipping, and NTRK gene fusion
	• **Malignant pleural mesothelioma**: prior therapy*, unless prescribed in combination with Yervoy
	• **Classical or pediatric Hodgkin lymphoma, anal carcinoma, vulvar cancer**: prior therapy*
	• **Squamous cell carcinoma of the head and neck**: platinum-containing regimen*
	• **Urothelial carcinoma**: platinum-containing regimen*, unless prescribed as adjuvant treatment and member is at high risk of recurrence after undergoing radical resection
	• **Esophageal squamous cell carcinoma**: fluoropyrimidine-based (e.g., 5- fluorouracil, capecitabine) and platinum-based chemotherapy*
	• **Gestational trophoblastic neoplasia**: platinum/etoposide-containing regimen*, unless disease is methotrexate-resistant and high-risk
	(*note some IV chemo may not require prior authorization*)

OnabotulinumtoxinA (Botox®)	PART B STEP: • **Upper limb spasticity, cervical dystonia**: Xeomin* and Dysport* • **Blepharospasm:** Xeomin* • **Lower limb spasticity:** Dysport*
Pegaptanib (Macugen®)	PART B STEP: • **Neovascular (wet) AMD**: bevacizumab intravitreal solution
Pegfilgrastim (Neulasta®, Fulphila™, Nyvepria™, Udenyca™, Ziextenzo™)	PART B STEP: • **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†

Drug Name	Part B Required Step-Through Agents*† By Indication **May require prior authorization* *†Exceptions for stage IV/metastatic cancer may apply; see Appendix C*
	▪ If unable to use Ziextenzo and request is for Neulasta: biosimilar pegfilgrastim product (e.g., Fulphila, Nyvepria, Udenyca)†
Pembrolizumab (Keytruda®)	PART B STEP: • **Head and neck squamous cell carcinoma**: platinum-containing chemotherapy*, unless prescribed as part of combination therapy or prescribed as a single agent for a tumor that expresses PD-L1 with a combined positive score (CPS) ≥ 1 • **Chronic Hodgkin lymphoma, primary mediastinal large B-cell lymphoma, esophageal squamous cell carcinoma, endometrial carcinoma, tumor mutational burden-high cancer, anal carcinoma, gestational trophoblastic neoplasia, malignant pleural mesothelioma, extranodal NK/T-cell lymphoma – nasal type, thymic carcinoma, vulvar carcinoma**: at least 1 prior therapy* • **Cervical cancer**: at least 1 prior therapy*, unless prescribed in combination with chemotherapy (e.g., paclitaxel/cisplatin, paclitaxel/carboplatin) • **Microsatellite instability-high/mismatch deficient cancer**: at least 1 prior therapy*, unless member has colorectal cancer • **Urothelial carcinoma**: platinum-containing chemotherapy*, unless ineligible • **Non-muscle invasive bladder cancer**: Bacillus Calemette-Gueron* • **Gastric, esophagogastric junction, or esophageal adenocarcinoma**: at least 1 prior therapy (if CPS ≥ 10) or 2 prior therapies*, unless prescribed in combination with fluoropyrimidine- and platinum-containing chemotherapy (*note some IV chemo may not require prior authorization*)
Polatuzumab vedotin-piiq (Polivy™)	PART B STEP: • **Diffuse large B-cell lymphoma, high-grade B-cell lymphoma, mantle cell lymphoma, monomorphic post-transplant lymphoproliferative disorder (B-cell type), AIDS-related B-cell lymphoma**: 2 prior therapies* • **Follicular lymphoma**: 1 prior therapy* (*note some IV chemo may not require prior authorization*)
Ramucirumab (Cyramza®)	PART B STEP: • **Esophageal, esophagogastric junction, and gastric cancer**: prior lines of systemic therapy* (*note some IV chemo may not require prior authorization*)
Ranibizumab (Lucentis®)	PART B STEP: • **Neovascular (wet) AMD, macular edema following RVO, DME, DR, or myopic choroidal neovascularization (mCNV)**: bevacizumab intravitreal solution
Rituximab (Rituxan®, Riabni™, Ruxience™, Truxima®), rituximab/ hyaluronidase (Rituxan Hycela™)	PART B STEP: • **All indications**, if request is for Rituxan: Ruxience, Truxima, and Riabni† • **All indications**, if request is for Riabni: Ruxience and Truxima†

Drug Name	Part B Required Step-Through Agents*† By Indication **May require prior authorization* *†Exceptions for stage IV/metastatic cancer may apply; see Appendix C*
	• **All oncology indications**, if request is for Rituxan Hycela: member has received at least one full dose of Rituxan, Riabni, Ruxience, or Truxima IN ADDITION: • **Rheumatoid arthritis**, if request is for Rituxan or Riabni: infliximab*
Romiplostim (Nplate®)	PART B STEP: • **Immune thrombocytopenia**: systemic corticosteroid (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™)	PART B STEP: • **Postmenopausal osteoporosis**: bisphosphonate, unless member is very high risk for fracture (BMD T-score at hip or spine ≤ -3.5, OR BMD T-score at hip or spine ≤ -2.5 and major osteoporotic fracture [i.e., hip, spine, forearm, wrist, humerus])
Sargramostim (Leukine®)	PART B STEP: • **All indications**: Zarxio†
Sipuleucel-T (Provenge®)	PART B STEP: • **Prostate cancer**: androgen deprivation therapy* (e.g., Zoladex, Vantas, leuprolide, Trelstar, Firmagon)
Teprotumumab-trbw (Tepezza™)	PART B STEP: • **Thyroid eye disease**: a systemic corticosteroid
Tisagenlecleucel (Kymriah®)	PART B STEP: • **B-cell precursor acute lymphoblastic leukemia**: at least two prior systemic therapies* *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®)	PART B STEP: • **Polyarticular juvenile idiopathic arthritis, systemic juvenile idiopathic arthritis, and rheumatoid arthritis**: a TNF inhibitor (e.g., infliximab)* (*note credit may be given if another TNF inhibitor was tried*)
Trastuzumab (Herceptin®, Ontruzant®, Herzuma®, Ogivri™, Trazimera™, Kanjinti™), trastuzumab/hyaluronidase (Herceptin Hylecta™)	PART B STEP: • **All indications**, if request is for an agent other than Trazimera: Trazimera† ○ If unable to use Trazimera and request is for Herceptin or Herceptin Hylecta: biosimilar trastuzumab product (e.g., Ogivri, Kanjinti)†
Triamcinolone ER injection (Zilretta®)	PART B STEP: • **Osteoarthritis of the knee**: intra-articular glucocorticoid injection
Ustekinumab (Stelara®)	PART B STEP:

Drug Name	Part B Required Step-Through Agents*† By Indication **May require prior authorization* *†Exceptions for stage IV/metastatic cancer may apply; see Appendix C*
	• **All indications**: a TNF inhibitor (e.g., infliximab)* (*note credit may be given if another TNF inhibitor was tried*)
Vedolizumab (Entyvio®)	PART B STEP: • **All indications**: a TNF inhibitor (e.g., infliximab)* (*note credit may be given if another TNF inhibitor was tried*)
Verteporfin (Visudyne®)	PART B STEP: • **Classic subfoveal CNV due to AMD, pathologic myopia, or presumed ocular histoplasmosis**: bevacizumab intravitreal solution

Approval duration:
H.P. Acthar – 3 weeks or through the end of the contract year, whichever is less
Hyaluronate derivatives – 6 months or through the end of the contract year, whichever is less
Zilretta – 3 months or through the end of the contract year, whichever is less
All other products – Duration of request or through the end of the contract year, whichever is less

II. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

ALK: anaplastic lymphoma kinase
AMD: age-related macular degeneration
ASCT: autologous stem cell transplant
BMD: bone mineral density
CMS: Centers for Medicare & Medicaid Services
CPS: combined positive score
DME: diabetic macular edema
DR: diabetic retinopathy
EGFR: epidermal growth factor receptor
FDA: Food and Drug Administration
HLH: hemophagocytic lymphohistiocytosis
IC: immune cells
LCA: local coverage article
LCD: local coverage determination
NCD: national coverage determination
PD-1: programmed death receptor-1
PD-L1: programmed death-ligand 1
RVO: retinal vein occlusion
TC: tumor cells
TMB: tumor mutation burden
TNF: tumor necrosis factor

Appendix B: CMS Approved Pharmacy Compendium

- Micromedex DrugDex® (with a IIb or higher rating)
- AHFS Drug Information
- Clinical Pharmacology
- NCCN Drugs and Biologics Compendium (with a Category 2B or higher rating)
- Lexi-Comp "Evidence Level A"

Appendix C: States with Regulations against Redirections in Stage IV or Metastatic Cancer

State	Step Therapy Prohibited?	Notes
FL	Yes	For stage 4 metastatic cancer and associated conditions
GA	Yes	For stage 4 metastatic cancer. Redirection does not refer to review of medical necessity or clinical appropriateness
IA	Yes	For standard of care stage 4 cancer drug use, supported by peer-reviewed, evidence-based literature, and approved by FDA
LA	Yes	For stage 4 advanced, metastatic cancer or associated conditions. Exception if "clinically equivalent therapy, contains identical active ingredient(s), and proven to have same efficacy
NV	Yes	For stage 3 and stage 4 cancer patients for a prescription drug to treat the cancer or any symptom thereof of the covered person
PA	Yes	For stage 4 advanced, metastatic cancer

State	Step Therapy Prohibited?	Notes
TN	Yes	For advanced metastatic cancer and associated conditions
TX	Yes	For stage 4 advanced, metastatic cancer and associated conditions

- The above regulations prohibit redirections for drugs that are used for Stage IV or metastatic cancer. However, the regulation does not prohibit appropriate use of therapy according to the prescribing information or NCCN guidelines.

III. Dosage and Administration
Refer to the individual prescribing information.

IV. Product Availability
Refer to the individual prescribing information.

V. References
Refer to the individual Envolve drug-specific policy.

Coding Implications
Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

HCPCS Codes	Description
Q2041	Axicabtagene Ciloleucel, up to 200 Million Autologous Anti-CD19 CAR T Cells, Including Leukapheresis And Dose Preparation Procedures, Per Infusion
J0718	Certolizumab pegol injection
Q2043	Chemotherapy administration, intravenous infusion technique; up to 1 hour, single or initial substance/drug
G2082	Office or other outpatient visit for the evaluation and management of an established patient that requires the supervision of a physician or other qualified health care professional and provision of up to 56 mg of esketamine nasal self-administration, includes 2 hours post administration observation
G2083	Office or other outpatient visit for the evaluation and management of an established patient that requires the supervision of a physician or other qualified health care professional and provision of greater than 56 mg esketamine nasal self-administration, includes 2 hours post administration observation
J7318	Hyaluronan or derivative, Durolane, for intra-articular injection, per dose
J7323	Hyaluronan or derivative, Euflexxa, for intra-articular injection, per dose
J7326	Hyaluronan or derivative, Gel-One, for intra-articular injection, per dose
J7328	Hyaluronan or derivative, Gel-Syn, for intra-articular injection, 0.1 mg
J7320	Hyaluronan or derivative, GenVisc 850, for intra-articular injection, 1 mg
J7321	Hyaluronan or derivative, Hyalgan or Supartz FX or Visco-3, for intra-articular injection, per dose (Hyalgan dose is 20 mg/2 mL, Supartz and Visco-3 dose is 25 mg/2.5 mL)
J7322	Hyaluronan or derivative, Hymovis, for intra-articular injection, 1 mg
J7327	Hyaluronan or derivative, Monovisc, for intra-articular injection, per dose
J7324	Hyaluronan or derivative, Orthovisc, for intra-articular injection, per dose
J7331	Hyaluronan or derivative, Synojoynt, for intra-articular injection, 1 mg
J7325	Hyaluronan or derivative, Synvisc or Synvisc-One, for intra-articular injection, 1 mg
J7332	Hyaluronan or derivative, Triluron, for intra-articular injection, 1 mg
J7329	Hyaluronan or derivative, TriVisc, for intra-articular injection, 1 mg
J7321	Hyaluronan or derivative, Visco-3, for intra-articular injection, per dose
J0129	Injection, abatacept, 10 mg (code may be used for Medicare when drug administered under the direct supervision of a physician, not for use when drug is self-administered)

HCPCS Codes	Description
J9354	Injection, ado-trastuzumab emtansine, 1 mg
J0178	Injection, aflibercept, 1 mg
J9022	Injection, atezolizumab, 10 mg
J9035	Injection, bevacizumab, 10 mg
Q5107	Injection, bevacizumab-awwb biosimilar 10 mg
Q5118	Injection, bevacizumab-bvzr, biosimilar, (Zirabev), 10 mg
J0179	Injection, brolucizumab-dbll, 1mg
J9119	Injection, cemiplimab-rwlc, 1 mg
J0717	Injection, certolizumab pegol, 1 mg (code may be used for Medicare when drug administered under the direct supervision of a physician, not for use when drug is self-administered)
J0800	Injection, corticotropin, up to 40 units
J9145	Injection, daratumumab, 10 mg
J9144	Injection, daratumumab, 10 mg and hyaluronidase-fihj
J0882	Injection, darbepoetin alfa, 1 microgram (for ESRD on dialysis)
J0881	Injection, darbepoetin alfa, 1 microgram (non-ESRD use)
J0897	Injection, denosumab, 1 mg
J7312	Injection, dexamethasone intravitreal implant, 0.1 mg
J9173	Injection, durvalumab, 10 mg
J1300	Injection, eculizumab 10 mg
J9176	Injection, elotuzumab, 1 mg
J9210	Injection, emapalumab-lzsg, 1 mg
C9050	Injection, emapalumab-lzsg, 1 mg
J0885	Injection, epoetin alfa, (for non-ESRD use), 1000 units
Q4081	Injection, epoetin alfa, 100 units (for ESRD on dialysis)
J1442	Injection, filgrastim (G-CSF), excludes biosimilars, 1 microgram
Q5110	Injection, filgrastim-aafi, biosimilar, 1 microgram
Q5101	Injection, filgrastim-sndz, biosimilar, 1 microgram
J7314	Injection, fluocinolone acetonide intravitreal implant, 0.18 mg (Yutiq)
J7313	Injection, fluocinolone acetonide intravitreal implant, 0.19 mg (Iluvien,)
J7311	Injection, fluocinolone acetonide intravitreal implant, 0.59 mg (Retisert)
J1602	Injection, golimumab, 1 mg, for intravenous use
J1554	Injection, immune globulin (Asceniv), 500 mg
J1556	Injection, immune globulin (Bivigam), 500 mg
J1555	Injection, immune globulin (Cuvitru), 100 mg
J1572	Injection, immune globulin (Flebogamma/Flebogamma DIF), intravenous, non-lyophilized (e.g., liquid), 500 mg
J1569	Injection, immune globulin (Gammagard liquid), intravenous, non-lyophilized (e.g., liquid), 500 mg
J1557	Injection, immune globulin (Gammaplex), intravenous, non-lyophilized (e.g., liquid), 500 mg
J1561	Injection, immune globulin (Gamunex-C/Gammaked), intravenous, non-lyophilized (e.g., liquid), 500 mg
J1559	Injection, immune globulin (Hizentra), 100 mg
J1568	Injection, immune globulin (Octagam), intravenous, non-lyophilized (e.g., liquid), 500 mg
J1459	Injection, immune globulin (Privigen), intravenous, non-lyophilized (e.g., liquid), 500 mg
J1558	Injection, immune globulin (Xembify), 100 mg
J1562	Injection; immune globulin 10%, 5 grams
J1566	Injection, immune globulin, intravenous, lyophilized (e.g., powder), not otherwise specified, 500 mg

HCPCS Codes	Description
J1599	Injection, immune globulin, intravenous, nonlyophilized (e.g., liquid), not otherwise specified, 500 mg
J1575	Injection, immune globulin/hyaluronidase (Hyqvia), 100 mg immuneglobulin
Q5103	Injection, Inflectra
Q5121	Injection, infliximab-axxq, biosimilar, (avsola), 10 mg
Q5109	Injection, infliximab-qbtx, biosimilar, 10 mg
J1745	Injection, infliximab, excludes biosimilar, 10 mg
J9223	Injection, lurbinectedin, 0.1 mg
J0896	Injection, luspatercept-aamt, 0.25 mg
J2323	Injection, natalizumab, 1 mg
J9299	Injection, nivolumab, 1 mg
J0585	Injection, onabotulinumtoxinA, 1 unit
J2503	Injection, pegaptanib sodium, 0.3 mg
J2505	Injection, pegfilgrastim, 6 mg
Q5122	Injection, pegfilgrastim-apfg, biosimilar, (Nyvepria), 0.5 mg
Q5120	Injection, pegfilgrastim-bmez, biosimlar, (Ziextenzo), 0.5 mg
Q5111	Injection, pegfilgrastim-cbqv, biosimilar, (Udenyca), 0.5 mg
Q5108	Injection, pegfilgrastim-jmdb, biosimilar, (Fulphila), 0.5 mg
J9271	Injection, pembrolizumab, 1 mg
J9309	Injection, polatuzumab vedotin-piiq, 1 mg
J9308	Injection, ramucirumab, 5mg
J2778	Injection, ranibizumab, 0.1 mg
Q5104	Injection, Renflexis
J9311	Injection, rituximab 10 mg and hyaluronidase
J9312	Injection, rituximab, 10 mg
Q5115	Injection, rituximab-abbs, biosimilar, (Truxima) 10 mg
Q5123	Injection, rituximab-arrx, biosimilar, (Riabni) 10 mg
Q5119	Injection, rituximab-pvvr, biosimilar, (Ruxience), 10 mg
J2796	Injection, romiplostim, 10 micrograms
J3111	Injection, romosozumab-aqqg, 1 mg
J2820	Injection, sargramostim (GM-CSF), 50 mcg
J1447	Injection, tbo-filgrastim, 1 microgram
C9061	Injection, teprotumumab-trbw, 10 mg
J3241	Injection, teprotumumab-trbw, 10 mg
J9355	Injection, trastuzumab, 10 mg
Q5112	Injection, trastuzumab-dttb, biosimilar, 10 mg
Q5113	Injection, trastuzumab-pkrb, biosimilar, 10 mg
Q5114	Injection, trastuzumab-dkst, biosimilar, 10 mg
Q5116	Injection, trastuzumab-qyyp, biosimilar, 10 mg
Q5117	Injection, trastuzumab-anns, biosimilar, 10 mg
J9356	Injection, trastuzumab, 10 mg and Hyaluronidase-oysk
J3304	Injection, triamcinolone acetonide, preservative-free, extended-release, microsphere formulation, 1 mg
J3380	Injection, vedolizumab, 1 mg
J3396	Injection, verteporfin, 0.1 mg
C9076	Lisocabtagene maraleucel per therapeutic dose
A9513	Lutetium Lu 177 dotatate therapeutic, 1 mci
J3262	Tocilizumab injection
Q2042	Tisagenlecleucel, up to 600 million car-positive viable t cells, including leukapheresis and dose preparation procedures, per therapeutic dose
J3358	Ustekinumab, for intravenous injection, 1 mg
J3357	Ustekinumab, for subcutaneous injection, 1 mg

HCPCS Codes	Description
Q2053	Brexucabtagene Autoleucel, up to 200 million autologous anti-CD19 car positive viable t cells, including leukapheresis and dose preparation procedures, per therapeutic dose

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created.	08.30.21	11.21

Important Reminder
This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information.

This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. 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.