Clinical Policy: Step Therapy

Reference Number: MCPB.ST.00
Effective Date: 01.01.21
Last Review Date: 06.25
Line of Business: Medicare Part B

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).

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 **May require prior authorization*
Abatacept (Orencia®)	PART B STEP: • **All indications, except prophylaxis for acute graft-versus-host disease**: 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*, UNLESS prescribed as adjuvant treatment (*note some IV chemo may not require prior authorization*)
Afamitresgene autoleucel (Tecelra®)	PART B STEP: • **Synovial sarcoma**: prior systemic chemotherapy* (*note some IV chemo may not require prior authorization*)
Aflibercept (Eylea®, Eylea® HD, Ahzantive™, Enzeevu™, Opuviz™, Pavblu™)	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)**: intravitreal bevacizumab solution

Drug Name	Part B Required Step-Through Agents* By Indication **May require prior authorization*
Atezolizumab (Tecentriq®), atezolizumab/ hyaluronidase-tqjs (Tecentriq Hybreza™)	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 high-risk stage IIA or stage IIIB with programmed death-ligand 1 (PD-L1) expression ≥ 1% OR is recurrent, advanced, or metastatic and 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: o Request is for use as a single agent, and disease is stage II to III with previous resection o Request is for use as a single agent as first-line therapy for tumors that have high 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%] o Disease is non-squamous, and Tecentriq/ Tecentriq Hybreza is prescribed as combination therapy o No prior progression on a programmed death receptor-1 (PD-1) or PD-L1 inhibitor (e.g., atezolizumab, nivolumab, pembrolizumab, durvalumab), and Tecentriq/Tecentriq Hybreza is prescribed as single agent as subsequent therapy
Axicabtagene ciloleucel (Yescarta®)	PART B STEP: • **Large B-cell lymphoma**: one of the following: o 2 lines of systemic therapy that includes rituximab* and one anthracycline-containing regimen (e.g., doxorubicin) o First-line chemoimmunotherapy that includes an anti-CD20 monoclonal antibody (e.g., rituximab*) and anthracycline-containing regimen (e.g., doxorubicin), if disease was refractory (defined as no complete remission) to or relapsed (defined as complete remission followed by biopsy-proven disease relapse) no more than 12 months after chemoimmunotherapy

Drug Name	Part B Required Step-Through Agents* By Indication **May require prior authorization*
	○ Disease relapsed more than 12 months after completion of first-line therapy and partial response following second-line therapy • **Relapsed or refractory follicular lymphoma:** 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®, Alymsys®, Mvasi®, Vegzelma™, Zirabev™)	PART B STEP: • **Oncology indications**, if request is for Avastin, Alymsys, or Vegzelma: Mvasi and Zirabev
Brentuximab vedotin (Adcetris®)	PART B STEP: • **Lymphomatoid papulosis, B-cell lymphomas:** prior systemic therapy* (*note some IV chemo may not require prior authorization*)
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, DME**: intravitreal bevacizumab solution
Cemiplimab-rwlc (Libtayo®)	PART B STEP: • **Cutaneous squamous cell carcinoma**: cisplatin*, UNLESS one of the following is met: ○ Curative radiation therapy or surgery is not feasible, or • Prescribed as neoadjuvant treatment
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*)
Ciltacabtagene autoleucel (Carvykti™)	PART B STEP: • **Lenalidomide-refractory multiple myeloma**: at least 1 prior line of therapy* that included both of the

Drug Name	Part B Required Step-Through Agents* By Indication **May require prior authorization*
	following: immunomodulatory agent (e.g., lenalidomide, Pomalyst, Thalomid) and proteasome inhibitor (e.g., bortezomib, Kyprolis) *Only for initial treatment dose; subsequent doses will not be covered*
Corticosteroid intravitreal implants: dexamethasone (Ozurdex®), fluocinolone acetonide (Iluvien®)	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®, Purified Cortrophin™ Gel)	PART B STEP: • **All indications, except infantile spasms**, if request is for H.P. Acthar: Purified Cortrophin Gel IN ADDITION: • **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, pomalidomide, bortezomib, carfilzomib, Venclexta, or Xpovio; OR 3 prior lines of systemic therapies (e.g., ixazomib*, bortezomib*, carfilzomib*) if prescribed as monotherapy; UNLESS the requested agent is prescribed as primary therapy in one of the following ways: o Member is ineligible for autologous stem cell transplant (ASCT), and prescribed in combination with lenalidomide/dexamethasone or bortezomib/melphalan/prednisone; or o Member is eligible for ASCT, and prescribed in combination with one of the following: bortezomib/thalidomide/dexamethasone, bortezomib/lenalidomide/dexamethasone, bortezomib/cyclophosphamide/dexamethasone, carfilzomib/lenalidomide/dexamethasone; or o Maintenance therapy as a single agent or in combination with lenalidomide for transplant candidates • **Systemic light chain amyloidosis**: 1 prior systemic therapy (e.g., bortezomib*) (*note some IV chemo may not require prior authorization*), UNLESS one of the following is met:

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	○ Member has significant neuropathy or has Mayo stage IIIb disease, and the requested agent is prescribed as a single agent for newly diagnosed disease; or ○ Darzalex Faspro is prescribed in combination with bortezomib, cyclophosphamide, and dexamethasone
Darbepoetin alfa (Aranesp®)	PART B STEP: • **All indications**: Retacrit ○ If Retacrit is unavailable due to shortage: Epogen
Efbemalenograstim alfa-vuxw (Ryzneuta®)	PART B STEP: • **All indications**: Udenyca^† or Nyvepria ○ If member is unable to use Udenyca^ or Nyvepria: biosimilar pegfilgrastim product (e.g., Fulphila, Fylnetra, Stimufend, Ziextenzo)† *^ Udenyca refers to all formulations (prefilled syringe, autoinjector, and on-body injector)*
Eflapegrastim-xnst (Rolvedon™)	PART B STEP: • **All indications**: Udenyca^† or Nyvepria ○ If member is unable to use Udenyca^ or Nyvepria: biosimilar pegfilgrastim product (e.g., Fulphila, Fylnetra, Stimufend, Ziextenzo)† *^ Udenyca refers to all formulations (prefilled syringe, autoinjector, and on-body injector)*
Elranatamab-bcmm (Elrexfio™)	PART B STEP: • **Multiple myeloma**: 4 prior lines of therapy* that include all of the following: immunomodulatory agent (e.g., lenalidomide, Pomalyst, Thalomid), proteasome inhibitor (e.g., bortezomib, Kyprolis), and anti-CD38 antibody (e.g., Darzalex/Darzalex Faspro, Sarclisa)
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* (*note some IV chemo may not require prior authorization*)
Epoetin alfa (Epogen®, Procrit®)	PART B STEP: • **All indications**: Retacrit ○ If Retacrit is unavailable due to shortage: Epogen
Faricimab-svoa (Vabysmo®)	PART B STEP:

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	• **Neovascular (wet) AMD, DME, macular edema following RVO**: bevacizumab intravitreal solution

Ferric carboxymaltose (Injectafer®)	PART B STEP:
	• **Iron deficiency anemia (IDA) with chronic kidney disease (CKD):** Ferrlecit and Venofer
	  ○ If unable to use or failure of Ferrlecit and Venofer: generic Feraheme
	• **IDA without CKD:** two of the following: Ferrlecit, Infed, Venofer
	  ○ If unable to use or failure of Ferrlecit, Infed, and Venofer: generic Feraheme

Ferric derisomaltose (Monoferric®)	PART B STEP:
	• **IDA with CKD:** Ferrlecit and Venofer
	  ○ If unable to use or failure of Ferrlecit and Venofer: generic Feraheme
	• **IDA without CKD:** two of the following: Ferrlecit, Infed, Venofer
	  ○ If unable to use or failure of Ferrlecit, Infed, and Venofer: generic Feraheme
	• **Management of cancer- and chemotherapy-induced anemia:** two of the following: Ferrlecit, Infed, Venofer
	  ○ If unable to use or failure of Ferrlecit, Infed, and Venofer: generic Feraheme

Ferumoxytol (Feraheme®)	PART B STEP: • **All indications,** if request is for Feraheme: generic ferumoxytol <u>IN ADDITION:</u> • **IDA with CKD:** Ferrlecit and Venofer • **IDA without CKD:** two of the following: Ferrlecit, Infed, Venofer
Fidanacogene elaparvovec-dzkt (Beqvez™)	PART B STEP: • **Congenital hemophilia B:** factor IX product (e.g., Alprolix, Benefix, Idelvion, Ixinity, Rebinyn, Rixubis)

Filgrastim (Neupogen®, Zarxio®, Nivestym™, Granix®, Releuko®, Nypozi™)	PART B STEP:
	• **All indications**, if request is for an agent other than Zarxio: Zarxio
	  ○ If unable to use Zarxio: Nivestym
	  ▪ If unable to use Zarxio and Nivestym and request is for Neupogen: biosimilar filgrastim product (e.g., Granix, Releuko, Nypozi)

Golimumab (Simponi®, Simponi Aria®)	PART B STEP:

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	• **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 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*
Idecabtagene vicleucel (Abecma™)	PART B STEP: • **Multiple myeloma**: 2 prior lines of therapy* that include all of the following: immunomodulatory agent (e.g., lenalidomide, Pomalyst, Thalomid), proteasome inhibitor (e.g., bortezomib, Kyprolis), and anti-CD38 antibody (e.g., Darzalex/Darzalex Faspro, Sarclisa) *Only for initial treatment dose; subsequent doses will not be covered*
Imetelstat (Rytelo™)	PART B STEP: • **All indications**: Retacrit†, unless member is ineligible for erythropoietin-stimulating agent (ESA) therapy or member has had inadequate response to another ESA therapy ○ If Retacrit is unavailable due to shortage: Epogen†, unless member is ineligible for ESA therapy or member has had inadequate response to another ESA therapy
Immune globulins (Alyglo™, Asceniv™, Bivigam®, Cutaquig®, Cuvitru™, Flebogamma® DIF, GamaSTAN®, GamaSTAN® S/D, Gammagard® liquid, Gammagard® S/D, Gammaked™, Gammaplex®, Gamunex®-	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 and Gamunex-C: Gammagard and Gamunex-C, UNLESS request is for Octagam for dermatomyositis <u>IN ADDITION:</u> • **Chronic idiopathic demyelinating polyneuropathy**: a systemic corticosteroid, unless the member has pure motor symptoms

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C, Hizentra®, HyQvia®, Octagam®, Panzyga®, Privigen®, Xembify®)	• **Polymyositis, myasthenia gravis, bullous pemphigoid, mucous membrane pemphigoid (a.k.a. cicatricial pemphigoid), epidermolysis bullosa acquisita**: a systemic corticosteroid • **Dermatomyositis**: rituximab* • **Idiopathic thrombocytopenic purpura**: a systemic corticosteroid or Rho(D) immune globulin* • **Pemphigus vulgaris, pemphigus foliaceus,**: one corticosteroid and rituximab* • **Adenosine deaminase (ADA)-severe combined immunodeficiency disorders (SCID)**: Revcovi*
IncobotulinumtoxinA (Xeomin®)	PART B STEP: • **Upper and lower limb spasticity, cervical dystonia, blepharospasm, overactive bladder and urinary incontinence, chronic migraine, primary axillary hyperhidrosis**: Botox and Dysport
Infliximab-ayyb (Zymfentra®)	PART B STEP: • **Crohn's disease, ulcerative colitis**: IV infliximab product (e.g., Remicade, Avsola, Inflectra, Renflexis)
Lanreotide (Somatuline® Depot)	PART B STEP: • **All indications**: Sandostatin LAR Depot

Lisocabtagene maraleucel (Breyanzi®)	PART B STEP:
	• **Large B-cell lymphoma**: one of the following:
	  ○ 2 lines of systemic therapy that includes an anti-CD20 therapy (e.g., rituximab)* and one anthracycline-containing regimen (e.g., doxorubicin)
	  ○ First-line chemoimmunotherapy that includes an anti-CD20 monoclonal antibody (e.g., rituximab*) and anthracycline-containing regimen (e.g., doxorubicin), if disease was refractory (defined as no complete remission) to or relapsed (defined as complete remission followed by biopsy-proven disease relapse) no more than 12 months after chemoimmunotherapy
	• **Relapsed or refractory follicular lymphoma:** 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)
	• **Mantle cell lymphoma:** 2 lines of systemic therapy that includes an anti-CD20 monoclonal antibody therapy (e.g., rituximab)* and an alkylating agent

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	(e.g., bendamustine, cyclophosphamide, platinum [carboplatin, cisplatin, or oxaliplatin]) *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: • **Myelodysplastic syndrome with ring sideroblasts < 15% (or ring sideroblasts < 5% with SFB3B1 mutation):** Retacrit† ○ If Retacrit is unavailable due to shortage: Epogen†
Lutetium Lu 177 dotatate (Lutathera®)	PART B STEP: • **Neuroendocrine tumor**: somatostatin analog (e.g., octreotide, lanreotide), unless member has a well-differentiated grade 3 neuroendocrine tumor
Marstacimab-hncq (Hympavzi™)	PART B STEP: • **Hemophilia A**: factor VIII product* used for routine prophylaxis AND Hemlibra* • **Hemophilia B**: factor IX product* used for routine prophylaxis
Mirikizumab-mrkz (Omvoh™)	PART B STEP: • **Crohn's disease, ulcerative colitis**: a TNF inhibitor (e.g., infliximab)* (*note credit may be given if another TNF inhibitor was tried*)
Motixafortide (Aphexda®)	PART B STEP: • **Multiple myeloma**: plerixafor
Nadofaragene firadenovec-vncg (Adstiladrin®)	PART B STEP: • **Non-muscle invasive bladder cancer**: Bacillus Calmette-Guerin (BCG) treatment*
Natalizumab (Tysabri®, Tyruko®)	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®), nivolumab/hyaluronidase-nvhy (Opdivo Qvantig™)	PART B STEP: • **Non-small cell lung cancer**: prior systemic therapy*, UNLESS one of the following is met: ○ Request is for Opdivo 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, or

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	○ Prescribed as neoadjuvant treatment, or ○ Prescribed as adjuvant treatment, following neoadjuvant treatment • **Malignant pleural mesothelioma**: prior therapy*, unless request is for Opdivo prescribed in combination with Yervoy • **Classical Hodgkin lymphoma:** prior therapy*, unless disease is stage III-IV or prescribed as palliative therapy • **Hepatocellular carcinoma, pediatric Hodgkin lymphoma, vulvar cancer, vaginal cancer, extranodal NK/T-cell lymphoma – nasal type, small cell lung cancer, cervical cancer, pediatric primary mediastinal large B-cell lymphoma, classic Kaposi sarcoma, pleomorphic rhabdomyosarcoma**: prior therapy* • **Squamous cell carcinoma of the head and neck**: platinum-containing regimen*, unless prescribed as combination therapy • **Urothelial carcinoma**: platinum-containing regimen*, unless prescribed as adjuvant treatment and member is at high risk of recurrence after undergoing resection, or member is at high risk of recurrence and did not previously receive a platinum-containing regimen, or prescribed in combination with cisplatin and gemcitabine • **Esophageal squamous cell carcinoma**: fluoropyrimidine-based (e.g., 5- fluorouracil, capecitabine) and platinum-based chemotherapy*, unless prescribed in combination with Yervoy (Opdivo only) or with fluoropyrimidine- and platinum-containing chemotherapy (Opdivo or Opdivo Qvantig) • **Gestational trophoblastic neoplasia**: prior multi-agent chemotherapy* • **Anal carcinoma:** prior therapy*, unless prescribed prior to resection (*note some IV chemo may not require prior authorization*)
Obecabtagene autoleucel (Aucatzyl®)	PART B STEP: • **B-cell precursor acute lymphoblastic leukemia**: prior systemic therapy*, unless disease has relapsed or is refractory following allogeneic stem cell transplantation (*note some IV chemo may not require prior authorization*)

Drug Name	Part B Required Step-Through Agents* By Indication **May require prior authorization*
Pasireotide (Signifor® LAR)	PART B STEP: • **Acromegaly**: Sandostatin LAR Depot
Pegfilgrastim (Neulasta®, Fulphila™, Fylnetra®, Nyvepria™, Stimufend®, Udenyca™, Ziextenzo™)	PART B STEP: • **All indications**: Udenyca^† or Nyvepria ○ If request is for Neulasta and member is unable to use Udenyca^ or Nyvepria: biosimilar pegfilgrastim product (e.g., Fulphila, Fylnetra, Stimufend, Ziextenzo)† *^ Udenyca refers to all formulations (prefilled syringe, autoinjector, and on-body injector)*
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 • **Classical Hodgkin lymphoma:** at least 1 prior therapy*, unless prescribed for palliative therapy • **Primary mediastinal large B-cell lymphoma, anal carcinoma, gestational trophoblastic neoplasia, extranodal NK/T-cell lymphoma, vulvar carcinoma, anaplastic large cell lymphoma, small cell lung cancer, soft tissue sarcoma subtypes (myxofibrosarcoma, undifferentiated pleomorphic sarcoma, dedifferentiated liposarcoma, cutaneous angiosarcoma, and undifferentiated sarcomas), ovarian cancer, fallopian tube cancer, primary peritoneal cancer**: at least 1 prior therapy* • **Endometrial carcinoma:** at least 1 prior therapy*, unless prescribed in combination with carboplatin and paclitaxel and continued as a single agent for maintenance therapy for advanced, recurrent, or Stage III-IV tumor • **Tumor mutational burden-high cancer**: at least 1 prior therapy*, unless member has ampullary adenocarcinoma or pancreatic adenocarcinoma • **Cervical cancer**: at least 1 prior therapy*, unless prescribed in combination with chemotherapy (e.g., paclitaxel/cisplatin, paclitaxel/carboplatin) or chemoradiotherapy • **Microsatellite instability-high/mismatch repair deficient cancer**: at least 1 prior therapy*, unless member has colorectal cancer, ampullary

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	adenocarcinoma, gallbladder cancer, gastric cancer, esophagogastric junction cancer, intrahepatic/ extrahepatic cholangiocarcinoma, non-nasopharyngeal head, and neck cancer, occult primary tumor, pancreatic adenocarcinoma, or small bowel adenocarcinoma • **Urothelial carcinoma**: at least 1 prior therapy*, unless ineligible for platinum-containing chemotherapy or prescribed in combination with Padcev • **Non-muscle invasive bladder cancer**: Bacillus Calmette-Guerin treatment* • **Squamous cell esophagogastric junction cancer**: at least 1 prior therapy (if CPS ≥ 10), unless prescribed in combination with fluoropyrimidine- and platinum-containing chemotherapy • **Stage IB, II, or IIIA non-small cell lung cancer:** platinum-containing chemotherapy*, unless one of the following is met: o Disease is PD-L1 positive (tumor proportion score [TPS] ≥ 1%) o Prescribed as part of combination therapy o Prescribed as part of combination therapy as neoadjuvant treatment, followed by single-agent adjuvant treatment after surgery for patients with resectable (tumors ≥ 4 cm or node positive) disease o Prescribed as single-agent continuation maintenance therapy if previously given first line as part of a chemotherapy regimen (*note some IV chemo may not require prior authorization*)
Polatuzumab vedotin-piiq (Polivy™)	PART B STEP: • **Diffuse large B-cell lymphoma (including histologic transformation of indolent lymphoma), high-grade B-cell lymphoma:** 1 prior therapy*, unless all of the following are met: o Prescribed for previously untreated disease o Prescribed in combination with a rituximab product, cyclophosphamide, doxorubicin, and prednisone o Member has an International Prognostic Index (IPI) score or stage modified IPI score ≥ 2

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	• **Monomorphic post-transplant lymphoproliferative disorder (B-cell type), HIV-related B-cell 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®, Byooviz®, Cimerli™, Susvimo™)	PART B STEP: • **Neovascular (wet) AMD, macular edema following RVO, DME, DR, or myopic choroidal neovascularization (mCNV)**: intravitreal bevacizumab solution
RimabotulinumtoxinB (Myobloc®)	PART B STEP: • **Cervical dystonia**: Botox and Dysport • **Chronic sialorrhea**: Xeomin
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* • **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*, unless member has had a history of failure of two TNF inhibitors
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*) • **Chemotherapy-induced thrombocytopenia**: prior chemotherapy* (*note some IV chemo may not require prior authorization*)
Romosozumab-aqqg (Evenity™)	PART B STEP: • **Postmenopausal osteoporosis**: bisphosphonate, unless member is very high risk for fracture (recent osteoporotic fracture within the past 12 months, BMD T-score at hip or spine ≤ -3.0, OR BMD T-score at hip

Drug Name	Part B Required Step-Through Agents* By Indication **May require prior authorization*
	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)
Talquetamab-tgvs (Talvey™)	PART B STEP: • **Multiple myeloma**: 4 prior lines of therapy* that include all of the following: immunomodulatory agent (e.g., lenalidomide, Pomalyst, Thalomid), proteasome inhibitor (e.g., bortezomib, Kyprolis), and anti-CD38 antibody (e.g., Darzalex/Darzalex Faspro, Sarclisa)
Teclistamab-cqyv (Tecvayli®)	PART B STEP: • **Multiple myeloma:** 4 prior lines of therapy* that include all of the following: immunomodulatory agent (e.g., lenalidomide, Pomalyst, Thalomid), proteasome inhibitor (e.g., bortezomib, Kyprolis, Ninlaro), and anti-CD38 antibody (e.g., Darzalex/Darzalex Faspro, Sarclisa)
Teprotumumab-trbw (Tepezza™)	PART B STEP: • **Thyroid eye disease**: a systemic corticosteroid, UNLESS member has significant proptosis or diplopia
Tisagenlecleucel (Kymriah®)	PART B STEP: • **B-cell precursor acute lymphoblastic leukemia**: at least two prior systemic therapies* • **Large B-cell lymphoma**: one of the following: ○ 2 lines of systemic therapy that includes rituximab* and one anthracycline-containing regimen (e.g., doxorubicin*) ○ Disease relapsed more than 12 months after completion of first-line therapy and partial response following second-line therapy • **Relapsed or refractory follicular lymphoma:** 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*
Tocilizumab (Actemra®, Tofidence™, Tyenne®)	PART B STEP: • **Polyarticular juvenile idiopathic arthritis, rheumatoid arthritis**: a TNF inhibitor (e.g.,

Drug Name	Part B Required Step-Through Agents* By Indication **May require prior authorization*
	infliximab)* (*note credit may be given if another TNF inhibitor was tried*)
Trastuzumab (Herceptin®, Ontruzant®, Herzuma®, Ogivri™, Trazimera™, Kanjinti™, Hercessi™), trastuzumab/hyaluronidase (Herceptin Hylecta™)	PART B STEP: • **All indications**, if request is for an agent other than Trazimera or Kanjinti: Trazimera or Kanjinti ○ If unable to use Trazimera or Kanjinti and request is for Herceptin or Herceptin Hylecta: biosimilar trastuzumab product (e.g., Hercessi, Ogivri, Ontruzant)
Triamcinolone ER injection (Zilretta®)	PART B STEP: • **Osteoarthritis of the knee**: intra-articular immediate-release glucocorticoid injection
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 choroidal neovascularization (CNV) due to AMD or pathologic myopia**: 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.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members, and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.