Pharmacy Management Drug Policy

SUBJECT: Oncology Clinical Review Prior Authorization (CRPA) Medical Drugs
POLICY NUMBER: PHARMACY-64
EFFECTIVE DATE: 10/2013
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If the member's subscriber contract excludes coverage for a specific service or prescription drug, it is not covered under that contract. In such cases, medical or drug policy criteria are not applied. This drug policy applies to the following line/s of business:

Policy Application

Category:	☒ Commercial Group (e.g., EPO, HMO, POS, PPO)	☒ Medicare Advantage
	☒ On Exchange Qualified Health Plans (QHP)	☐ Medicare Part D
	☒ Off Exchange Direct Pay	☒ Essential Plan (EP)
	☒ Medicaid & Health and Recovery Plans (MMC/HARP)	☒ Child Health Plus (CHP)
	☐ Federal Employee Program (FEP)	☐ Ancillary Services
	☒ Dual Eligible Special Needs Plan (D-SNP)	

POLICY:

The oncology drug Clinical Review Prior-Authorization (CRPA) process is designed to ensure that newly approved (FDA) prescription drugs are used appropriately in cases where a drug poses potential efficacy, quality, toxicity, or utilization concerns for the members and the Health Plan. In addition, this policy may be used for medications that have significant concerns about safety or inappropriate use, but do not warrant a stand-alone policy. The Pharmacy Management clinical team reviews the oncology drugs falling into these categories under the process of Clinical Review Prior Authorization (CRPA). A Letter of Medical Necessity (LOMN), Exception Form, or Prior Authorization Form completion is required for consideration of drug coverage under this policy.

Prior Authorization criteria listed in this policy is based on FDA labeled indication or NCCN level of evidence 1 or 2A. For requests that do not meet the policy criteria defined below, please refer to the Off-Label Use of FDA Approved Drugs policy.

POLICY GUIDELINES:

1. This policy is subject to frequent revisions as new medications come onto the market. Some drugs will require prior authorization prior to approved language being added to the policy.
2. Supportive documentation of previous drug use must be submitted for any criteria which require trial of a preferred agent if the preferred drug is not found in claims history.
3. Dose and frequency should be consistent with FDA labeling, NCCN Compendia, or Indication Specific Peer-Reviewed Literature. When the dose and/or frequency is requested in excess of established parameters, the request may be subject to an off-label review for medical necessity.
4. Not all contracts cover all Medical Infusible drugs. Refer to specific contract/benefit plan language for exclusions of Injectable Medications.
5. Requests for drugs under the medical benefit that are both self-administered (covered under the pharmacy benefit) and healthcare professional-administered (covered under the medical benefit), but are typically self-administered, will be evaluated for medical necessity using the criteria located in the self-administered (pharmacy benefit) drug policy (e.g., Besremi) unless otherwise specified
6. Prior authorization for Blincyto (blinatumomab) and Elzonris (tragraxofusp-erzs) will apply regardless of the site of administration (applies to both the inpatient and outpatient setting)

7. For contracts where Insurance Law § 4903(c-1), and Public Health Law § 4903(3-a) are applicable, if trial of preferred drug(s) is the only criterion that is not met for a given condition, and one of the following circumstances can be substantiated by the requesting provider, then trial of the preferred drug(s) will not be required.
    - The required prescription drug(s) is (are) contraindicated or will likely cause an adverse reaction or physical or mental harm to the member;
    - The required prescription drug is expected to be ineffective based on the known clinical history and conditions and concurrent drug regimen;
    - The required prescription drug(s) was (were) previously tried while under the current or a previous health plan, or another prescription drug or drugs in the same pharmacologic class or with the same mechanism of action was (were) previously tried and such prescription drug(s) was (were) discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event;
    - The required prescription drug(s) is (are) not in the patient's best interest because it will likely cause a significant barrier to adherence to or compliance with the plan of care, will likely worsen a comorbid condition, or will likely decrease the ability to achieve or maintain reasonable functional ability in performing daily activities;
    - The individual is stable on the requested prescription drug. The medical profile of the individual (age, disease state, comorbidities), along with the rational for deeming stability as it relates to standard medical practice and evidence-based practice protocols for the disease state will be taken into consideration.
    - The above criteria are not applicable to requests for brand name medications that have an AB rated generic. We can require a trial of an AB-rated generic equivalent prior to providing coverage for the equivalent brand name prescription drug.
8. This policy does not apply to Medicare Part D and D-SNP pharmacy benefits. The drugs in this policy may apply to all other lines of business including Medicare Advantage.
9. For members with Medicare Advantage, medications with a National Coverage Determination (NCD) and/or Local Coverage Determination (LCD) will be covered pursuant to the criteria outlined by the NCD and/or LCD. NCDs/LCDs for applicable medications can be found on the CMS website at https://www.cms.gov/medicare-coverage-database/search.aspx. Indications that have not been addressed by the applicable medication's LCD/NCD will be covered in accordance with criteria determined by the Health Plan (which may include review per the Health Plan's Off-Label Use of FDA Approved Drugs policy). Step therapy requirements may be imposed in addition to LCD/NCD requirements.
10. Unless otherwise indicated within drug specific criteria, the drugs listed in this policy are administered by a healthcare professional and therefore are covered under the medical benefit.
11. Unless otherwise stated below within the in Drug Specific Criteria (TABLE 4) or the Drug Specific Approval Timeframes (TABLE 2), approval time periods are listed in TABLE 1 below
    a. Continued approval at time of recertification will require documentation that the drug is providing ongoing benefit to the patient in terms of improvement or stability in disease state or condition. Such documentation may include progress notes, imaging or laboratory findings, and other objective or subjective measures of benefit which support that continued use of the requested product is medically necessary. Also, ongoing use of the requested product must continue to reflect the current policy's preferred formulary [Recertification reviews may result in the requirement to try more cost-effective treatment alternatives as they become available (i.e., generics, biosimilars, or other guideline-supported treatment options)] and the requested dose must continue to meet FDA approved or off-label/guideline supported dosing

b. Recertifications will be evaluated for the regimen that is currently being prescribed (monotherapy, combination therapy, etc.). If this differs from the initial review, the request will be reviewed based on the level of evidence that is available for the current regimen.

12. All requests will be reviewed to ensure they are being used for an appropriate indication and may be subject to an off-label review in accordance with our Off-Label Use of FDA Approved Drugs Policy (Pharmacy-32). This includes any request that is made for drug(s) that was (were) previously tried (including in the same pharmacologic class or with the same mechanism of action) and such drug(s) was (were) discontinued due to a lack of efficacy.

TABLE 1. APPROVAL TIME PERIODS:

Line of Business	Initial approval	Continued approval
Commercial, Exchange, and SafetyNet (Medicaid, HARP, CHP, Essential Plan)	All sites of service – 6 months	All sites of service – 6 months
Medicare Advantage	All sites of service – 6 months	All sites of service – 6 months

TABLE 2. DRUG SPECIFIC APPROVAL TIMEFRAMES:

Drug Name	Initial Approval	Continued Approval
Onivyde (irinotecan liposome injection)	3 months	3 months
Folotyn (pralatrexate), pralatrexate (generic Folotyn)	7 weeks	14 weeks
Elitek (rasburicase)	1 month	Not Applicable
Imdelltra (tarlatamab-dlle)	3 months	3 months
Anktiva (nogapendekin alfa inbakicept-pmln)	3 months	3 months

TABLE 3. MEDICAL ONCOLOGY DRUGS INCLUDED IN THIS POLICY:

Drug name (generic or brand name)	HCPCS
Abraxane (paclitaxel protein-bound particles)	J9264
Paclitaxel protein-bound particles (generic Abraxane)	J9264
Paclitaxel protein-bound particles (Teva 505(b)(2))	J9264
Paclitaxel protein-bound particles (American Regent 505(b)(2))	J9264
Adstiladrin (nadofaragene firadenovec-vncg)	J9029
Adcetris (brentuximab vedotin)	J9042
Amtagvi (lifileucel)	J9999 (NOC)
Anktiva (nogapendekin alfa inbakicept-pmln)	J9028
Arzerra (ofatumumab)	J9302
Asparlas (calaspargase pegol-mknl)	J9118
Beleodaq (belinostat)	J9032
Belrapzo (bendamustine HCL)	J9036
Bendamustine HCL (Apotex 505(b)(2))	J9036
Bendamustine HCL (Baxter 505(b)(2))	J9036
Bendeka (bendamustine HCL)	J9034
Treanda (bendamustine HCL)	J9033
Bendamustine HCL (generic Treanda)	J9033
Vivimusta (bendamustine HCL)	J9056
Besponsa (inotuzumab ozogamicin)	J9229
Bizengri (zenocutuzumab-zbco)	J9999 (NOC)
Blincyto (blinatumomab)	J9039

Boruzu (bortezomib)	J9999 (NOC)
Camcevi (leuprolide mesylate)	J1952
Columvi (glofitamab-gxbm)	J9286
Cyramza (ramucirumab)	J9308
Danyelza (naxitamab-gqgk)	J9348
Darzalex (daratumumab)	J9145
Darzalex Faspro (daratumumab and hyaluronidase-fihj)	J9144
Docivyx (docetaxel)	J9172
Elahere (mirvetuximab soravtansine-gynx)	J9063
Elitek (rasburicase)	J2783
Elrexfio (elranatamab-bcmm)	J1323
Elzonris (tragraxofusp-erzs)	J9269
Empliciti (elotuzumab)	J9176
Enhertu (fam-trastuzumab deruxtecan-nxki)	J9358
Epkinly (epcoritamab-bysp)	J9321
Erwinaze (asparaginase)	J9019
Folotyn (pralatrexate)	J9307
Pralatrexate (generic Folotyn)	J9307
Fyarro (sirolimus protein-bound particles)	J9331
Gazyva (obinutuzumab)	J9301
Hepzato Kit (melphalan for injection/Hepatic Delivery System[HDS])	J9248
Imdelltra (tarlatamab-dlle)	J9026
Infugem (gemcitabine)	J9198
Istodax (romidepsin)	J9319
Romidepsin (generic Istodax)	J9319
Romidepsin (branded)	J9318
Jelmyto (mitomycin gel)	J9281
Kadcyla (ado-trastuzumab emtansine)	J9354
Kimmtrak (tebentafusp)	J9274
Kyprolis (carfilzomib)	J9047
Lartruvo (olaratumab injection)	J9285
Leuprolide Acetate Depot	J1954
Lumoxiti (moxetumomab pasudotox-tdfk)	J9313
Lunsumio (mosunetuzumab-axgb)	J9350
Margenza (margetuximab-cmkb)	J9353
Monjuvi (tafasitamab-cxix)	J9349
Mylotarg (gemtuzumab ozogamicin)	J9203
Omisirge (omidubicel-onlv)	J9999 (NOC)
Oncaspar (pegaspargase)	J9266
Onivyde (irinotecan liposome injection)	J9205
Padcev (enfortumab vedotin-ejfv)	J9177
Pedmark (sodium thiosulfate)	J0208
Pemfexy (pemetrexed)	J9304
Pemrydi RTU (pemetrexed)	J9324
Axtle (pemetrexed(avyxa))	J9292
Phesgo (pertuzumab/trastuzumab/hyaluronidase-zzxf)	J9316
Polivy (polatuzumab vedotin-piiq)	J9309
Portrazza (necitumumab)	J9295

Posfrea (palonosetron)(Avyxa 505(b)(2))	J2468
Poteligeo (mogamulizumab-kpkc)	J9204
Provenge (sipuleucel-T)	Q2043
Rybrevant (amivantamab-vmjw)	J9061
Rylaze (asparaginase erwinia chrysanthemi [recombinant]-rywn)	J9021
Rytelo (imetelstat)	J0870
Sarclisa (isatuximab-irfc)	J9227
Talvey (talquetamab-tgvs)	J3055
Tecelra (afamitresgene autoleucel)	J9999 (NOC)
Tecvayli (teclistamab)	J9380
Tivdak (tisotumab vedotin-tftv)	J9273
Torisel (temsirolimus)	J9330
Temsirolimus (generic Torisel)	J9330
Trodelvy (sacituzumab govitecan-hziy)	J9317
Vectibix (panitumumab)	J9303
Vyloy (zolbetuximab-clzb)	J9999 (NOC)
Vyxeos (Daunorubicin/Cytarabine)	J9153
Xgeva (denosumab)	J0897
Yondelis (trabectedin)	J9352
Zaltrap (ziv-aflibercept)	J9400
Zepzelca (lurbinectedin)	J9223
Ziihera (zanidatamab-hrii)	J9999 (NOC)
Zynlonta (loncastuximab tesirine-lpyl)	J9359

UNIVERSAL CRITERIA:

The drugs listed in this policy will be reviewed in accordance with criteria described below.

Please note select drugs are subject to additional and/or more comprehensive coverage criteria which can be found in the Drug Specific Criteria table (TABLE 4):

1. Must prescribed by, or in consultation with an Oncologist, Hematologist, or appropriate specialist **AND**
2. The requested use (indication AND regimen) must meet **one** of the following:
   a. Approved by the U.S. Food and Drug Administration (FDA) **OR**
   b. A National Comprehensive Cancer Network (NCCN) category level 1 or 2A recommendation **OR**
   c. Satisfied by the criteria required for the applicable line of business (LOB) for the treatment of cancer in the Off-Label Use of FDA Approved Drugs policy (Pharmacy-32) **AND**
3. Step therapy requirements must be met for select drugs (see TABLE 5)

TABLE 4. DRUG SPECIFIC CRITERIA:

Drug specific criteria may include but is not limited to unique approval timeframes, step therapy requirements, and additional limitations to universal coverage criteria

DRUG NAME
Drug Specific Criteria
Adstiladrin (nadofaragene firadenovec-vncg)
1. Must be prescribed by an Oncologist or Urologist **AND** 2. The patient must be 18 years of age or older **AND**

3. The patient must have a diagnosis of Bacillus Calmette-Guerin (BCG)-unresponsive, high-risk non-muscle invasive bladder cancer (NMIBC) with carcinoma in situ (CIS) with or without papillary tumors
    a. BCG-unresponsive is defined as one of the following:
        i. Having received at least 2 previous courses of BCG within a 12-month period defined as:
            A. At least 5 of 6 induction BCG instillations and at least 2 out of 3 instillations of maintenance BCG **OR**
            B. At least two of six instillations of a second induction course where maintenance BCG is not given
        ii. Recurrence of high-grade Ta or T1 non-muscle-invasive bladder cancer within 6 months of disease-free state after BCG therapy
        iii. Recurrence of CIS within 12 months of disease-free state after BCG therapy
        iv. Persistent high-grade Ta or CIS or progression to T1 disease after BCG therapy **AND**
4. The patient must be ineligible for or have elected not to undergo cystectomy
5. Approval Timeframe/Recertifications:
    a. Initial and subsequent approvals will be for 6-months.
    b. All recertifications will require documentation that the patient does not have evidence of high-grade disease recurrence
6. Approved Dosing: 75 mL of Adstiladrin at a concentration of 3 x 10^{11} viral particles (vp)/mL, instilled once every 3-months

Amtagvi (lifileucel)

1. Must be prescribed by an Oncologist at an Authorized Treatment Center (ATC), **AND**
2. Must be ≥ 18 years of age, **AND**
3. Must have a diagnosis of unresectable or Stage IV metastatic melanoma, **AND**
4. Must have progressed following ≥ 1 prior systemic therapy including the following:
    a. Patient has been treated with a programmed death receptor-1 (PD-1) blocking antibody or a programmed death-ligand 1 (PD-L1) blocking antibody (pembrolizumab, nivolumab, atezolizumab, etc.), **AND**
    b. If patient if BRAF V600 mutation positive, the patient has been treated with a BRAF inhibitor (dabrafenib, vemurafenib, etc.) or a BRAF inhibitor in combination with a MEK inhibitor (dabrafenib/trametinib, vemurafenib/cobimetinib, encorafenib/binimetinib, etc), **AND**
5. Must have an Eastern Cooperative Oncology Group (ECOG) performance status score of 0 or 1, **AND**
6. Prescriber attestation patient does not have any of the following:
    a. Uncontrolled brain metastases
    b. Organ allograft or prior cell transfer therapy
    c. Melanoma of uveal or ocular origin
    d. Systemic steroid therapy for any reason
    e. Grade 2 or higher hemorrhage within 14 days prior to tumor resection
    f. LVEF < 45% or NYHF functional classification > Class 1
    g. FEV1 of ≤ 60%, **AND**
7. Retreatment with lifileucel (Amtagvi) has not been proven to be safe and effective. Retreatment will be considered Experimental/Investigational when FDA approved tumor-infiltrating lymphocyte therapy, or any other tumor-infiltrating lymphocyte therapy still under investigation, has been previously administered.
8. Approval will be provided for 6 months to allow one-time administration

Anktiva (nogapendekin alfa inbakicept-pmln)

1. Must be prescribed by an Oncologist or Urologist **AND**
2. The patient must be 18 years of age or older **AND**
3. The patient must have a diagnosis of Bacillus Calmette-Guerin (BCG)-unresponsive, high-risk non-muscle invasive bladder cancer (NMIBC) with carcinoma in situ (CIS) with or without papillary tumors
    a. BCG-unresponsive is defined as one of the following:

i. Having received at least 2 previous courses of BCG within a 12-month period defined as:
   A. At least 5 of 6 induction BCG instillations and at least 2 out of 3 instillations of maintenance BCG **OR**
   B. At least two of six instillations of a second induction course where maintenance BCG is not given
ii. Recurrence of high-grade Ta or T1 non-muscle-invasive bladder cancer within 6 months of disease-free state after BCG therapy
iii. Recurrence of CIS within 12 months of disease-free state after BCG therapy
iv. Persistent high-grade Ta or CIS or progression to T1 disease after BCG therapy **AND**

4. The patient must be ineligible for or have elected not to undergo cystectomy **AND**
5. The patient must have received prior treatment with Adstiladrin (nadofaragene firadenovec-vncg) or Keytruda (pembrolizumab), or clinical documentation of why these therapies are not appropriate for use in this patient must be provided
6. Approval Timeframe/Recertifications:
   a. Initial and subsequent approvals will be for 3 months
   b. All recertifications will require documentation that the patient does not have evidence of high-grade disease recurrence
   c. Maximum treatment duration is 37 months
7. Approved dosing:
   a. **Induction:** 400 mcg instilled with BCG once a week for 6 weeks. A second induction course may be administered if complete response if not achieved at month 3.
   b. **Maintenance:** 400 mcg instilled with BCG once a week for 3 weeks at months 4,7,10,13, and 19 (for a total of 15 doses). Patients with an ongoing complete response at month 25 and later, maintenance instillations with BCG may be administered once a week for 3 weeks at months 25, 31, and 37 for a maximum of 9 additional instillations.

Elahere (mirvetuximab soravtansine-gynx)

1. Must be prescribed by an Oncologist **AND**
2. Must have a confirmed diagnosis of platinum-resistant high-grade serous epithelial ovarian cancer (EOC), primary peritoneal cancer, or fallopian tube cancer **AND**
3. Must have high FRα expression as defined by the Ventana FOLR1 Assay (at least 75% of the cancer cells having 2+ or higher FRα staining intensity) **AND**
4. Must have received 1-3 prior lines of systemic therapy **AND**
5. Approved Dose: 6 mg/kg adjusted ideal body weight (AIBW) administered once every 3 weeks (21-day cycle) as an intravenous infusion until disease progression or unacceptable toxicity

Hepzato Kit (melphalan for injection/Hepatic Delivery System [HDS])

1. Must be prescribed by an oncologist **AND**
2. Patient must be ≥ 18 years of age **AND**
3. Patient must receive treatment at a REMS certified healthcare center **AND**
4. Patient must have a diagnosis of unresectable metastatic uveal melanoma **AND**
5. Patient must have histologically or cytologically-proven ocular melanoma metastases affecting less than 50% of the parenchyma of the liver, and no or limited extrahepatic disease (disease that is limited to the bone, lymph nodes, subcutaneous tissues, or lung and is amenable to resection or radiation). Documentation confirming metastatic disease is affecting < 50% of the liver by CT and/or MRI must be submitted.
6. Prescriber attestation patient does not have any of the following:
   a. Active intracranial metastases or brain lesions with a propensity to bleed
   b. Child-Pugh Class B or C cirrhosis or evidence of portal hypertension
   c. Active liver infection, including Hepatitis B and Hepatitis C infection
   d. New York Heart Association functional classification II, III, or IV active cardiac conditions
   e. Surgery or medical treatment of the liver in the previous 4 weeks

f. Uncorrectable coagulopathy
g. Inability to safely undergo general anesthesia
h. History of allergies or known hypersensitivity to melphalan or a component or material used within the Hepzato Kit including natural rubber latex, heparin, and severe hypersensitivity to iodinated contrast not controlled by antihistamines and steroids

7. Authorization will be provided for a maximum of 6 infusions.
8. The approved dose is 3 mg/kg based on ideal body weight up to a maximum of 220 mg per dose.
9. Hepzato Kit will not be covered for any non-FDA approved diagnosis.

Lartruvo (Olaratumab injection)

1. Lartruvo will only be approved for patients who have currently been receiving Lartruvo. Per FDA statement released on January 24, 2019, a recently completed clinical trial of Lartruvo has failed to confirm clinical benefit of Lartruvo and the FDA recommends that Lartruvo not be initiated in new patients outside of an investigational study. Those patients who are currently receiving Lartruvo should consult with their healthcare practitioner about whether to remain on the treatment

Lunsumio (mosunetuzumab-axgb)

1. Must be at least 18 years of age **AND**
2. Must be prescribed by an Oncologist or Hematologist **AND**
3. Must have a diagnosis of relapsed or refractory Follicular Lymphoma (FL)
   a. Must have grade 1,2, or 3A FL **AND**
4. Must have had at least 2 lines of systemic therapy including an anti-CD20 therapy (e.g., a rituximab containing product) and an alkylating agent **AND**
5. Must not have a prior history of allogenic transplant **AND**
6. Must not have a prior history of CNS lymphoma or CNS disorders
7. If the above criteria are met, Lunsumio will be covered for 8–21-day cycles (6 months).
   a. Patients who do not achieve a complete response after 8 cycles but achieve a partial response or have stable disease will be covered for an additional 9 cycles of treatment (7 months). Documentation confirming a partial response or stable disease as defined by the Revised Response Criteria for Malignant Lymphoma (Cheson et al. 2007) must be submitted.

Omisirge (omidubicel-onlv)

1. The patient must be treated by a hematologist or oncologist **AND**
2. The patient must be 12 years of age or older **AND**
3. The patient must have a hematologic malignancy **AND** must be eligible for an allogeneic hematopoietic (stem) cell transplant **AND**
4. The prescriber must attest that the umbilical cord unit used will be HLA-matched at a minimum of 4 loci (including HLA-A, B at the antigen-level, and DRB1 at the allele level) **AND**
5. The requested treatment must be used to reduce the time to neutrophil recovery and the incidence of infection **AND**
6. The requested treatment must be used following myeloablative conditioning **AND**
7. The prescriber must attest that the patient does not have a readily available, matched related donor, matched unrelated donor, mismatched unrelated donor, or a haploidentical related donor
   a. If a more appropriately matched umbilical cord blood unit is available, a mismatched unrelated donor or haploidentical related donor would not be required
8. The requested treatment will be covered for 3-months to allow a one-time treatment administration
9. The requested treatment will require a review for Medical Necessity regardless of a previous approval

Pedmark (sodium thiosulfate)

1. Must be prescribed by, or in consultation with an oncologist **AND**
2. Must be ≥ 1 month to < 18 years of age **AND**
3. Must have a localized, non-metastatic solid tumor **AND**
4. Must be receiving cisplatin-based therapy

5. Pedmark will not be covered for any indications that have not been approved by the Food and Drug Administration (FDA)
6. See prescribing information for approved dosing
7. Generic sodium thiosulfate (J3490), indicated for the treatment of acute cyanide poisoning and other compendia supported uses, is available as a 12.5 g/50 mL single-dose vial (manufactured by Hope Pharmaceuticals; NDC 60267-0705-50) and does not require Prior Authorization. This drug and other compounded forms are NOT interchangeable with Pedmark.

Rytelo (imetelstat)

1. Patient must be ≥ 18 years of age **AND**
2. Must be followed by a hematologist, oncologist, or physician knowledgeable in the treatment of myelodysplastic syndromes **AND**
3. Must have diagnosis of low- to intermediate-1 risk myelodysplastic syndrome (LR-MDS) **AND**
4. Patient must have transfusion-dependent anemia **AND**
5. Patient must have required four or more RBC units transfused over an 8-week period in the preceding 16 weeks; **AND**
    a. Patient must be refractory to an erythropoiesis stimulating agents (ESA), where refractory is defined as lack of 1.5 gm/dL rise in hemoglobin or lack of decrease in RBC transfusion requirement by 6 to 8 weeks of treatment **OR**
    b. Patient must have documented ineligibility to an ESA which is defined as a serum erythropoietin (EPO) level ≥ 500 mU/mL **OR**
    c. Patient must have documented intolerance, adverse event, or contraindication to an ESA
6. Patient meets ALL of the following:
    a. Patient does not have del(5q) MDS
    b. No prior treatment with lenalidomide
    c. No prior treatment with a hypomethylating agent (e.g., azacitidine, decitabine) **AND**
7. Patient must have had serious side effects or drug failure to Reblozyl (luspatercept- aamt), unless contraindicated
    a. This applies to new starts only
8. The recommended dosage is 7.1 mg/kg every 4 weeks. Dose reductions may be required for Grade 3 and 4 adverse reactions. Dosing less than 4.4 mg/kg will not be approved.
9. Current body weight and requested dosage regimen must be submitted for initial review and each recertification request
10. Initial approval will be granted for 6 months
11. Recertification will be for 6 months at a time and requires documented reduction in RBC transfusion burden after receiving Reytelo.
    a. If patient does not experience a decrease in RBC transfusion burden after the initial 24 weeks (6 doses) of treatment, recertification will not be provided.

Tecelra (afamitresgene autoleucel)

1. Must be prescribed by an oncologist at an authorized treatment center (ATC) **AND**
2. Must be ≥ 18 years of age **AND**
3. Must have a diagnosis of unresectable or metastatic (Stage IV) synovial sarcoma **AND**
4. Must be HLA-A*02:01P, -A*02:02P, -A*02:03P or -A*02:06P positive as determined by FDA-approved or cleared companion diagnostic device
    a. Patient must not be heterozygous or homozygous for HLA-A*02:05P **AND**
5. Must be MAGE-A4 antigen positive as determined by FDA-approved or cleared companion diagnostic device **AND**
6. Must have progressed following ≥ 1 prior systemic chemotherapy including an anthracycline and/or ifosfamide-containing regimen
    a. Patients who are intolerant to both an anthracycline and ifosfamide must have still received at least one systemic therapy **AND**

7. Patient must be fit for leukapheresis, and adequate venous access can be established for cell collection **AND** 8. Patient must not have received an allogenic hematopoietic stem cell transplant. 9. Retreatment with Tecelra (afamitresgene autoleucel) has not been proven to be safe and effective. Treatment with Telecra will be considered Experimental/Investigational when an FDA approved T cell immunotherapy, or any other T cell immunotherapy still under investigation, has been previously administered. 10. Approval will be for 6 months to allow one-time administration.
Ziihera (zanidatamab-hrii)
1. Must be prescribed by an oncologist **AND** 2. Patient must be 18 years of age or older **AND** 3. Must have one of the following (a, b, or c): a. Intrahepatic cholangiocarcinoma; **OR** b. Extrahepatic cholangiocarcinoma; **OR** c. Gallbladder cancer; **AND** 4. Patient has unresectable or metastatic disease **AND** 5. Must be HER-2 positive with immunohistochemistry score of 3+ (IHC 3+) as detected by an FDA-approved test **AND** 6. Patient has progressed following ≥ 1 prior systemic therapy **AND** 7. Patient does not have a history or progression on prior HER-2 targeted therapy.

TABLE 5. DRUGS WITH STEP THERAPY REQUIREMENTS:

- Unless otherwise specified, step therapy will apply to:
  - New Starts ONLY **AND**
  - All Lines of Business
- Step Therapy criteria listed below applies to all *shared* FDA labeled or compendia supported *indications/regimens*, defined as NCCN level of evidence 1 or 2A.

Drug Name	Diagnosis	Requirement
Abraxane & Paclitaxel protein-bound particles	For all FDA approved, and compendia supported indications except for patients with ampullary adenocarcinoma, biliary tract cancer, or pancreatic adenocarcinoma	Must have had hypersensitivity, intolerable side effects, or contraindication to conventional paclitaxel/Taxol
Anktiva (nogapendekin alfa inbakicept-pmln)	For all FDA approved, and compendia supported indications	There must be documentation of a contraindication to, or failure of Adstiladrin (nadofaragene firadenovec-vncg) or Keytruda (pembrolizumab)
Axtle (pemetrexed (avyxa))	For all FDA approved, and compendia supported indications	There must be a medical reason why Alimta/pemetrexed cannot be used
Boruzu (bortezomib)	For all FDA approved, and compendia supported indications	Must have had hypersensitivity, intolerable side effects, or contraindication to bortezomib (Velcade and generics; J9041 and/or J9049).
Kyprolis (carfilzomib)	Primary therapy for a diagnosis of Multiple Myeloma	There must be a medical reason why bortezomib (Velcade) cannot be used

	Primary therapy for Waldenstrom's Macoglobulinemia/Lymphoplasmacytic Lymphoma	There must be a medical reason why bortezomib (Velcade) cannot be used
Camcevi (leuprolide mesylate)	For all FDA approved, and compendia supported indications	There must be a medical reason why Eligard or Lupron Depot cannot be used
Docivyx (docetaxel)	For all FDA approved, and compendia supported indications	There must be a medical reason why docetaxel (Taxotere) cannot be used
Infugem (gemcitabine)	For all FDA approved, and compendia supported indications	There must be a medical reason why Gemzar/gemcitabine cannot be used
Leuprolide Acetate Depot	For all FDA approved, and compendia supported indications	There must be a medical reason why Eligard or Lupron Depot cannot be used
Pemfexy (pemetrexed)	For all FDA approved, and compendia supported indications	There must be a medical reason why Alimta/pemetrexed cannot be used
Pemrydi RTU (pemetrexed)	For all FDA approved, and compendia supported indications	There must be a medical reason why Alimta/pemetrexed cannot be used
Posfrea (palonosetron) Applies to all requests, not just new starts. *Does not apply to Medicare Advantage	For all FDA approved, and compendia supported indications	Must have had hypersensitivity, intolerable side effects, or contraindication to palonosetron (Aloxi).
Rytelo (imetelstat)	For all FDA approved, and compendia supported indications	There must be documentation of serious side effects, failure, or a contraindication to Reblozyl (luspatercept-aamt)
Vectibix (panitumumab)	For all FDA approved, and compendia supported indications	Must have had hypersensitivity, intolerable side effects, or contraindication to cetuximab (Erbitux)
Vivimusta (bendamustine)	For all FDA approved, and compendia supported indications	There must be a medical reason why an alternative bendamustine cannot be used
Xgeva (denosumab)	For the prevention of skeletal-related events in patients with multiple myeloma and in patients with bone metastases from solid tumors other than prostate or breast cancer	There must be documentation of a contraindication to, or failure of Zoledronic Acid
Zaltrap (ziv-aflibercept)	For all FDA approved, and compendia supported indications	There must be a medical reason why a bevacizumab-containing product cannot be used

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DRUGS WITH MAXIMUM DURATION OF THERAPY BASED ON DIAGNOSIS:

Drug Name	Diagnosis	Maximum Duration of Therapy (Months, Cycles, Doses)
Adcetris (brentuximab vedotin)	Previously Untreated Stage III or IV cHL	12 doses
	Classical Hodgkin Lymphoma Consolidation	16 cycles
	Previously Untreated Systemic ALCL or other CD30-expression PTCL	6-8 doses
	Relapsed Primary Cutaneous ALCL or CD30-expressing Mycosis Fungoides	16 cycles
	Classic Hodgkin Lymphoma Maintenance Therapy	1 year
Anktiva (nogapendekin alfa inbakicept-pmln)	BCG-unresponsive nonmuscle invasive bladder cancer (NMIBO) with carcinoma in situ (CIS) with or without papillary Tumors	37 months
Arzerra (ofatumumab)	Previously untreated CLL	300 mg on day 1 followed by 1,000 mg on Day 8 (Cycle 1), followed by 1,000 mg on Day 1 of subsequent 28-day cycles for a minimum of 3 cycles until best response or a maximum of 12 cycles
	Refractory CLL	300 mg initial dose, followed 1 week later by 2,000 mg weekly for 7 doses, followed 4 weeks later by 2,000 mg every 4 weeks for 4 doses
	Extended treatment in CLL	300 mg on Day 1 followed by 1,000 mg 1 week later on Day 8, followed by 1,000 mg 7 weeks later and every 8 weeks thereafter for up to a maximum of 2 years
Elitek (rasburicase)	Management of plasma uric acid levels	1 treatment course
Gazyva (obinutuzumab)	CLL/SLL	A maximum of 6 (28 day) cycles
	Follicular Lymphoma	2 years
Hepzato Kit (melphalan injection/Hepatic Delivery System[HDS])	Uveal melanoma with unresectable hepatic metastases	6 doses

Jelmyto (mitomycin gel)	Low-grade Upper Tract Urothelial Cancer	Initial approval will be for 3 months to allow the first 6-weekly doses to be given. Jelmyto will be approved for 12 months to allow for up to 11 additional instillations. Max of 17 total instillations (6 initial + 11 additional instillations)
Kadcyla (ado-trastuzumab emtansine)	Early breast cancer	14 cycles (42 total weeks of therapy)
Lumoxiti (moxetumomab pasudotox-tdfk)	Relapsed or refractory hairy cell leukemia (HCL)	24 weeks (six 28-day cycles)
Phesgo (pertuzumab/trastuzumab/hyaluronidase-zzxf)	Adjuvant or neoadjuvant treatment	1 year
Polivy (polatuzumab vedotin-piiq)	Relapsed or refractory diffuse large B-cell lymphoma (DLBCL), nos	6 cycles of therapy (5 months)
Provenge (sipuleucel-T)	Prostate cancer	3 doses
Vyxeos (Daunorubicin/Cytarabine)	AML	4 cycles

IMPORTANT INFORMATION ON ACCELERATED APPROVAL:

Refer to the following FDA websites for up-to-date information on ongoing, verified, and withdrawn accelerated approval indications:

Ongoing Cancer Accelerated Approvals: https://www.fda.gov/drugs/resources-information-approved-drugs/ongoing-cancer-accelerated-approvals

Verified Clinical Benefit Cancer Accelerated Approvals: https://www.fda.gov/drugs/resources-information-approved-drugs/verified-clinical-benefit-cancer-accelerated-approvals

Withdrawn Cancer Accelerated Approvals*: https://www.fda.gov/drugs/resources-information-approved-drugs/withdrawn-cancer-accelerated-approvals

*Note: Individuals currently receiving treatment for a withdrawn indication should consult with their healthcare practitioner whether to remain on treatment. Coverage of a treatment with a withdrawn indication will only be considered should the patient be established on therapy prior to the withdrawal date listed on the FDA website.

UPDATES:

Date	Revision
02/03/2025	Revised
01/17/2025	Revised
01/14/2025	Revised
12/15/2024	Revised
12/10/2024	Revised
11/21/2024	Reviewed / Approved P&T Committee
11/14/2024	Revised
10/18/2024	Revised

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10/01/2024	Revised
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07/01/2024	Revised
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05/30/2024	Revised
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3/20/2023	Revised
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03/2022	Revised
02/2022	Revised/P&T Committee Approval
12/2021	Revised
11/2021	Revised
10/2021	Revised
09/2021	Revised
08/2021	Revised
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05/2021	Revised
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02/2015	Revised
01/2015	Revised
11/2014	Revised

10/2014	Revised
09/2014	Revised
08/2014	Revised
07/2014	Revised
06/2014	Revised

REFERENCES:

In addition to the full prescribing information for each individual drug and NCCN Drugs and Biologic Compendium, the following references have been utilized in creating drug specific criteria

Folotyn –
1. Drug approval package Application # 02268 http://www.accessdata.fda.gov/drugsatfda_docs/nda/2009/022468s000TOC.cfm

Treanda –
1. Rummel MJ, von Gruenhagen U, Niederle N. et al. Bendamustine plus rituximab versus CHOP plus rituximab in the first line treatment of patients with follicular, indolent, and mantle cell lymphoma: Results of a randomized phase II study of the Study Group Indolent Lymphoma. Blood. (ASH Annual Meeting Abstracts). 2008; 112:2596.