Pharmacy Management Drug Policy

SUBJECT: Oncology Clinical Review Prior Authorization (CRPA) Medical Drugs
POLICY NUMBER: PHARMACY-64
EFFECTIVE DATE: 10/2013
LAST REVIEW DATE: 09/12/2023

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 (tagraxofusp-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. The drugs in this policy may apply to all other lines of business including Medicare Part B.
9. For members with Medicare Part B, 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.

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 Part B	All sites of service – 6 months	All sites of service – 6 months

TABLE 2. DRUG SPECIFIC APPROVAL TIMEFRAMES:

Drug Name	Initial Approval	Continued Approval
Adstiladrin (nadofaragene firadenovec-vncg)	3 months	3 months
Onivyde (irinotecan liposome injection)	3 months	3 months
Folotyn (pralatrexate), pralatrexate (generic Folotyn)	7 weeks	14 weeks
Elitek (rasburicase)	1 month	Not Applicable

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 (American Regent 505(b)(2))	J9259
Adstiladrin (nadofaragene firadenovec-vncg)	J9029
Adcetris (brentuximab vedotin)	J9042
Aliqopa (copanlisib)	J9057
Arzerra (ofatumumab)	J9302
Asparlas (calaspargase pegol-mknl)	J9118
Beleodaq (belinostat)	J9032
Belrapzo (bendamustine HCL)*	J9036
Bendeka (bendamustine HCL)*	J9034
Treanda (bendamustine HCL)*	J9033
Bendamustine HCL (generic Treanda)*	J9033
Vivimusta (bendamustine HCL)*	J9056
Besponsa (inotuzumab ozogamicin)	J9229
Blincyto (blinatumomab)	J9039
Camcevi (leuprolide mesylate)	J1952
Columvi (glofitamab-gxbm)	J9999 (NOC)
Cyramza (ramucirumab)	J9308
Danyelza (naxitamab-gqgk)	J9348
Darzalex (daratumumab)	J9145
Darzalex Faspro (daratumumab and hyaluronidase-fihj)	J9144
Elahere (mirvetuximab soravtansine-gynx)	J9063
Elitek (rasburicase)	J2783
Elrexfio (elranatamab-bcmm)	J9999 (NOC)

Elzonris (tragraxofusp-erzs)	J9269
Empliciti (elotuzumab)	J9176
Enhertu (fam-trastuzumab deruxtecan-nxki)	J9358
Epkinly (epcoritamab-bysp)	J9999 (NOC)
Erwinaze (asparaginase)	J9019
Folotyn (pralatrexate)	J9307
Pralatrexate (generic Folotyn)	J9307
Fyarro (sirolimus protein-bound particles)	J9331
Gazyva (obinutuzumab)	J9301
Istodax	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	NDC: 69097-0909-50
Lumoxiti (moxetumomab pasudotox-tdfk)	J9313
Lunsumio (mosunetuzumab-axgb)	J9350
Margenza (margetuximab-cmkb)	J9353
Marqibo (vincristine sulfate liposome injection)	J9371
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
Phesgo (pertuzumab/trastuzumab/hyaluronidase-zzxf)	J9316
Polivy (polatuzumab vedotin-piiq)	J9309
Portrazza (necitumumab)	J9295
Poteligeo (mogamulizumab-kpkc)	J9204
Provenge (sipuleucel-T)	Q2043
Rybrevant (amivantamab-vmjw)	J9061
Rylaze (asparaginase erwinia chrysanthemi [recombinant]-rywn)	J9021
Sarclisa (isatuximab-irfc)	J9227
Synribo (omacetaxine mepesuccinate)	J9262
Talvey (talquetamab-tgvs)	J9999 (NOC)
Tecvayli (teclistamab)	J9380
Tivdak (tisotumab vedotin-tftv)	J9273
Torisel (temsirolimus)	J9330
Temsirolimus (generic Torisel)	J9330
Trodelvy (sacituzumab govitecan-hziy)	J9317
Vyxeos (Daunorubicin/Cytarabine)	J9153
Xgeva (denosumab)	J0897
Yondelis (trabectedin)	J9352

Zaltrap (ziv-aflibercept)	J9400
Zepzelca (lurbinectedin)	J9223
Zynlonta (loncastuximab tesirine-lpyl)	J9359
*Prior Authorization only applies to Managed Medicaid (MMC)/Child Health Plus (CHP)/Essential Plan (EP); no prior authorization is required for lines of business other than MMC/CHP/EP	

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. Must have a diagnosis that meets **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

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

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 initia¬ted 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.

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	There must be a medical reason why (i.e., contraindication, hypersensitivity) conventional paclitaxel/Taxol cannot be used
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
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
Vivimusta (bendamustine)	For all FDA approved, and compendia supported indications	There must be a medical reason why Treanda/bendamustine (generic Treanda) 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

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
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
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:

Please 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
09/12/2023	Revised
06/21/2023	Revised
05/18/2023	Revised
04/01/2023	Revised
3/20/2023	Revised
03/01/2023	Revised
02/09/2023	P&T Committee Approval
12/15/2022	Revised
11/2022	Revised
07/2022	Revised
05/2022	Revised
04/2022	Revised
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
06/2021	Revised
05/2021	Revised
04/2021	Revised
03/2021	Revised
02/2021	Revised
02/11/2021	P&T Approved
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12/2020	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.