Pharmacy Drug Policy

SUBJECT: Oncology Clinical Review Prior Authorization (CRPA) Medical Drugs Policy
POLICY NUMBER: PHARMACY-64
EFFECTIVE DATE: 10/2013
LAST REVIEW DATE: 10/01/2026

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. Utilization Management is contract dependent. Refer to specific contract/benefit language for exclusion.
    a. Coverage criteria may be dependent on the contract renewal date.
    b. Coverage of drugs listed in this policy are contract dependent.
    c. Not all contracts/benefits allow coverage of healthcare professional administered drugs as part of their pharmacy benefit
    d. Not all contracts/benefits cover all medical infusible drugs.
2. This policy is subject to ongoing revision. Newly marketed drugs and existing drugs with new indications may be subject to prior authorization until formal coverage criteria are established. Inclusion of a drug in this policy does not guarantee its current availability on the market, as some agents may be discontinued, withdrawn, or otherwise unavailable. As product status changes, drugs may be removed from the policy.
3. Dose and frequency should be in accordance 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. 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

5. 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)
6. 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.
7. 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. In the absence of a Medicare National Coverage Determination (NCD), Local Coverage Determination (LCD), or other Medicare coverage guidance, CMS permits a Medicare Advantage Organization (MAO) to establish its own coverage determinations in accordance with 42 CFR § 422.101(b)(6). 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.
8. 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.
9. Unless otherwise stated below within the Drug Specific Criteria (TABLE 4) or the Drug Specific Approval Timeframes (TABLE 2), approval time periods are listed in TABLE 1 below
10. Clinical documentation must be submitted for each request (initial and recertification) unless otherwise specified (e.g., provider attestation required). Supporting documentation includes, but is not limited to, progress notes documenting previous treatments and treatment history, diagnostic testing, laboratory test results, genetic testing or biomarker results, imaging, and other objective or subjective measures of clinical benefit. For recertification, continued approval requires documentation demonstrating that the requested product is providing ongoing benefit to the patient, evidenced by improvement or stability in the disease state or condition, and that continued use remains medically necessary. Ongoing use of the requested product must continue to align with the current policy's preferred formulary. Recertification reviews may result in a requirement to trial more cost-effective treatment alternatives as they become available (e.g., generics, biosimilars, or other guideline-supported treatment options). Requested dosing must remain consistent with FDA-approved or off-label/guideline-supported dosing recommendations.
    a. 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.
11. 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.
12. All utilization management requirements outlined in this policy are compliant with applicable New York State insurance laws and regulations. Policies will be reviewed and updated as necessary to ensure ongoing compliance with all state and federally mandated coverage requirements.
13. This policy is based on available evidence as of the last review date. Coverage determinations are subject to applicable plan documents, state and federal regulations, and individual patient circumstances. This policy does not constitute medical advice.
14. For commercial contracts, medical necessity determinations align with the Certificate of Coverage issued by the Health Plan, which states that covered services must be clinically appropriate and not primarily for the convenience of the member, the member's family, or the provider.
15. Manufacturers may either discontinue participation in, or may not participate in, the Medicaid Drug Rebate Program (MDRP). Under New York State Medicaid requirements, physician-administered

drugs must be produced by manufacturers that participate in the MDRP. Products made by manufacturers that do not participate in the MDRP will not be covered under Medicaid Managed Care/HARP lines of business. Drug coverage will not be available for any product from a non-participating manufacturer. For a complete list of New/Reinstated & Terminated Labelers please visit: https://www.medicaid.gov/medicaid/prescriptiondrugs/medicaid-drug-rebate-program/newreinstated-terminated-labeler-information/index.html

16. The requested site of care may impact approval timeframe and is subject to review.
17. The following applies to all gene and cellular therapies unless otherwise specified within the drug-specific coverage criteria:
    a. Administration, Retreatment, and Treatment with Additional or Other Gene/Cellular Therapies
        i. One-Time Administration
            1. Most gene and cellular therapies, whether autologous, allogeneic ("off-the-shelf"), or in vivo gene-transfer therapies, are designed and studied as one-time treatments.
            2. Repeat dosing, reinfusion, or sequential therapy with other gene or cellular products has not been established as safe, effective, or clinically appropriate.
        ii. Retreatment/Repeat Administration
            1. Retreatment with the same gene or cellular therapy product is considered experimental and investigational because:
                a. Clinical trials evaluated these therapies as single-administration interventions
                b. Safety, efficacy, and durability of a second administration have not been established
                c. Risks of immune activation, insertional mutagenesis, or vector immunity may be increased with repeat dosing
        iii. Treatment with an Additional or Other Gene/Cellular Therapy
            1. Treatment with an additional or different gene or cellular therapy after prior exposure to any gene or cellular therapy is currently considered experimental and investigational as there is lack of evidence demonstrating the following (a-c):
                a. Anticipated clinical benefit beyond available standard therapies
                b. Safety of sequential administration
                c. Justification for selecting a second gene/cellular intervention after a prior one
            2. This includes, but is not limited to:
                a. Switching between CAR-T products (e.g., CD19 → CD19 or CD19 → BCMA)
                b. Switching between autologous and allogeneic cellular therapies
                c. Sequential use of CAR-T, TCR-T, NK-cell therapies, or other genetically engineered cell therapies
                d. Receiving a gene therapy after previous gene or cellular therapy exposure
                e. Receiving an in vivo gene therapy following any prior vector-based therapy
        iv. Prior Gene/Cell Therapy Exposure
            1. An individual is generally not eligible for additional gene or cellular therapy if they have previously received:
                a. Any autologous cellular therapy (e.g., CAR-T, TCR-T, TIL),
                b. Any allogeneic genetically modified cellular therapy,
                c. Any in vivo gene therapy (e.g., AAV, lentiviral vector)
                d. Any ex vivo gene-modified cell product
                e. Are being considered for any other gene or cellular therapy without documented evidence supporting safety and anticipated benefit.
18. Approval timeframes may be extended to align authorization periods for drugs administered as part of a multidrug regimen, including when regimen components are administered across different benefits. This provision does not apply when the approval timeframe reflects a drug-specific limitation on duration of therapy.

TABLE 1. APPROVAL TIME PERIODS:

Line of Business	Initial approval	Continued approval
Commercial, Exchange, and SafetyNet (Medicaid, HARP, CHP, Essential Plan)	6 months	6 months
Medicare Advantage	6 months	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
Zusduri (mitomycin)	3 months	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 (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
Avgemsi (gemcitabine – Avyxa 505(b)(2))	J9184
Avopef (etoposide)	J9999 (NOC)
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
Beizray (docetaxel)	J9174
Besponsa (inotuzumab ozogamicin)	J9229
Bizengri (zenocutuzumab-zbco)	J9382
Blenrep (belantamab mafodotin-blmf)	J9053
Blincyto (blinatumomab)	J9039
Boruzu (bortezomib)	J9054
Camcevi (leuprolide mesylate)	J1952
Cinvanti (aprepitant)	J0185
Cligavyx (fulvestrant)	J9999 (NOC)
Columvi (glofitamab-gxbm)	J9286
Cyclophosphamide, Baxter 505(b)(2)	J9076

Cyclophosphamide, Sandoz 505(b)(2)	J9074
Cyramza (ramucirumab)	J9308
Danyelza (naxitamab-gqgk)	J9348
Darzalex (daratumumab)	J9145
Darzalex Faspro (daratumumab and hyaluronidase-fihj)	J9144
Datroway (datopotamab deruxtecan-dlnk)	J9011
Decnupaz (pivekimab sunirine-pvzy)	J9999 (NOC)
Docivyx (docetaxel)	J9172
Elahere (mirvetuximab soravtansine-gynx)	J9063
Elitek (rasburicase)	J2783
Elrexfio (elranatamab-bcmm)	J1323
Elzonris (tragraxofusp-erzs)	J9269
Empliciti (elotuzumab)	J9176
Emrelis (telisotuzumab vedotin-tllv)	J9326
Enhertu (fam-trastuzumab deruxtecan-nxki)	J9358
Epkinly (epcoritamab-bysp)	J9321
Erwinaze (asparaginase)	J9019
Evdi (trabectedin)	J9999 (NOC)
Favlyxa (fluorouracil)	J9999 (NOC)
Focinvez (fosaprepitant)	J1434
Folotyn (pralatrexate)	J9307
Frindovyx (cyclophosphamide)	J9072
Pralatrexate (generic Folotyn)	J9307
Fosaprepitant (Teva/Actavis 505(b)(2))	J1456
Fyarro (sirolimus protein-bound particles)	J9331
Gazyva (obinutuzumab)	J9301
Gemcitabine, Accord 505(b)(2)	J9196
Hepzato Kit (melphalan for injection/Hepatic Delivery System [HDS])	J9248
Imdelltra (tarlatamab-dlle)	J9026
Infugem (gemcitabine)	J9198
Inlexzo (gemcitabine intravesical system))	J9183
Istodax (romidepsin), lyophilized,	J9319
Romidepsin (generic Istodax), lyophilized	J9319
Romidepsin, non-lyophilized	J9318
Ivra (melphalan hcl)	J9999 (NOC)
Jelmyto (mitomycin gel)	J9281
Kadcyla (ado-trastuzumab emtansine)	J9354
Kimmtrak (tebentafusp)	J9274
Kyprolis (carfilzomib)	J9047
Kyxata (carboplatin)	J9278
Lartruvo (olaratumab injection)	J9285
Leuprolide Acetate Depot	J1954
Lutrate Depot (leuprolide acetate)	J1954
Lumoxiti (moxetumomab pasudotox-tdfk)	J9313
Lunsumio (mosunetuzumab-axgb)	J9350
Lunsumio Velo (monsunetuzumab-axgb)	J9350
Lymphir (denileukin difitox-cxdl)	J9161
Lynozyfic (linvoseltamab-gcpt)	J9601
Margenza (margetuximab-cmkb)	

Not covered for MMC/HARP due to lack of participation in MDRP	J9353
Monjuvi (tafasitamab-cxix)	J9349
Mylotarg (gemtuzumab ozogamicin)	J9203
Navitrux (fosaprepitant)	J3490
Niktimvo (axatilimab-csfr)	J9038
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
Revtorpyk (gedatolisib)	J9999
Rybrevant (amivantamab-vmjw)	J9061
Rybrevant Faspro (amivantamab and hyaluronidase-lpuj)	J9062
Rylaze (asparaginase erwinia chrysanthemi [recombinant]-rywn)	J9021
Rytelo (imetelstat)	J0870
Sarclisa (isatuximab-irfc)	J9227
Sarclisa Escena (isatuximab-irfc)	J9999
Talvey (talquetamab-tgvs)	J3055
Tecelra (afamitresgene autoleucel)	Q2057
Tecvayli (teclistamab)	J9380
Tepylute (thiotepa)	J9341
Tivdak (tisotumab vedotin-tftv)	J9273
Torisel (temsirolimus)	J9330
Temsirolimus (generic Torisel)	J9330
Trodelvy (sacituzumab govitecan-hziy)	J9317
Vectibix (panitumumab)	J9303
Vyloy (zolbetuximab-clzb)	J1326
Vyxeos (Daunorubicin/Cytarabine)	J9153
Xgeva (denosumab)	J0897
Aukelso (denosumab-kyqq)	Q5161
Bilprevda (denosumab-nxxp)	Q5162
Bomyntra (denosumab-bnht)	Q5158
Jubereq (denosumab-desu)	Q5166
Osenvelt (denosumab-bmwo)	Q5157
Wyost (denosumab-bbdz)	Q5136
Xbryk (denosumab-dssb)	Q5159
Xtrenbo (denosumab-qbde)	Q5167
Yondelis (trabectedin)	J9352
Zaltrap (ziv-aflibercept)	J9400
Zepzelca (lurbinectedin)	J9223
Ziihera (zanidatamab-hrii)	J9276

Zusduri (mitomycin)	J9282
Zynlonta (loncastuximab tesirine-lpyl)	J9359

UNIVERSAL CRITERIA:

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

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) a. BCG-unresponsive is defined as one of the following (i-iv): 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. Patient has one of the following (a or b): a. Carcinoma in situ (CIS) with or without papillary tumors **OR** b. Papillary Ta/T1 tumors without CIS **AND** 6. 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 7. 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)
   a. BCG-unresponsive is defined as one of the following (i-iv)::
      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. Patient has met <u>one</u> of the following (a or b):
   a. Carcinoma in situ (CIS) with or without papillary tumors **AND** 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 **OR**
   b. Papillary Ta/T1 tumors without CIS **AND** the patient must have received prior treatment with Adstiladrin (nadofaragene firadenovec-vncg), or clinical documentation of why this therapy is 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.

Bispecific T-cell Engagers (BiTE) – Applies to Blincyto (blinatunonab), Columvi (glofitamab-gxbm), Elrexfio (erlanatamab-bcmm), Epkinly (epcoritamab-bysp), Imdelltra (tarlatamab-dlle), Kimmtrak (tebentafusp), Lynozyfic (linvoseltamab-gcpt), Talvey (talquetamab-tgvs), and Tecvayli (teclistamab)

1. Must meet Universal Criteria as listed above.
2. For members receiving bispecific T-cell engager (BiTE) therapy, coverage of intravenous (IV) tocilizumab for the management of cytokine release syndrome (CRS) is available under the medical benefit. To facilitate timely access to treatment should CRS occur, prescribers are encouraged to submit requests for coverage of the applicable tocilizumab code(s) concurrently with the request for BiTE therapy. Tocilizumab requests for CRS may also be submitted separately, as clinically appropriate. Dose and frequency should be in accordance with the FDA label or recognized compendia (for off label uses). When services are performed in excess of established parameters, they may be subject to review for medical necessity.

Blenrep (belantamab mofodotin-blmf)

1. Must be prescribed by, or in consultation with an Oncologist, Hematologist or appropriate specialist **AND**
2. Must be 18 years of age or older **AND**
3. Must have a diagnosis of relapsed or refractory multiple myeloma **AND**
4. Must have measurable laboratory (serum or urine) disease defined as having one of the following (not required if patient has non-secretory disease):
   a. Urine M-protein excretion ≥ 200 mg per 24-hour **OR**
   b. Serum-M protein concentration ≥ 0.5 g/dL **OR**
   c. Serum free light chain (FLC) assay: involved FLC level ≥ 10mg/dL (100 mg/L) and an abnormal serum free light chain ratio (<0.26 or >1.65) **AND**
5. Must meet one of the following (a or b):
   a. Will be used in combination with bortezomib and dexamethasone **AND**
      i. Must have received at least two prior lines of therapy, including a proteasome inhibitor and an immunomodulatory agent **OR**
   b. Will be used as a single agent **AND**
      i. Must have received at least three prior lines of therapy
6. Must not have received a prior allogenic stem cell transplant.
7. See prescribing information for approved dose.
8. Initial and subsequent approvals will be provided for 6 months.
   a. All recertifications will require documentation that the patient does not have evidence of disease progression or unacceptable toxicity.

Datroway (datopotamab deruxtecan-dlnk)

1. Must be prescribed by an oncologist **AND**
2. Patient must be 18 years of age or older **AND**
3. Patient must have **ONE** of the following (a, b, or c):
   a. Must have a **diagnosis of unresectable or metastatic, hormone receptor (HR)-positive breast cancer AND**

i. Patient has human epidermal growth factor receptor 2 (HER2)-negative (immunohistochemistry [IHC] 0, 1+, or IHC 2+/in situ hybridization [ISH]-negative disease) **AND**
ii. Patient has received prior endocrine-based therapy **AND**
iii. Patient has received prior chemotherapy for unresectable or metastatic disease **AND**
iv. For patients with IHC 1+ or IHC 2+/ISH negative disease:
1. Patient must have received an Enhertu-containing regimen, unless a contraindication to Enhertu exists **(Does not apply to Medicare Advantage) AND**
2. There must be a medical reason why Trodelvy cannot be used **OR**
v. For patients with IHC 0/ISH negative disease:
1. There must be a medical reason why Trodelvy cannot be used

b. Must have a diagnosis **of unresectable or metastatic, triple-negative breast cancer (TNBC) AND**
i. Must be used in the first line setting **AND**
ii. Patient is not a candidate for PD-1/PD-L1 inhibitor therapy OR PD-L1 CPS < 10 **AND**
iii. If there is a germline BRCA1/2 pathogenic variant, patient is NOT a candidate for PARPi or platinum therapy **OR**

c. Must have a **diagnosis of advanced or metastatic non-small cell lung cancer (NSCLC**) **AND**
i. Must have documentation of an EGFR mutation **AND**
ii. Must have received prior EGFR-directed therapy and platinum-based chemotherapy for advanced or metastatic disease **AND**
iii. Must not have received prior treatment with any of the following:
1. Any chemotherapeutic agent targeting topoisomerase I, including antibody drug conjugate (ADC) containing such agent
2. TROP2-targeted therapy

4. Approved dosing is 6 mg/kg given as an intravenous infusion once every 3 weeks (21-day cycle) until disease progression or unacceptable toxicity.

Decnupaz (pivekimab sunirine-pvzy)

1. Must be prescribed by, or in consultation with, an oncologist or hematologist
2. Must have a diagnosis of blastic plasmacytoid dendritic cell neoplasm (BPDCN) **AND**
3. Must be 18 years or older **AND**
4. Patient does not have any of the following:
a. Central nervous system (CNS) involvement
b. History of sinusoidal obstruction syndrome (SOS)
c. History of grade 4 capillary leak syndrome
d. Non-cardiac grade 4 edema; **AND**
5. For relapsed/refractory disease, patient has not progressed while receiving Decnupaz
6. Approved dosing is 0.045 mg/kg once every 3 weeks until disease progression or unacceptable toxicity.

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

Gazyva (obinutuzumab)

1. For all oncology indications, must meet Universal Criteria.
2. For the treatment of lupus nephritis, refer to the Clinical Review Prior Authorization (CRPA) Medical policy (Pharmacy-63).

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.

Inlexzo (gemcitabine intravesical system)

1. Must be prescribed by an Oncologist or Urologist **AND**
2. Patient must be 18 years of age or older **AND**
3. Must have a diagnosis of Bacillus Calmette-Guerin (BCG)-unresponsive, high-risk non-muscle invasive bladder cancer (NMIBC)
   a. BCG-unresponsive is defined as **ONE** of the following (i-iv):
      i. Having received at least 2 previous courses of BCG within a 12-month period defined as:
         1. At least 5 or 6 induction BCG instillation and at least 2 out of 3 instillations of maintenance BCG **OR**
         2. 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. Patient has met one of the following (a or b):
   a. Carcinoma in situ (CIS) with or without papillary tumors **AND** 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 **OR**
   b. Papillary Ta/T1 tumors without CIS **AND** the patient must have received prior treatment with Adstiladrin (nadofaragene firadenovec-vncg), or clinical documentation of why this therapy is not appropriate for use in this patient must be provided
6. 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 disease-recurrence
c. Maximum treatment duration is 2 years (14 doses)

7. Approved dosing: 225 mg intravesically every 3 weeks for 6 months, followed by once every 12 weeks for up to 18 months

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 and Lunsumio Velo (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, authorization will be provided 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.
8. For members receiving bispecific T-cell engager (BiTE) therapy, coverage of intravenous (IV) tocilizumab for the management of cytokine release syndrome (CRS) is available under the medical benefit. To facilitate timely access to treatment should CRS occur, prescribers are encouraged to submit requests for coverage of the applicable tocilizumab code(s) concurrently with the request for BiTE therapy. Tocilizumab requests for CRS may also be submitted separately, as clinically appropriate. Dose and frequency should be in accordance with the FDA label or recognized compendia (for off label uses). When services are performed in excess of established parameters, they may be subject to review for medical necessity.

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**

a. Patient must have transfusion-dependent anemia having required four or more RBC units transfused over an 8-week period in the preceding 16 weeks **AND**
b. Patient does not have del(5q) MDS

4. For patients with ring sideroblasts (RS) ≥ 15% (or RS ≥ 5% with an SF3B1 pathogenic variant):
   a. Patient must have had serious side effects or drug failure to Reblozyl (luspatercept- aamt)
5. For patients with ring sideroblasts (RS) < 15% (or RS < 5% with an SF3B1 pathogenic variant):
   a. Patient must meet one of the following (i or ii):
      i. Patient has serum EPO > 500 mU/mL and the following:
         1. Poor probability to respond to immunosuppressive therapy defined as > 60 years, those having normocellular or hypercellular bone marrow, PHN clone negativity or wild-type STAT3-mutant cytotoxic T-cell clones **OR**
      ii. Patient has serum EPO ≤ 500 mU/mL and the following:
         1. Patient must have had serious side effects or drug failure to erythropoiesis stimulating agents (ESA) **OR** Reblozyl (luspatercept- aamt)
6. 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.
7. Current body weight and requested dosage regimen must be submitted for initial review and each recertification request
8. Initial approval will be granted for 6 months
9. 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 ≥ 12 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 or b):
   a. Must have a diagnosis of biliary tract cancer **AND**
      i. Must meets one of the following (i,ii, OR iii):

A. Intrahepatic cholangiocarcinoma; **OR**
B. Extrahepatic cholangiocarcinoma; **OR**
C. Gallbladder cancer; **AND**

ii. Patient has unresectable or metastatic disease **AND**
iii. Must be HER-2 positive with immunohistochemistry score of 3+ (IHC 3+) as detected by an FDA-approved test **AND**
iv. Patient has progressed following ≥ 1 prior systemic therapy **AND**

v. Patient does not have a history or progression on prior HER-2 targeted therapy **OR**

b. Must have a diagnosis of gastric, gastroesophageal junction, or esophageal adenocarcinoma **AND** meet Universal Criteria.

Zusduri (mitomycin)

1. Must be prescribed by an Oncologist or Urologist **AND**
2. Patient must be 18 years of age or older **AND**
3. Patient has a diagnosis of recurrent low grade, intermediate risk, non-muscle invasive bladder cancer (LG-IR-NMIBS) confirmed by cystoscopy and pathology **AND**
4. Documentation disease recurrence occurred following prior transurethral resection of bladder tumor (TURBT) **AND**
5. Patient does not have a history of high-grade non-muscle invasive bladder cancer (HG-NMIBC) within the past 2 years **AND**
6. Patient has not received BCG treatment for urothelial carcinoma within the past year **AND**
7. Patient has not received treatment with intravesical chemotherapy (except for a single dose immediately following TURBT) within the past 2 years
8. FDA approved dosing is 75mg (56 mL) instilled into the bladder once weekly for 6 weeks
9. Approval will be provided for 3 months
10. Retreatment with Zusduri has not been proven to be safe and effective. Retreatment with Zusduri will be considered Experimental/Investigational.
11. Zusduri will not be covered for any non-FDA approved diagnosis.

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. This step requirement does not apply for individuals taking Lifyorli which requires combination use with Abraxane/paclitaxel protein-bound particles.	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)
Avgemsi (gemcitabine)	For all FDA approved, and compendia supported indications	There must be a medical reason why Gemzar/gemcitabine cannot be used
Avopef (etoposide)	For all FDA approved, and compendia supported indications	There must be a medical reason why etoposide or Etopophos (J9181) cannot be used
Axtle (pemetrexed (avyxa))	For all FDA approved, and compendia supported indications	There must be a medical reason why Alimta/pemetrexed cannot be used
Beizray (docetaxel)	For all FDA approved, and compendia supported indications	There must be a medical reason why docetaxel (Taxotere) 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).
Cligavyx (fulvestrant)	For all FDA approved, and compendia supported indications	There must be a medical reason why fulvestrant (J9395 and J9394) cannot be used.
Datroway (datopotamab deruxtecan-dlnk)	For unresectable or metastatic HR-positive, HER-2 negative breast cancer	**For IHC 1+ or IHC 2+/ISH negative disease:** There must be documentation of a contraindication to, or failure of Enhertu **(Does not apply to Medicare Advantage)** AND there must be a medical reason why Trodelvy cannot be used **For IHC 0/ISH negative disease:** There must be a medical reason why Trodelvy cannot be used
Evdi (trabectedin)	For all FDA approved, and compendia supported indications	There must be a medical reason why Yondelis (J9352) 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,Lupron Depot or Vabrinty cannot be used

Cinvanti (aprepitant), Focinvez (fosaprepitant) and fosaprepitant (Teva/Actavis 505(b)(2)), Navitrux (fosaprepitant dimeglumine) **Apply to all requests, not just new starts for Commercial and SafetyNet. Applies to new starts only for Medicare Advantage.**	For all FDA approved, and compendia supported indications	There must be a medical reason why fosaprepitant (Emend IV) cannot be used
Cyclophosphamide: Baxter 505(b)(2); J9076 Sandoz 505(b)(2); J9074 **Frindovyx (cyclophosphamide); J9072**	For all FDA approved, and compendia supported indications	There must be a medical reason why cyclophosphamide J9071, J9075, and J9073 cannot be used.(Cytoxan and generics, Auromedics/Eugia 505(b)(2), and Dr. Reddy's 505(b)(2), respectively)
Docivyx (docetaxel)	For all FDA approved, and compendia supported indications	There must be a medical reason why docetaxel (Taxotere) cannot be used
Favlyxa (fluorouracil)	For all FDA approved, and compendia supported indications	There must be a medical reason why fluorouracil (J9190) cannot be used
Gemcitabine, Accord 505(b)(2)	For all FDA approved, and compendia supported indications	There must be a medical reason why Gemzar/gemcitabine cannot be used (J9201)
Infugem (gemcitabine)	For all FDA approved, and compendia supported indications	There must be a medical reason why Gemzar/gemcitabine cannot be used
Inlexzo (gemcitabine intravesical system)	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)
Ivra (melphalan hcl)	For all FDA approved, and compendia supported indications	Must have had hypersensitivity, intolerable side effects, or contraindication to melphalan (J9245)
Kyxata (carboplatin)	For all FDA approved, and compendia supported indications	There must be a medical reason why Paraplatin/carboplatin (J9045) cannot be used
Leuprolide Acetate Depot	For all FDA approved, and compendia supported indications	There must be a medical reason why Eligard, Lupron Depot or Vabrinty cannot be used

Lutrate Depot (leuprolide acetate)	For all FDA approved, and compendia supported indications	There must be a medical reason why Eligard, Lupron Depot or Vabrinty 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 LR-MDS that is RS+	There must be documentation of serious side effects, failure, or a contraindication to Reblozyl (luspatercept-aamt)
Tepylute (thiotepa)	For all FDA approved, and compendia supported indications	There must be a medical reason why thiotepa/Tepadina (J9342) cannot be used
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), Wyost (denosumab-bbdz), Aukelso (denosumab-kyqq), Bomyntra (denosumab-bnht), Jubereq (denosumab-desu), Osenvelt (denosumab-bmwo) & Xbryk (denosumab-dssb) **This applies to new starts and existing users for Commercial and Safety Net lines of business, and new starts only for Medicare.**	For all FDA approved, and compendia supported indications	There must be a medical reason why Bilprevda (denosumab-nxxp) and Xtrenbo (denosumab-qbde) cannot be used
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
Anktiva (nogapendekin alfa inbakicept-pmln)	BCG-unresponsive non-muscle 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
Inlexzo (gemcitabine intravesical system)	Bacillus Calmette-Guerin (BCG)-unresponsive, non-muscle invasive bladder cancer (NMIBC) with carcinoma *in situ* (CIS) with or without papillary tumors	2 years (14 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 installations. 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)
Lunsumio (mosunetuzumab-axgb) and Lunsumio Velo (mosunetuzumab-axgb)	Relapsed or refractory follicular lymphoma	17 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
Zusduri (mitomycin)	Recurrent low-grade intermediate-risk non-muscle invasive bladder cancer (LG-IR-NMIBC)	6 doses

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
10/01/2026	Revised
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07/10/2025	Revised
06/23/2025	Revised
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05/21/2025	Revised
05/08/2025	Reviewed / P&T Committee Approval
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09/2017	Revised
08/2017	Revised
05/2017	Revised
04/2017	Revised
02/2017	Revised
01/2017	Revised
11/2016	Revised
10/2016	Revised
09/2016	Revised
08/2016	Revised
06/2016	Revised
05/2016	Revised
04/2016	Revised
03/2016	Revised
02/2016	Revised
01/2016	Revised
12/2015	Revised
11/2015	Revised
10/2015	Revised
08/2015	Revised
07/2015	Revised
06/2015	Revised
05/2015	Revised
03/2015	Revised
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

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1. Drug approval package Application # 02268
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