Pharmacy Management Drug Policy

SUBJECT: Oncology Clinical Review Prior Authorization (Oncology-CRPA) Medical Drugs
POLICY NUMBER: Pharmacy-64
ANNUAL REVIEW DATE: 1/2/2021
EFFECTIVE DATE: 10/13
LAST REVIEW DATE: 03/23/2020

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. Medical or drug policies apply to commercial, SafetyNet, and Health Care Reform products only when a contract benefit for the specific service exists.

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 FLRx 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.

Please see the Safety-Net Oncology Clinical Review Prior Authorization Medical Drugs Policy for criteria pertaining to the following oncology medications: Bendeka, Jevtana, Perjeta, Treanda, and Belrapzo.

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 approve 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 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.
4. 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.

5. Unless otherwise stated below within the individual drug criteria, approval time periods are listed in the table 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.
6. 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.

Approval time periods

Line of Business	**Initial approval**	**Continued approval**
Medicaid	6 months	12 months
Commercial/Exchange	Outpatient hospital – 6 months	Outpatient hospital – 6 months
	Home Care or Office Based- 2 years	Home Care or Office Based- 2 years
Medicare	Outpatient hospital – 2 years	Outpatient hospital – 2 years
	Home Care or Office Based- 2 years	Home Care or Office Based- 2 years

CURRENT CRPA MEDICAL DRUGS:

DRUG NAME (Medical benefit)
Authorization Criteria
Adcetris (brentuximab vedotin) - Medical

1. Must be prescribed by an Oncologist
2. Must be 18 years of age or older
3. Diagnosis of:
    a. Classical Hodgkin Lymphoma (cHL)
        i. Previously untreated stage III or IV disease, in combination with chemotherapy **OR**
        ii. Failure of autologous stem cell transplant (ASCT) or failure of at least two prior multi-agent chemotherapy regimens in patients who are not ASCT candidates **OR**
        iii. Disease at high risk of relapse or progression as post-autologous hematopoietic stem cell transplantation (auto-HSCT) consolidation **OR**
        iv. Second-line or subsequent systemic therapy (if not previously used) for relapsed or refractory disease as a single agent or in combination with bendamustine **OR**
        v. Primary treatment in combination with dacarbazine for stage I-II unfavorable or stage III-IV disease in patients ≥ 60 years old **OR**
        vi. Used as a single agent palliative therapy for relapsed or refractory disease in patients ≥ 60 years old
    b. Non-Hodgkin's Lymphomas (NHL)
        i. Relapsed or refractory systemic anaplastic large cell lymphoma (sALCL) or CD30+ peripheral T-cell lymphoma as second-line or subsequent therapy **OR**
        ii. Previously untreated systemic anaplastic large cell lymphoma (sALCL) or other CD30-expressing peripheral T-cell lymphomas (PTCL), including angioimmunoblastic T-cell lymphoma and PTCL, not otherwise specified, in combination with cyclophosphamide, doxorubicin, and prednisone **OR**
        iii. Primary cutaneous ALCL with multifocal lesions /cutaneous ALCL with regional nodes as primary treatment or therapy for relapsed or refractory disease **OR**
        iv. As a single agent for symptomatic lymphomatoid papulosis (LyP) or LyP with extensive lesions if refractory to all primary treatment options **OR**
        v. Second-line or subsequent therapy for CD30+ B-Cell Lymphoma (see NCCN compendium for appropriate types) **OR**
        vi. Use as adjuvant systemic therapy for Breast Implant-Associated ALCL that is localized to capsule/implant/breast following incomplete excision or partial capsulectomy with residual disease if node positive, if radiation therapy is not possible, or for extended disease **OR**
        vii. Mycosis Fungoides (MF) /Sezary Syndrome (SS) (please refer to NCCN compendia for specific staging requirements)
4. The recommended dose as monotherapy is 1.8mg/kg administered only as an intravenous infusion over 30 minutes every 3 weeks. For patients > 100kg, 100kg should be used as the dosing weight. The recommended dose in combination with chemotherapy for previously untreated Stage III or IV cHL is 1.2 mg/kg up to a maximum or 120mg every 2 weeks for a maximum of 12 doses
5. Approval time periods will be limited to the following for the below diagnoses:
    a. Previously Untreated Stage III or IV cHL : 12 doses
    b. Classical Hodgkin Lymphoma Consolidation: 16 cycles

c. Previously Untreated Systemic ALCL or other CD30-expression PTCL: 6-8 doses
d. Relapsed Primary Cutaneous ALCL or CD30-expressing Mycosis Fungoides: 16 cycles

HCPCS: J9042

Aliqopa (copanlisib) - Medical

1. Must be 18 years of age or older **AND**
2. Must be prescribed by an Oncologist or Hematologist **AND**
3. Must have a diagnosis of relapsed/refractory Follicular Lymphoma or relapsed/refractory Marginal Zone Lymphoma (e.g. Nodal Marginal Zone Lymphoma, Nongastric MALT Lymphoma, Gastric MALT Lymphoma, Splenic Marginal Zone Lymphoma) **AND**
4. Must have received ≥ 2 prior systemic therapies
5. Recommended dosage is 60mg IV infusion on days 1,8, and 15 of a 28-day treatment cycle

HCPCS: J9057

Arzerra (ofatumumab) - Medical

1. Must be prescribed by an Oncologist or Hematologist **AND**
2. Must be 18 years of age or older **AND**
3. Must have Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma (CLL/SLL) **and**
   a. Must be used as a single agent therapy for disease that is relapsed or refractory to fludarabine and alemtuzumab **or**
   b. Must be used in combination with chlorambucil for the treatment of previously untreated patients with CLL for whom fludarabine-based therapy is considered inappropriate (patients ≥ 70 years, in younger patients with significant comorbidities who have indications for treatment, patients who are unable to tolerate purine analogs) **or**
   c. Must be used in combination with fludarabine and cyclophosphamide for relapsed disease **or**
   d. Must be used as maintenance therapy for extended treatment of patients who are in complete or partial response after at least two lines of therapy for recurrent or progressive CLL **or**
   e. Must be used for relapsed/refractory disease with del(17p)/TP53 mutation and with indications for treatment as single agent therapy or in combination with a fludarabine-cyclophosphamide regimen in patients < 65 years old without significant comorbidities **or**
   f. Must be used in combination with bendamustine as first-line therapy for disease without del(17p)/TP53 mutation in patients age ≥65 years and younger patients with or without significant comorbidities who have indications for treatment (not recommended for frail patients) **or**
   OR
4. Must have Waldenstrom's macroglobulinemia/Lymphoplasmacytic lymphoma **and**
   a. Must be used as single-agent or combination salvage therapy in rituximab-intolerant patients for disease that does not respond to primary therapy or for progressive or relapsed disease
5. Must have a diagnosis of B-Cell Lymphoma (see NCCN compendium for appropriate types) **and**
   a. Must be used as a substitute for rituximab (Rituxan) or obinutuzumab (Gazyva) in patients experiencing rare complications such as mucocutaneous reactions including paraneoplastic pemphigus, Stevens-Johnson syndrome, lichenoid dermatitis, vesiculobullous dermatitis, and toxic epidermal necrolysis
6. Recommended dose and schedule is as follows:
   a. **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
   b. **Refractory CLL:** 300 mg initial dose, followed 1 week later by 2,000 mg weekly for 7 doses, followed 4 weeks later by2,000 mg every 4 weeks for 4 doses
   c. **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

HCPCS: J9302

Asparlas (calaspargase pegol-mknl)- Medical

1. Must be prescribed by and Oncologist or Hematologist **AND**
2. Must be 1 month to 21 years of age **AND**
3. Must have a diagnosis of acute lymphoblastic leukemia (ALL) **AND**
4. Must have adequate justification as to why Oncaspar (pegaspargase) cannot be used **AND**
5. Must be used in combination with other chemotherapy
6. Recommended dose is 2,500 units/m2 IV administered no more frequently than every 21 days

HCPCS: J9118

Bavencio (avelumab)- Medical

1. Must be followed by an Oncologist or Hematologist **AND**
2. Must be ≥ 12 years of age and have a diagnosis of Metastatic Merkel Cell Carcinoma **OR**
3. Must be ≥ 18 years of age and have locally advanced or metastatic urothelial carcinoma
   a. There must be a proven contraindication to the following FDA approved drugs: Keytruda (pembrolizumab) and Tecentriq (atezolizumab) **AND**
   b. Must meet the following criteria:
      i. Must have disease progression during or following platinum-containing chemotherapy **or**
      ii. Must have disease progression within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy **OR**
4. Must be ≥ 18 years of age and have advanced renal cell carcinoma (RCC) with clear cell histology
   a. Used as first-line treatment in combination with axitinib (Inlyta)
5. The use of Bavencio following disease progression on prior anti-PD-1/PD-L1 therapy is considered experimental and investigational and will not be approved

HCPCS: J9023

Beleodaq (belinostat) - Medical

1. Must be prescribed by an Oncologist or Hematologist **AND**
2. Must be 18 years of age or older **AND**
3. Must have a diagnosis of relapsed or refractory peripheral T-cell lymphoma **OR**
4. Must have a diagnosis primary cutaneous anaplastic large cell lymphoma (ALCL) with multifocal lesions/cutaneous ALCL with regional nodes as single agent therapy for therapy for relapsed or refractory disease **OR**
5. Must have a diagnosis of Mycosis Fungoides (MF) /Sezary Syndrome (SS) (please refer to NCCN compendia for specific staging requirements)
6. The recommended dosage of Beleodaq is 1,000 mg/m^2 administered over 30 minutes by

intravenous infusion once daily on days 1-5 of a 21-day cycle.
7. Approval will be for 6 months at a time. Continued coverage of Beleodaq will require stabilization or reduction in disease. Patients will not be authorized for coverage if there is a:
   a. 50% increase in size of sentinel lesion **OR**
   b. New site of disease including new liver or spleen metastases or lymphadenopathy **OR**
   c. Increase in circulating tumor cells **OR**
   d. Need for radiotherapy

HCPCS: J9032

Besponsa (inotuzumab ozogamicin) – Medical

1. Must be prescribed by an Oncologist **AND**
2. Must have a diagnosis of relapsed or refractory Philadelphia chromosome-positive B-cell Acute Lymphoblastic Leukemia (B-ALL)
   a. Must be tyrosine kinase inhibitor (TKI) intolerant or refractory (TKIs include: Sprycel [dasatinib], Gleevec [imatinib], or Iclusig [ponatinib]) **OR**
3. Must have a diagnosis of relapsed or refractory Philadelphia chromosome-negative B-cell acute lymphoblastic leukemia (ALL)
4. B-cell ALL must be CD22 positive.
5. Initial approval will be for 3 months. Further approval (up to a maximum of 6 cycles) will require documentation that the patient has achieved complete remission (CR) or complete remission with incomplete hematologic recovery (CRi)
   a. CR is defined as < 5% blasts in the bone marrow and the absence of peripheral blood leukemic blasts, full recovery of peripheral blood counts (platelets ≥ 100 × 109/L and absolute neutrophil counts [ANC] ≥ 1 × 109/L) and resolution of any extramedullary disease
   b. CRi is defined as < 5% blasts in the bone marrow and the absence of peripheral blood leukemic blasts, incomplete recovery of peripheral blood counts (platelets < 100 × 109/L and/or ANC < 1 × 109/L) and resolution of any extramedullary disease.
6. Besponsa will not be approved for a diagnosis of ALL in combination with any other chemotherapeutic agent as current literature does not support this

HCPCS: J9229

Blincyto (blinatumomab) - Medical

1. Must be prescribed by an oncologist **AND**
2. Must have a diagnosis of relapsed or refractory B-cell precursor acute lymphoblastic leukemia (B-ALL)
   a. If used for Philadelphia chromosome positive disease, must be TKI intolerant/refractory **OR**
3. Must be used as consolidation therapy for Philadelphia chromosome-negative B-ALL in patients with minimal residual disease positive (MRD+) following a complete response to induction therapy **OR**
4. Must have a diagnosis of Philadelphia chromosome-positive B-ALL with less than complete response, MRD+ at end of consolidation, or high-risk genetics **OR**
5. Must have a diagnosis of Philadelphia chromosome-negative B-ALL or Philadelphia chromosome-like B-ALL that is minimal residual disease positive (MRD+) after consolidation therapy **OR**
6. Must have a diagnosis of B-cell precursor Philadelphia chromosome negative ALL in first or

second complete remission with minimal residual disease (MRD) greater than or equal to 0.1% **AND**

7. **For Relapsed/refractory B-cell ALL:**
    a. Initial approval will be limited to 12 weeks (2 cycles of drug consisting of a 4-week drug interval followed by a 2-week drug-free interval) for induction.
        i. Documentation of response to treatment will be required prior to approval of an additional 18 weeks for consolidation treatment (3 consolidation cycles)
        ii. After a total of 5 treatment Blincyto cycles have been received, an additional 24 weeks of Blincyto therapy (up to 4 additional cycles of continued therapy) may be approved with documentation of continued response to treatment
            1. Response is defined as 5% or fewer blasts AND platelets greater than 50,000/ µL AND absolute neutrophil count (ANC) greater than 500/ µL
    b. Hospitalization is recommended for the first 9 days of the first cycle and the first 2 days of the second cycle. A single cycle of treatment consists of 4 weeks of continuous intravenous infusion followed by a 2-week treatment free interval (total 42 days)
    c. for patients greater than or equal to 45 kg, in Cycle 1, administer Blincyto at 9mcg/day on days 1-7 and 28mcg/day on days 8-28. For subsequent cycles, administer Blincyto at 28 mcg/day on days 1-28 For patients less than 45 kg, use a BSA-based dose, as listed in the package insert
    d. Blincyto will not be approved beyond a total of 9 treatment cycles
8. **For MRD-positive B-cell ALL:**
    a. Initial approval will be limited to 6 weeks (1 cycle of drug consisting of a 4-week drug interval followed by a 2-week drug-free interval) for induction. Documentation of response to treatment will be required prior to approval of an additional 18 weeks for consolidation treatment (total treatment course= up to a total of 4 cycles)
        i. Response is defined as the absence of detectable MRD confirmed in assay
    b. Hospitalization is recommended for the first 3 days of the first cycle and the first 2 days of the second cycle. A single cycle of treatment consists of 4 weeks of continuous intravenous infusion followed by a 2-week treatment free interval (total 42 days)
    c. For patients greater than or equal to 45 kg, administer Blinctyo at 28mcg/day on days 1-28 for all cycles. For patients less than 45kg, use a BSA-based dose, as listed in the package insert
    d. Blincyto will not be approved beyond a total of 4 treatment cycles
9. Blincyto will not be approved for a diagnosis of ALL in combination with any other chemotherapeutic agent as current literature does not support this
10. Prior authorization for Blincyto will apply regardless of the site of administration (applies to both the inpatient and outpatient setting)

HCPCS: J9039

Cyramza (ramucirumab) - Medical

1. Patient must be followed by an oncologist **AND**

2. Must have a diagnosis of advanced gastric cancer or gastro-esophageal junction adenocarcinoma with Karnofsky performance score ≥ 60% or ECOG performance score ≤2
    a. Must be used as a single-agent or in combination with paclitaxel after prior fluoropyridmidine or platinum-containing chemotherapy.
    b. The recommended dose of Cyramza for gastric cancer is 8 mg/kg every 2 weeks administered as an IV infusion over 60 minutes **OR**
3. Must have a diagnosis of metastatic non-small cell lung cancer (NSCLC)
    a. Must be used in combination with docetaxel after disease progression on or after first-line chemotherapy or for further progression on a systemic immune checkpoint inhibitors or other systemic therapy
    b. Patients with EGFR or ALK genomic tumor aberrations must have disease progression on FDA-approved therapy for these aberrations prior to receiving Cyramza
    c. The recommended Cyramza dose for NSCLC is 10mg/kg intravenously on day 1 of a 21-day cycle prior to docetaxel infusion **OR**
4. Must have a diagnosis of metastatic colorectal cancer
    a. Must be used in combination with FOLFIRI or irinotecan as primary treatment for patients with unresectable metachronous metastases and previous adjuvant FOLFOX or CapeOX within the past 12 months OR
    b. Must be used in combination with FOLFIRI or irinotecan as subsequent therapy for progression of unresectable advanced or metastatic disease (should not use with FOLFIRI if patient was previously treated with irinotecan-based therapy)
    c. The recommended Cyramza dose for colorectal cancer is 8mg/kg IV every 2 weeks, prior to FOLFIRI administration **OR**
5. Must have a diagnosis of hepatocellular carcinoma
    a. Used as a single agent in patients with alpha fetoprotein of ≥ 400 ng/mL and patients must have been treated with sorafenib (Nexavar)
6. Initial approval will be for 2 year for a diagnosis of gastric cancer/gastro-esophageal junction adenocarcinoma, NSCLC, or metastatic colorectal cancer. Initial approval will be 6 months for any off-label diagnoses that meet off-label criteria. Continued approval will require submission of progress notes demonstrating stable disease without progression.

HCPCS: J9308

Darzalex (daratumumab) - Medical

1. Must be prescribed by an Oncologist or Hematologist AND
2. Must be 18 years of age or older AND
3. Must have a diagnosis of Multiple Myeloma
    a. Must be used as a single agent in patients that have received at least 3 prior lines of therapy, including a proteasome inhibitor (Velcade[bortezomib], Kyprolis [carfilzomib]) and an immunomodulatory agent (Revlimid [lenalidomide], Pomalyst [pomalidomide], Thalomid [thalidomide]) **OR**
    b. Must be used as a single agent in patients double- refractory to a proteasome inhibitor and an immunomodulatory agent **OR**
    c. Must be used in combination with Velcade (bortezomib) and dexamethasone and have received at least one prior therapy **OR**
    d. Must be used in combination with Revlimid (lenalidomide) and dexamethasone
        i. Must have received at least one prior therapy **OR**

ii. Used in newly diagnosed patients who are ineligible for autologous stem cell transplant **OR**

e. Must be used in combination with Pomalyst and dexamethasone in patients who have received at last two prior therapies including an immunomodulatory agent and a proteasome inhibitor and who have demonstrated disease progression on or within 60 days of completion of the last therapy **OR**

f. Must be used in combination with Velcade (bortezomib), melphan, and prednisone in newly diagnosed patients who are ineligible for autologous stem cell transplant **OR**

g. Must be used in combination with Velcade (bortezomib), Thalomid (thalidomide), and dexamethasone in newly diagnosed patients who are eligible for autologous stem cell transplant

4. Recommended dose is 16mg/kg administered as an intravenous infusion weekly during weeks 1-8, every 2 weeks during weeks 9-24, and every four weeks at week 25 onwards until disease progression
5. Initial approval will be for 6 months. Requests for an additional 6 months at a time will require documentation of stable or improved disease

HCPCS: J9145

Elzonris (tragraxofusp-erzs) - Medical

1. Must be 2 years of age or older **AND**
2. Must be prescribed by an oncologist or hematologist **AND**
3. Must have a diagnosis of blastic plasmacytoid dendritic cell neoplasm (BPDCN)
4. Elzonris must be administered at a dose of 12mcg/kg over 15 minutes once daily on days 1-5 of 21-day cycles
5. Prior authorization for Elzonris will apply regardless of the site of administration (applies to both the inpatient and outpatient setting)

HCPCS: J9269

Empliciti (elotuzumab) - Medical

1. Must be prescribed by an Oncologist or Hematologist **AND**
2. Must be 18 years of age or older **AND**
3. Must have be used for a diagnosis of Multiple Myeloma:
    a. Must be used in combination with lenalidomide and dexamethasone AND must have relapsed or been refractory to at least one prior therapy OR
    b. Must be used in combination with pomalidomide and dexamethasone and have received at least 2 prior therapies including lenalidomide and a proteasome inhibitor (bortezomib, carfilzomib, ixazomib) Or
    c. Must be used in combination with bortezomib and dexamethasone
4. Recommended dosing in combination with lenalidomide and dexamethasone is 10mg/kg administered intravenously every week for the first two 28-day cycles and every 2 weeks, thereafter, until disease progression or unacceptable toxicity. Recommended dosing in combination with pomalidomide and dexamethasone is 10mg/kg administered intravenously every week for the first two cycles and 20mg/kg every 4 weeks thereafter until disease progression or unacceptable toxicity

HCPCS: J9176

Enhertu (fam-trastuzumab deruxtecan-nxki) - Medical

1. Must be at least 18 years of age
2. Must be prescribed by an Oncologist
3. Must be used as a single agent for unresectable and/or metastatic HER2-positive breast cancer that has previously been treated with 2 or more anti-HER2-based regimens in the metastatic setting
4. Recommending dosing is 5.4 mg/kg IV, over 90 minutes initially then over 30 minutes if well tolerated, once every 3 weeks (21-day cycle) until disease progression or unacceptable toxicity

Erwinaze (asparaginase) - Medical

1. Must be prescribed by or in consultation with an oncologist or hematologist **AND**
2. Must have a diagnosis of acute lymphoblastic leukemia (ALL) with hypersensitivity to *E. coli* derived asparaginase [Oncaspar (pegaspargas] or Asparlas [calaspargase pegol-mknl]) **AND**
3. Must be used in combination with other chemotherapy
4. Approval will be for 3 months. Dose should not exceed 25,000 units/m^2 IM /IV 3 times a week for 6 doses when substituting for pegaspargas.

HCPCS: J9019

Folotyn (pralatrexate) - Medical

1. Must be prescribed by an oncologist/hematologist
2. Must have a diagnosis of relapsed or refractory Peripheral T Cell Lymphoma (PTCL), transformed mycosis fungoides or blastic NK lymphoma. **Excluding:** Precursor T/NK neoplasms; T-cell prolymphocytic leukemia (T-PLL); T-cell large granular lymphocytic leukemia; and primary cutaneous CD30+ disorders: ALCL and lymphomatoid papulosis.
3. Patient must have had failure of at least one anthracycline based systemic therapy (daunorubicin, doxorubicin, epirubicin, idarubicin, valrubicin, mitoxantrone), or if anthracyclines contraindicated, one non-anthracycline based chemotherapy regimen. Prior immunotherapy alone will not qualify patient.
4. Dosage is 30mg/m^2 once weekly for 6 weeks (then off for 1 week) until progressive disease or unacceptable toxicity
5. Requirement of dose reduction below 20mg/m^2 or progressive disease should trigger discontinuation.
6. Must be administered with Vitamin B12 and Folic Acid Supplementation
7. Recertification required after first cycle then every two cycles thereafter.
8. Continued coverage of Folotyn will require stabilization or reduction in disease. Patients will not be authorized for coverage if there is a:
   a. 50% increase in size of sentinel lesion **OR**
   b. New site of disease including new liver or spleen metastases or lymphadenopathy **OR**
   c. Increase in circulating tumor cells **OR**
   d. Need for radiotherapy
9. Please note that the FDA approval of Folotyn was based on an overall response rate of 27% and an 8% complete response

HCPCS: J9307

Gazyva (obinutuzumab) - Medical

1. Must be prescribed by an oncologist **AND**
2. Used in combination with chorambucil as first-line therapy for chronic lymphocytic

leukemia/small lymphocytic lymphoma (CLL/SLL) **OR**

3. Used in combination with chlorambucil or ibrutinib for CLL/SLL in patients with indications for treatment who are unable to tolerate purine analogs or for those with significant comorbidities **OR**
4. Used for relapsed or refractory CLL/SLL without del (17p)/TP53 mutation and with or without del (11q) in patients with indications for treatment **OR**
5. Used as first-line therapy in combination with venetoclax or as a single agent for CLL/SLL with del(17p)/TP53 in patients with indications for treatment **OR**
6. Used as first-line therapy for CLL/SLL without del(17p)/TP53 mutation:
    a. In combination with venetoclax
    b. In combination with bendamustine
    c. As a single agent **OR**
7. In combination with bendamustine, followed by Gazyva monotherapy, for the treatment of patients with follicular lymphoma who relapsed after, or are refractory to, a rituximab-containing regimen **OR**
8. Used in combination with chemotherapy followed by Gazyva monotherapy in patients achieving at least a partial remission, for the treatment of adult patients with previously untreated stage II bulky, III or IV follicular lymphoma **OR**
9. Preferred second-line or subsequent therapy (if not previously given as first-line) for refractory or progressive disease in patients with indications for treatment in combination with:
    a. CHOP (cyclophosphamide, doxorubicin, vincristine, and prednisone) regimen
    b. CVP (cyclophosphamide, vincristine, and prednisone) regimen
    c. Bendamustine **OR**
10. Used a maintenance therapy in Follicular Lymphoma (grade 1-2):
    a. as optional first-line consolidation or extended dosing
    b. as optional second-line consolidation or extended dosing for rituximab-refractory disease
    c. can be considered for patients with histologic transformation to diffuse large B-cell lymphoma that is coexisting with extensive follicular lymphoma who achieve a complete response to chemoimmunotherapy **OR**
11. Used in combination with bendamustine as second-line or subsequent therapy for recurrent or progressive gastric /non-gastric MALT, nodal marginal zone, or splenic marginal zone lymphoma **OR**
12. Used as maintenance therapy as second-line consolidation or extended dosing in rituximab refractory gastric/non-gastric MALT, nodal marginal zone, or splenic marginal zone lymphoma patients treated with Gazyva and Bendamustine for recurrent disease **OR**
13. Used a substitute for rituximab in patients experiencing rare complications such as mucocutaneous reactions including paraneoplastic pemphigus, Stevens-Johnson syndrome, lichenoid dermatitis, vesiculobullous dermatitis, and toxic epidermal necrolysis for B-Cell Lymphomas *see NCCN compendium for appropriate types*
14. Recommended dosage for CLL/SLL:
    a. 100 mg on day 1 Cycle 1
    b. 900 mg on day 2 Cycle 1
    c. 1000 mg on day 8 and 15 of Cycle 1
    d. 1000 mg on day1 of Cycles 2-6
15. Recommended dosage for follicular lymphoma:
    a. 1000 mg on day 1,8, and 15 of cycle 1
    b. 1000 mg on day 1 of cycles 2-6, then 1000mg every 2 months for 2 years

16. A maximum of 6 (28 day) cycles will be approved for a diagnosis of CLL/SLL.

HCPCS: J9301

Herceptin Hylecta (trastuzumab and hyaluronidase-oysk) - Medical

1. Must be ≥ 18 years of age **AND**
2. Must be followed by an Oncologist or Hematologist **AND**
3. Herceptin Hylecta will only be approved if there is a proven contraindication to intravenous trastuzumab (intravenous Herceptin) or if the patient has poor venous access **AND**
4. Must be used as preoperative therapy, adjuvant therapy, or for the treatment of metastatic HER2-positive breast cancer:
    a. For preoperative therapy, as part of a combination therapy regimen
    b. For adjuvant therapy, as part of a combination therapy regimen or as a single agent following prior chemotherapy
    c. For treatment of HER2-positive metastatic breast cancer, as part of a combination therapy regimen or as a single agent following prior chemotherapy
5. The recommended dose of Herceptin Hylecta is 600mg/10,000 units (600mg trastuzumab and 10,000 units hyaluronidase) administered subcutaneously over approximately 2-5 minutes once every 3 weeks

HCPCS: J9356

Imfinzi (durvalumab) - Medical

1. Must be ≥ 18 years of age **AND**
2. Must be followed by an Oncologist **AND**
3. Must be used for a diagnosis of locally advanced or metastatic urothelial carcinoma
    a. There must be a proven contraindication to the following FDA approved drugs: Keytruda (pembrolizumab) and Tecentriq (atezolizumab) **AND**
    b. Must meet the following criteria:
        i. Must have disease progression during or following platinum-containing chemotherapy OR
        ii. Must have disease progression within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy **OR**
4. Must be used for a diagnosis of unresectable stage III non-small cell lung cancer (NSCLC) whose disease has not progressed following concurrent platinum-based chemotherapy and radiation therapy
    a. As consolidation therapy OR
5. Preferred initial treatment for small cell lung cancer (SCLC) in combination with etoposide and either cisplatin or carboplatin followed by single agent maintenance for extensive stage disease.
6. Imfinizi will not be approved in combination with any other chemotherapeutic agent as current medical literature does not currently support this
7. The use of Imfinzi following disease progression on prior anti-PD-1/PD-L1 therapy is considered experimental and investigational and will not be approved

HCPCS: J9173

Istodax and romidepsin (romidepsin) - Medical

1. Must be prescribed by a dermatologist with advanced knowledge of CTCL/PTCL or oncologist **AND**
2. Diagnosis of cutaneous T-cell Lymphoma **OR** Diagnosis of peripheral T-cell Lymphoma

(relapsed or refractory angioimmunoblastic T-cell lymphoma, peripheral T-cell lymphoma not otherwise specified, anaplastic large cell lymphoma, or enteropathy-associated T-cell lymphoma, monomorphic epitheliotropic intestinal T-cell lymphoma, nodal peripheral T-cell lymphoma with TFH phenotype, or follicular T-cell lymphoma) **OR** Adult T-Cell Leukemia/Lymphoma **AND**
   a. Patient must have failed at least one prior systemic therapy **OR**
3. Preferred therapy as a single agent for relapsed/refractory Extranodal NK/T-Cell Lymphoma, nasal type, T-Cell Lymphoma with an alternate combination chemotherapy regimen (asparaginase-based) not previously used **OR**
4. Preferred second-line and subsequent therapy as a single agent for refractory Hepatosplenic Gamma-Delta T-Cell Lymphoma after 2 primary treatment regimens **OR**
5. As systemic treatment for a diagnosis of Mycosis Fungoides (MF)/Sezary Syundrome (SS) *see NCCN compendium for appropriate types and treatment regimens*

HCPCS: J9315

Kadcyla (ado-trastuzumab emtansine) - Medical

1. Must be prescribed by an Oncologist **AND**
2. Must be used as a single agent for the diagnosis of HER2-positive metastatic breast cancer
   a. Patient must have previously received trastuzumab and a taxane (i.e paclitaxel, docetaxel), separately or in combination.
      i. Must have received prior therapy for metastatic disease **OR**
      ii. Developed disease recurrence during or within six months of completing adjuvant therapy **OR**
2. Must be used as single-agent therapy for recurrent or stage IV (M1) HER-2 positive breast cancer **OR**
3. Must be used for HER-2 positive early breast cancer
   a. Used for adjuvant treatment of patients who have residual invasive disease after neoadjuvant taxane and traztuzumab-based treatment **OR**
4. Used for metastatic non-small cell lung cancer (NSCLC) in patients with a HER-2 positive mutation
5. Approval for Kadcyla will be for 6 months at a time. Approval for further use will require documentation of stable disease without progression (If used for early breast cancer, further approval will not exceed 42 total weeks of therapy)
6. Recommended dosage is 3.6 mg/kg given as an IV infusion every 3 weeks until disease progression or unacceptable toxicity, or a total of 14 cycles for patients with early breast cancer. Kadcyla should not be administered at doses greater than 3.6mg/kg.
7. Kadcyla cannot be substituted for or with trastuzumab.
8. Hepatic function left ventricular ejection fraction, and platelet counts should be monitored upon initiation and prior to each dose.

HCPCS: J9354

Keytruda (pembrolizumab) - Medical

1. Must be followed by an oncologist **AND**
2. Must be used as preferred first-line therapy as a single agent for metastatic or unresectable melanoma **OR**
3. Must be used as preferred second-line or subsequent therapy as a single agent for metastatic or unresectable Cutaneous Melanoma after disease progression or maximum clinical benefit from BRAF targeted therapy:
   a. if anti PD-1 therapy checkpoint inhibitor immunotherapy was not previously used
   b. may be considered as re-induction therapy if prior checkpoint inhibitor

immunotherapy resulted in disease control (complete response, partial response, or stable disease) and no residual toxicity, and disease progression/relapse occurred >3 months after treatment discontinuation **OR**

4. Must be used for the adjuvant treatment of patients with melanoma with involvement of lymph node(s) following complete resection **OR**
5. Must be used for non-small cell lung cancer (NSCLC)
    a. In combination with pemetrexed (Alimta) and platinum chemotherapy, as first-line treatment of patients with metastatic non-squamous NSCLC, with no EGFR or ALK genomic tumor aberrations OR
    b. In combination with carboplatin and either paclitaxel or nab-paclitaxel, as first-line treatment of patients with metastatic squamous NSCLC OR
    c. as a single agent for the first-line treatment of patients with stage III NSCLC, who are not candidates for surgical resection or definitive chemoradiation, or metastatic NSCLC, whose tumors have high PD-L1 expression (TPS ≥50%) with no EGFR or ALK genomic tumor aberrations OR
    d. Used in combination with carboplatin or carboplatin and pemetrexed OR in combination with either carboplatin and either paclitaxel or albumin-bound paclitaxel as:
        i. initial systemic therapy for EGFR, ALK, ROS1, BRAF negative and PD-L1 <1%
        ii. first-line or subsequent therapy for BRAF V600E-mutation positive tumors
        iii. first-line or subsequent therapy for NTRK gene fusion positive tumors
        iv. Subsequent therapy for sensitizing EGFR mutation-positive tumors and prior erlotinib, afatinib, geftinib, osimertinib, or dacomitinib therapy
        v. Subsequent therapy for ALK rearrangement-positive tumors and prior crizotinib, ceritinib, alectinib, or brigatinib therapy
        vi. Subsequent therapy for ROS1 rearrangement positive tumors and prior crizotinib or ceritinib therapy
        vii. Subsequent therapy for PD-L1 expression-positive (≥1%) tumors and EGFR, ALK, ROS1, BRAF negative and no prior platinum-doublet chemotherapy and PD-1/PD-L1 inhibitor OR
    e. Used as single agent therapy (if not previously given) as subsequent therapy for metastatic disease in patients with PD-L1 expression levels ≥ 1%, and following progression on or after platinum-containing chemotherapy
    f. Continuation maintenance therapy in combination with pemetrexed if given first line as part of a pembrolizumab/pemetrexed and either cisplatin or carboplatin regimen for recurrent, advanced or metastatic disease, non-squamous cell histology in patients with performance status 0-2, who achieve tumor response or stable disease following initial systemic therapy
    g. Continuation maintenance therapy for recurrent, advanced or metastatic disease for PD-L1 expression positive (≥1%) tumors that are EGFR, ALK, ROS1, BRAF negative and no contraindications to the addition of pembrolizumab or atezolizumab and performance status 0-2, who achieve tumor response
        i. as a single agent if pembrolizumab monotherapy given first-line for non-squamous cell histology
        ii. in combination with pemetrexed if given first-line as part of a pembrolizumab/pemetrexed and either cisplatin or carboplatin regimen for non-squamous cell histology
        iii. as a single agent if pembrolizumab was given as monotherapy or as part of a

pembrolizumab/carboplatin/ (paclitaxel or albumin-bound paclitaxel) regimen for squamous cell histology

h. Treatment for recurrent, advanced or metastatic disease as first-line therapy for PD-L1 expression-positive (≥1%) tumors that are EGFR, ALK, ROS1, BRAF negative and no contraindications to the addition of pembrolizumab or atezolizumab and performance status 0-2:
    i. as a single agent
    ii. in combination with pemetrexed and either carboplatin or cisplatin for non-squamous cell histology
    iii. in combination with carboplatin and either paclitaxel or albumin-bound paclitaxel for squamous cell histology
i. Single-agent continuation maintenance therapy if given first line as part of a pembrolizumab/carboplatin/(paclitaxel or albumin-bound paclitaxel) regimen for recurrent, advanced or metastatic disease, squamous cell histology, in patients with performance status 0-2 who achieve tumor response or stable disease following initial systemic therapy
j. Preferred single agent as subsequent therapy for recurrent, advanced or metastatic disease in patients with performance status 0-2 and tumors with PD-L1 expression levels ≥1% and no prior progression on a PD-1/PD-L1 inhibitor **OR**

6. Must be used as a single agent for head and neck squamous cell carcinoma (HNSCC)
    a. In combination with platinum and FU for the first-line treatment of patients with metastatic or unresectable, recurrent HNSCC
    b. As a single agent for the first-line treatment of patients with metastatic or unresectable, recurrent HNSCC whose tumors express PD-L1 [Combined Postivie score (CPS) ≥ 1] as determined by an FDA-approved test
7. As a single agent for the treatment of patients with recurrent or metastatic HNSCC with disease progression on or after platinum-containing chemotherapy **OR**
8. Must be used for Classical Hodgkin lymphoma
    a. Subsequent systemic therapy as a single agent for refractory disease or for those who have relapsed after ≥ 3 prior lines of OR
    b. Palliative therapy as a single agent for:
        i. disease that has relapsed or progressed after autologous hematopoietic stem cell transplant (HSCT) ± brentuximab vedotin
        ii. patients with relapsed/refractory disease who are transplant-ineligible based on comorbidity or failure of second-line chemotherapy
        iii. post-allogeneic transplant **OR**
9. Must be used for unresectable metastatic colon or rectal cancer that is deficient mismatch repair/microsatellite instability-high (dMMR/MSI-H)
    a. Tumor status must have been determined using laboratory (polymerase chain reaction-PCR) tests for MSI-H or immunohistochemistry (IHC) tests for deficient mismatch repair (dMMR):
        i. To be classified as MSI-H, there must be ≥2 out of 5 microsatellite markers (BAT25, BAT26, D2S123, D58346, and D17S250) that show insability
        ii. Tumor is considered mismatch repair deficient on IHC if at least one MMR gene (MLH1, MSH2, MSH6, PMS2) is not expressed AND
    b. Must be used as primary treatment as a single agent and previous adjuvant FOLFOX (fluorouracil, leucovorin, and oxaliplatin) or CapeOX (capecitabine and oxaliplatin) within the past 12 months OR

c. As initial therapy as a single agent for patients who are not appropriate for intensive therapy OR
d. As subsequent therapy as a single agent (if nivolumab or pembrolizumab not previously given) following previous oxaliplatin-, irinotecan- and/or fluoropyrimidine-based therapy **OR**

10. Must be used for Merkel Cell Carcinoma
    a. as preferred treatment for disseminated, clinical M1 disease with or without surgery and/or radiation therapy OR
    b. May be considered as a treatment option if curative surgery and curative radiation therapy are not feasible for: recurrent locally advanced disease or recurrent regional disease **OR**
11. Must be used for locally advanced or metastatic urothelial carcinoma
    a. Must not be eligible for cisplatin-containing chemotherapy and tumors must express PD-L1 (Combined Positive Score (CPS) ≥ 10) or must not be eligible for any platinum-containing chemotherapy, regardless of PD-L1 status or
    b. Must have disease progression during or following platinum-containing chemotherapy or within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy **OR**
12. Must be used for high-risk, non-muscle invasive bladder cancer with Tis
    a. Must be Bacillus Calmette-Guérin (BCG)-unresponsive
    b. Used in patients with or without papillary tumors
    c. Used in patients who are ineligible or unwilling to undergo cystectomy **OR**
13. Must be used for Malignant pleural Mesothelioma
    a. As a single agent for subsequent systemic therapy **OR**
14. Must have microsatellite instability (MSI-H) or mismatch repair deficient (dMMR) solid tumors that have progressed following prior treatment and who have no satisfactory alternative treatment options
    a. Tumor status must have been determined using laboratory (polymerase chain reaction-PCR) tests for MSI-H or immunohistochemistry (IHC) tests for deficient mismatch repair (dMMR):
        i. To be classified as MSI-H, there must be ≥2 out of 5 microsatellite markers (BAT25, BAT26, D2S123, D58346, and D17S250) that show instability
        ii. Tumor is considered mismatch repair deficient on IHC if at least one MMR gene (MLH1, MSH2, MSH6, PMS2) is not expressed **OR**
15. Must have recurrent locally advanced or metastatic gastric or gastroesophageal junction (GEJ) adenocarcinoma
    a. Tumors must express PD-L1 (Combined Positive Score (CPS) ≥ 1) AND
    b. Must have disease progression on or after two or more prior lines of therapy including fluoropyrimidine- and platinum-containing chemotherapy and if appropriate, HER2/neu-targeted therapy **OR**
16. Must be used as palliative therapy for patients who are not surgical candidates or have unresectable locally advanced, recurrent, or metastatic Esophageal and Esophagogastric Junction Cancers and Karnofsky performance score ≥60% or ECOG performance score ≤2 as:
    a. preferred second-line or subsequent therapy as a single agent for microsatellite instability-high (MSI-H) or deficient mismatch repair (dMMR) tumors
    b. preferred second-line therapy for esophageal squamous cell carcinoma (SCC) with PD-L1 expression by CPS of levels ≥10
    c. preferred third-line or subsequent therapy as a single agent for esophageal and EGJ

adenocarcinoma with PD-L1 expression levels by CPS of ≥1 **OR**

17. Must be used as palliative therapy for locoregional disease in patients who are not surgical candidates, recurrent, or metastatic Gastric Cancer and Karnofsky performance score ≥60% or ECOG performance score ≤2 as:
    a. preferred second-line or subsequent therapy as a single agent for microsatellite instability-high (MSI-H) or deficient mismatch repair (dMMR) tumors
    b. preferred third-line or subsequent therapy as a single agent for gastric adenocarcinoma with PD-L1 expression levels by CPS of ≥1 **OR**
18. Must have a diagnosis of metastatic anal carcinoma
    a. Used as a single agent for second-line therapy **OR**
19. Must have brain metastases
    a. Treatment as a single agent for limited (1-2) brain metastases if active against primary tumor OR
    b. Treatment as a single agent for stable systemic disease with multiple (>3) brain metastases if active against primary tumor OR
    c. Treatment as a single agent for recurrent brain metastases in patients with melanoma or PD-L1-positive non-small cell lung cancer and stable systemic disease or reasonable systemic treatment options OR
    d. Treatment as a single agent for brain metastases in patients with melanoma or PD-L1-positive non-small cell lung cancer for:
        i. newly diagnosed brain metastases in select patients (eg, patients with small asymptomatic brain metastases) and stable systemic disease or reasonable systemic treatment options
        ii. recurrent brain metastases **OR**
20. Must have relapsed/refractory Extranodal NK/T-cell Lymphoma (Nasal type)
    a. For relapsed/refractory disease following additional therapy with an alternate combination chemotherapy regimen (asparaginase-based) not previously used, if a clinical trial is unavailable **OR**
21. Used to treat relapsed or refractory primary mediastinal large B-cell lymphoma **OR**
22. Must have recurrent or metastatic cervical cancer
    a. with disease progression on or after chemotherapy whose tumors express PD-L1 (CPS≥1) OR
    b. instability-high (MSI-H) or mismatch repair deficient (dMMR) tumors **OR**
23. Must have hepatocellular carcinoma (HCC) and have been previously treated with sorafenib (Nexavar) **OR**
24. Must be used as subsequent treatment as a single agent for progressive hepatocellular carcinoma in patients (Child-Pugh Class A only) who:
    a. have unresectable disease and are not a transplant candidate
    b. are inoperable by performance status or comorbidity, or have local disease or local disease with minimal extrahepatic disease only
    c. have metastatic disease or extensive liver tumor burden
25. Must have advanced (relapsed or stage IV) Renal Cell Carcinoma (RCC)
    a. In combination with axitinib (Inlyta) for first-line treatment for clear cell histology **OR**
    b. In combination with axitinib (Inlyta) for subsequent therapy for clear cell histology **OR**
26. Must have metastatic small cell lung cancer (SCLC)
    a. with disease progression on or after platinum-based chemotherapy and at least one other prior line of therapy
    b. as subsequent systemic therapy for patients with performance status 0-2 as a single

agent for:
   i. relapse within 6 months following complete or partial response or stable disease with initial treatment (not recommended for relapse disease in patients on maintenance atezolizumab at time of relapse)
   ii. primary progressive disease **OR**

27. Must have recurrent, locally advanced or metastatic squamous cell carcinoma of the esophagus whose tumors express PD-L1 [Combined Positive Score (CPS) ≥ 10] as determined by an FDA-approved test, with disease progression after one or more prior lines of systemic therapy **OR**
28. Must have a diagnosis of advanced endometrial cell carcinoma that is not microsatellite instability high (MSI-H) or mismatch repair deficient (dMMR)
    a. Must be used in combination with Lenvima
    b. Must have disease that has progressed following at least one prior systemic therapy
    c. Must not be a candidate for curative surgery or radiation
29. Must be used as Single-agent therapy for Gestational Trophoblastic Neoplasia for:
    a. recurrent or progressive intermediate trophoblastic tumor (placental site trophoblastic tumor or epithelioid trophoblastic tumor) following treatment with a platinum/etoposide-containing regimen
    b. methotrexate-resistant high-risk disease **OR**
30. Must be used for Intrahepatic Cholangiocarcinoma, Extrahepatic Cholangiocarcinoma, or Gallbladder Cancer that is microsatellite instability-high (MSI-H) and/or deficient mismatch repair (dMMR) as:
    a. a single agent primary treatment for unresectable or metastatic
    b. a single agent treatment for resected gross residual disease (R2) **OR**
31. Must be used for a diagnosis of Mycosis Fungoides/Sezary Syndrome *see NCCN compendium for appropriate types and treatment regimens* **OR**
32. Must be used as therapy for primary cutaneous anaplastic large cell lymphoma (ALCL) with multifocal lesions, or cutaneous ALCL with regional nodes (excludes systemic ALCL), as a single agent for relapsed/refractory disease **OR**
33. Must be used for thymic carcinoma as second-line therapy as a single agent for:
    a. unresectable disease following first-line chemotherapy for potentially resectable locally advanced disease, solitary metastasis, or ipsilateral pleural metastasis
    b. extrathoracic metastatic disease **OR**
34. Consider as single agent therapy for distant metastatic Uveal Melanoma **OR**
35. Used as second-line therapy as a single agent Vulvar Squamous Cell Carcinoma for advanced, recurrent or metastatic disease if:
    a. microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) tumors
    b. disease progression on or after chemotherapy in patients whose tumors express PD-L1 (Combined Positive Score ≥1) as determined by an FDA-approved test
36. The use of Keytruda following disease progression on prior anti-PD-1/PD-L1 therapy is considered experimental and investigational and will not be approved
37. Keytruda will not be approved for a diagnosis of Multiple Myeloma. Keytruda is not approved for the treatment of multiple myeloma and the FDA has issued a statement about the risks associated with the use of Keytruda in combination with dexamethasone and an immunomodulatory agent for the treatment of patients with multiple myeloma
38. Thyroid function tests should be monitored at the start of treatment, periodically during treatment, and as indicated based on clinical evaluation.
39. Withhold Keytruda for Grade 2 pneumonitis, Grade 2 or 3 colitis, Grade 3 nephritis, Grade 3 hyperthyroidism, symptomatic hypophysitis, AST or ALR >3 and <=5 times ULN, total bilirubin

>1.5 and <=3 times ULN, or any other Grade 3 treatment-related adverse reaction. Patients may resume Keytruda if adverse reactions recover to Grade 0-1.

40. Permanently discontinue for any life-threating adverse reactions, Grade 3 or 4 pneumonitis, Grade 3 or 4 nephritis, AST or ALT >5 times ULN , total bilirubin >3 times ULN, Grade 3 or 4 infusion-related reactions, inability to reduce corticosteroid dose to <=10 mg prednisone equivalents per day within 12 weeks, persistent Grade 2 or 3 reactions that do not recover within 12 weeks after last dose, and any severe or Grade 3 reaction that recurs

HCPCS: J9271

Kymriah (tisagenleucel) - Medical

1. Must be prescribed by a Hematologist or Oncologist at a Certified Treatment center AND
2. Must have a diagnosis of B-Cell Precursor Acute Lymphoblastic Leukemia (ALL) AND
    a. Must be ≤ 25 years of Age AND
    b. Must have refractory disease or be in second or later relapse
        i. Members with Philadelphia chromosome positive B-ALL must have failure of at least 2 TKIs [Sprycel (dasatinib), Gleevec (imatinib), Iclusig (ponatinib) , Tasigna (nilotinib), Bosulif (bosutinib)] AND
    c. Must not have previously received treatment with tisageniecleucel (Kymriah) or axicaptagene ciloleucel (Yescarta) **OR**
3. Must have a diagnosis of relapsed or refractory large B-cell lymphoma including diffuse large B-cell lymphoma (DLBCL) not otherwise specified, high grade B-cell lymphoma, and DLBCL arising from follicular lymphoma **AND**
    a. Must be 18 year of age AND
    b. Must be used after two or more lines of systemic therapy AND must not have previously received treatment with tisageniecleucel (Kymriah) or axicaptagene ciloleucel (Yescarta) **OR**
4. Must have a diagnosis of Pediatric Acute Lymphoblastic Leukemia **AND**
    a. Must be used for relapsed/refractory Ph-negative B-ALL that is refractory or ≥2 relapses OR for relapsed/refractory Ph-positive TKI intolerant/refractory B-ALL or relapse post-HSCT **AND**
    b. Must not have previously received treatment with tisageniecleucel (Kymriah) or axicaptagene ciloleucel (Yescarta)
5. Kymriah will not be approved for a diagnosis of primary central nervous system lymphoma
6. Patients approved for Kymriah will also receive approval of Actemra for a period of 6 months. If severe or life-threatening cytokine-release syndrome is suspected (CRS), administer Actemra as either 12mg/kg IV over 1 hour for patients <30kg or 8mg/kg IV over 1 hour for patients ≥30kg
7. Prior authorization for Kymriah will apply regardless of the site of administration (applies to both the inpatient and outpatient setting)
8. A maximum of 1 CAR-T infusion will be approved per patient lifetime

HCPCS: Q2042

Kyprolis (carfilzomib) - Medical

1. Must be prescribed by an Oncologist **AND**
2. Must be prescribed for previously treated relapsed, refractory, or progressive multiple myeloma
    a. Must be used as a single agent for patients who have received one or more lines of therapy OR
    b. Used in combination with dexamethasone or with lenalidomide plus dexamethasone, for patients who have received one to three lines of therapy OR

c. Used in combination with dexamethasone and cyclophosphamide OR
d. Used in combination with daratumumab and dexamethasone
e. Used in combination with panobinostat in patients who have received at least two prior regimens, including bortezomib and an immunomodulatory agent OR
f. Used in combination with Pomalyst (pomalidomide) and dexamethasone for patients who have received at least 2 prior therapies, including an immunomodulatory agent and a proteasome inhibitor, and have demonstrated disease progression on or within 60 days of completion of the last therapy
g. Used in combination with dexamethasone, cyclophosphamide, and thalidomide **OR**

3. Used as primary therapy for active (symptomatic) myeloma or for disease relapsed after 6 months following primary induction therapy with the same regimen in combination with:
   a. Dexamethasone and lenalidomide OR
   b. Dexamethasone and cyclophosphamide for non-transplant candidates **OR**
4. Used as a component of CaRD (carfilzomib, rituximab and dexamethasone) regimen for a diagnosis of Waldenstrom's Macoglobulinemia/Lymphoplasmacytic Lymphoma
   a. as primary therapy OR
   b. for relapse ≥12 months if used as primary therapy
5. Approval will be for 6 months. Continuation of therapy will not be approved if there is evidence of disease progression, or unacceptable toxicity.

HCPCS: J9047

Lartruvo (Olaratumab injection)- Medical

1. Must be prescribed by an oncologist/hematologist **AND**
2. Must be greater than or equal to 18 years of age **AND**
3. Must have a diagnosis of metastatic soft tissue sarcoma (STS) with histologic subtype for which an anthracycline-containing (i.e doxorubicin) regimen is appropriate **AND**
4. Must not be a candidate for curative treatment with radiotherapy or surgery **AND**
5. Must be receive doxorubicin in conjunction with Lartruvo for the first 8 cycles of therapy
6. Initial approval will be for 12 months. Further approval for 12 months at a time will require documentation of stable or improved disease
7. Please Note: 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 provider about whether to remain on the treatment

HCPCS: J9285

Libtayo (cemiplimub-rwlc)- Medical

1. Must be 18 years of age or older AND
2. Must be prescribed by an oncologist AND
3. Must have a diagnosis of metastatic cutaneous squamous cell carcinoma (CSCC) or locally advanced squamous cell carcinoma
   a. Must not be a candidate for curative surgery or curative radiation

4. Dosage should not exceed 350mg every 3 weeks
5. The use of Libtayo following disease progression on prior checkpoint inhibitor therapy (including prior PD-1 or PD-L1 therapy) is considered experimental and investigational and will not be approved

HCPCS: J9119

Lumoxiti (moxetumomab pasudotox-tdfk) - Medical

1. Must be ≥ 18 years of age AND
2. Must be prescribed an Oncologist/Hematologist AND
3. Must have relapsed/refractory hairy cell leukemia (HCL)
    a. Must have received at least 2 prior systemic therapies, including treatment with a purine nucleoside analog (Cladribine or Pentostatin) AND
    b. Must have at least one of the following indications for treatment:
        i. Systemic symptoms (i.e Fever, night sweats)
        ii. Splenic discomfort
        iii. Recurrent infection
        iv. Hemoglobulin <11 g/dL
        v. Platelets <100,000/mcL
        vi. ANC <1000/mcL
        vii. Symptomatic organomegaly
        viii. Progressive lymphocytosis or lymphadenopathy
        ix. Unexplained weight loss (>10% within the prior 6 months)
        x. Excessive Fatigue
4. Dose must not exceed 0.04 mg/kg as an IV infusion over 30 minutes on days 1,3, and 5 of each 28 day cycle. Lumoxiti will be approved for a maximum of 24 weeks (six 28-day cycles)

HCPCS: J9313

Marqibo (vincristine sulfate liposome injection) - Medical

1. Must be prescribed by an oncologist or hematologist **AND**
2. Must be ≥ 18 years of age **AND**
3. Must have a diagnosis Philadelphia chromosome negative (Ph-) acute lymphoblastic leukemia (ALL) with ≥ 2 relapses or progression following two or more anti-leukemia therapies (such as cyclophosphamide, cytarabine, anthracyclines, methotrexate, vincristine, L-aspariginase, 6 MP, etc). **OR**
4. Must have a diagnosis Philadelphia chromosome positive (Ph+) acute lymphoblastic leukemia (ALL) and used in patients that are tyrosine kinase inhibitor (TKI) intolerant or refractory (TKIs include: Sprycel [dasatinib], Gleevec [imatinib], or Iclusig [ponatinib])
5. Marqibo will not be approved in combination with other chemotherapeutic agents as current evidence does not support this use.
6. Recommended dosing is 2.25 mg/m^2 IV over 1 hour once every 7 days.
7. Initial approval will be for 6 months. Continued approval will require submission of progress notes demonstrating no evidence of disease progression.

HCPCS: J9371

Mylotarg (gemtuzumab ozogamicin)- Medical

1. Must be prescribed by an oncologist or hematologist AND
2. Must have a diagnosis of CD33-positive acute myeloid leukemia (AML) as documented by laboratory testing AND
    a. Must be ≥ 18 years of age and have newly diagnosed disease
        i. Used in combination with Daunorubicin and Cytarabine (in patients < 60 years of age OR
        ii. Used as a single agent OR
    b. Must be ≥ 2 year of age and have relapsed or refractory disease
        i. Must be used a single agent OR
    c. Used for post-remission therapy
        i. in combination with high-dose cytarabine for patients age <60 years with core binding factor (CBF) cytogenetic translocations without KIT mutation
        ii. in combination with intermediate-dose cytarabine and daunorubicin for patients age <60 years with core binding factor (CBF) cytogenetic translocations without KIT mutation, or intermediate-risk cytogenetics and/or molecular abnormalities
        iii. in combination with intermediate-dose cytarabine and daunorubicin for patients age ≥60 years with complete response to previous intensive therapy
3. Must have a diagnosis of acute promyelocytic leukemia (APL):
    a. used for induction in high-risk disease (white blood cell count >10,000/mcL) in patients with no cardiac issues in combination with tretinoin (ATRA) and arsenic trioxide OR
    b. used for induction in high-risk disease (white blood cell count >10,000/mcL) in patients with cardiac issues
        i. in combination with tretinoin (ATRA) and arsenic trioxide (if low ejection fraction) OR
        ii. in combination with ATRA (if prolonged QTc) OR
    c. used for first relapse in combination with arsenic trioxide, with or without tretinoin (ATRA), in patients with no prior exposure to arsenic trioxide or early relapse (<6 months) after ATRA + anthracycline-containing regimen OR
    d. used for first relapse in combination with arsenic trioxide, with or without ATRA, in patients with late relapse (≥6 months) after arsenic trioxide-containing regimen OR
    e. used for consolidation therapy in high-risk disease (white blood cell count >10,000/mcL) in patients with cardiac issues (low ejection fraction [EF] or prolonged QTc)
        i. in combination with tretinoin (ATRA) if arsenic trioxide was discontinued due to toxicity (if low ejection fraction)
        ii. in combination with arsenic trioxide if ATRA was discontinued due to toxicity (if low ejection fraction)
        iii. in combination with ATRA (if prolonged QTc) OR
    f. used for consolidation therapy in high-risk disease (white blood cell count >10,000/mcL) in patients with no cardiac issues
        i. in combination with tretinoin (ATRA) if arsenic trioxide was discontinued due to toxicity (preferred regimen)
        ii. in combination with arsenic trioxide if ATRA was discontinued due to toxicity (preferred regimen)

4. Approval will be limited to:
    a. Up to 1 induction cycle and 2 consolidation cycles (28 days) for newly-diagnosed AML when Mylotarg
    b. is used in combination with Daunorubicine and Cytarabine (If a second induction cycle is needed Mylotarg should not be administered)
        i. Induction: 3mg/m^2 (up to one 4.5mg vial) on days 1, 4, and 7 in combination with Daunorubicin and Cytarabine
        ii. Consolidation: 3mg/m^2 on day 1 (up to one 4.5mg vial) in combination with Daunorubicin and Cytarabine for up to 2 cycles
    c. Up to 1 induction dose and up to 8 continuous consolidation doses (36 weeks) when Mylotarg is used for newly diagnosed AML as a single agent
        i. Induction: 6mg/m^2 on day 1 and 3mg/m^2 on day 8
        ii. Continuation: for patients without evidence of disease progression following induction, up to 8 continuous courses of 2mg/m^2 on day 1 every 4 weeks
    d. Up to 1 induction dose (7 days) when Mylotarg is used for relapsed or refractory AML as monotherapy
        i. 3mg/m^2 on days 1, 4, and 7

HCPCS: J9203, J9300

Oncaspar (pegaspargase)

1. Must be prescribed by or in consultation with an oncologist or hematologist **AND**
2. Must have a diagnosis of acute lymphoblastic leukemia (ALL) **OR**
3. Extranodal natural killer T-cell lymphoma, nasal type (ENKL) **AND**
4. Must be used in combination with other chemotherapy
5. Recommended dose is 2,500 units/m^2 IM or IV administered no more frequently than ever 14 days

HCPCS: J9266

Onivyde (irinotecan liposome injection) - Medical

1. Must be prescribed by an oncologist AND
2. Must be 18 years of age or older AND
3. Must be used in combination with fluorouracil and leucovorin for the treatment of locally advanced or metastatic adenocarcinoma of the pancreas AND
4. Must have had disease progression following gemcitabine-based therapy or fluoropyrimidine-based therapy and no prior irinotecan
5. Onivyde will not be approved as a single agent for the treatment of metastatic adenocarcinoma of the pancreas and it will not be approved as a substitute for irinotecan HCL in other drug regimens
6. The recommended dose of Onivyde is 70mg/m^2 intravenous infusion over 90 minutes every two weeks. Recommended starting dose is 50mg/m^2 every 2 weeks in patients homozygous for UGT1A1*28.
7. Initial approval will be for 3 months, Further approvals for 3 months at a time will require documentation of stable or improved disease

HCPCS: J9205

Opdivo (nivolumab) - Medical

1. Must be ≥18 years of age **AND**
2. Must be followed by an oncologist **AND**
3. Must be used for unresectable or metastatic melanoma and must be used as:
    a. single agent adjuvant therapy following complete resection of lymph node involvement or metastatic disease OR
    b. single agent or in combination with ipilimumab (Yervoy) for unresectable or metastatic malignant disease as first-line therapy OR
    c. second-line or subsequent therapy for metastatic or unresectable disease after disease progress or maximum clinical benefit from BRAF targeted therapy
        i. as a single agent or in combination with ipilimumab (Yervoy) if checkpoint inhibitor immunotherapy was not previously used
        ii. in combination with ipilimumab (Yervoy) for patients who progress on single-agent checkpoint inhibitor immunotherapy
        iii. may be considered as re-induction therapy (as a single agent or in combination with ipilimumab) if prior checkpoint inhibitor immunotherapy resulted in disease control (complete response, partial response, or stable disease) and no residual toxicity, and disease progression/relapse occurred >3 months after treatment discontinuation **OR**
4. Must be used as a single agent for metastatic non-small cell lung cancer (NSCLC- including adenocarcinoma, squamous cell carcinoma, and large cell carcinoma) if no prior progression on anti-PD-1/PD-L1 therapy
    a. EGFR and ALK testing must have been completed AND Opdivo must be used as a single agent for disease progression on or after platinum-containing chemotherapy OR FDA approved therapy for EGFR (Tarceva, Gilotrif, Iresssa), ALK (Xalkori), or ROS1 (Xalkori) aberrations, if present
        i. There must be a proven contraindication to the following FDA approved drugs: Keytruda (pembrolizumab) and Tecentriq (atezolizumab) OR
    b. Used as a single agent or in combination with ipilimumab (Yervoy) for activity against tumor mutational burden (TMB) **OR**
5. Must be used as a single agent or in combination with Yervoy (ipilimumab) as subsequent systemic therapy for patients with Small Cell Lung Cancer (SCLC)
    a. After platinum-based chemotherapy and at least one other line of therapy
6. Must be used as a single agent for relapsed or stage IV renal cell carcinoma:
    a. As preferred subsequent therapy for predominant clear cell histology
    b. As systemic therapy for non-clear cell histology **OR**
7. Must be used in combination with ipilimumab (Yervoy) for a diagnosis of Renal Cell Carcinoma
    a. As first-line treatment of advanced disease in patients with intermediate or poor risk for clear cell or non-clear cell histology
    b. For relapse or stage IV disease:
        i. as first-line therapy for clear cell histology and favorable risk
        ii. as preferred first-line therapy for clear cell histology and poor/intermediate risk
        iii. as preferred subsequent therapy for clear cell histology **OR**
8. Must be used for patients with a diagnosis of classical Hodgkin lymphoma (cHL)
    a. There must be a proven contraindication to Keytruda (pembrolizumab) AND
    b. Must be used as a single agent for disease that has relapsed or progressed after autologous hematopoietic stem cell transplantation (HSCT) and post-transplant brentuximab vedotin [Adcetris]) or for disease that has relapsed or progressed after 3

or more lines of systemic therapy that includes autologous HSCT **OR**

9. Must be used as a single agent for locally advanced or metastatic urothelial carcinoma
    a. There must be a proven contraindication to the following FDA approved drugs: Keytruda (pembrolizumab) and Tecentriq (atezolizumab) AND
    b. Must meet the following criteria:
        i. Must have disease progression during or following platinum-containing chemotherapy OR
    c. Must have disease progression within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy **OR**
10. Must be used as a single agent or in combination with ipilimumab (Yervoy) for unresectable metachronous metastatic colorectal cancer that is defective for mismatch repair/high microsatellite instability (dMMR/MSI-H)
    a. If used as a single agent, there must be a proven contraindication to Keytruda (pembrolizumab) AND
    b. Tumor status must have been determined using laboratory (polymerase chain reaction-PCR) tests for MSI-H or immunohistochemistry (IHC) tests for deficient mismatch repair (dMMR)
        i. To be classified as MSI-H, there must be ≥2 out of 5 microsatellite markers (BAT25, BAT26, D2S123, D58346, and D17S250) that show instability
        ii. Tumor is considered mismatch repair deficient on IHC if at least one MMR gene (MLH1, MSH2, MSH6, PMS2) is not expressed AND
    c. There must have been no previous treatment with a PD-1/PD-L1 inhibitor
        i. If used in combination with Yervoy, there must have been no previous treatment with a checkpoint inhibitor AND
    d. Must meet one of the following:
        i. Must have previous adjuvant FOLFOX (fluorouracil, leucovorin, and oxaliplatin) or CapeOX (capecitabine and oxaliplatin) within the past 12 months OR
        ii. Must have received previous oxaliplatin-, irinotecan-, and/or fluoropyrimidine-based therapy OR
        iii. Used as initial, single agent, therapy for patients who are not appropriate for intensive therapy OR
11. Must be used as a single agent for recurrent or metastatic squamous cell carcinoma of the head and neck (SCCHN) with disease progression on or after platinum-based therapy **OR**
12. Must have a diagnosis of malignant pleural mesothelioma
    a. Used as subsequent systemic therapy as a single agent or in combination with Yervoy (ipilimumab) **OR**
13. Must have a diagnosis of advanced hepatocellular carcinoma
    a. Used in patients who have been previously treated with Nexavar (sorafenib)
        i. As monotherapy or in combination with ipilimumab (Yervoy)
    b. Used as subsequent treatment as a single agent for progressive hepatocellular carcinoma in patients (Child-Pugh Class A or B7 only) who:
        i. have unresectable disease and are not a transplant candidate
        ii. are inoperable by performance status or comorbidity, or have local disease or local disease with minimal extrahepatic disease only
        iii. have metastatic disease or extensive liver tumor burden **OR**
14. Must have a diagnosis of metastatic anal carcinoma
    a. Used as second-line or subsequent therapy as a single agent OR

15. Must have a Brain metastases
    a. Used as a single agent or in combination with ipilimumab (Yervoy) as treatment for newly diagnosed or recurrent brain metastases in patients with melanoma **OR**
16. Must have Merkel Cell Carcinoma
    a. Used as treatment for disseminated, clinical M1 disease with or without surgery and/or radiation therapy
17. Must be used as Single-agent therapy for Gestational Trophoblastic Neoplasia for:
    a. recurrent or progressive intermediate trophoblastic tumor (placental site trophoblastic tumor or epithelioid trophoblastic tumor) following treatment with a platinum/etoposide-containing regimen
    b. methotrexate-resistant high-risk disease
18. Must have a diagnosis of advanced or metastatic small bowel adenocarcinoma that is deficient mismatch repair/microsatellite instability-high (dMMR/MSI-H) and used as:
    a. Initial therapy as a single agent or in combination with ipilimumab (Yervoy) for advanced or metastatic disease in patients with prior oxaliplatin exposure in the adjuvant setting or contraindication
    b. Subsequent therapy as a single agent or in combination with ipilimumab (Yervoy) for advanced or metastatic disease
19. Must be used as single-agent therapy or in combination with ipilimumab (Yervoy) for a diagnosis of distant metastatic Uveal Melanoma
20. With the exception of second-line/subsequent therapy for Melanoma (as noted above), the use of Opdivo following disease progression on prior anti-PD-1/PD-L1 therapy is considered experimental and investigational and will not be approved
21. Patients with autoimmune disease, those requiring systemic immunosuppression, and patients who experienced prior ipilimumab-related Grade 4 toxicities or ipilimumab-related grade 3 toxicities that were not resolved/controlled within 12 weeks of the initiating event will be excluded from coverage
22. Monitoring for changes in renal function and thyroid function should occur.
23. Immune-mediated adverse reactions may occur. Administer corticosteroids based on the severity of the reaction.
24. Withhold for moderate and discontinue for severe or life-threatening pneumonitis, colitis, transaminase or total bilirubin elevation, or serum creatinine elevation.

HCPCS: J9299

Padcev (enfortumab vedotin-ejfv) - Medical

1. Must be at least 18 years of age
2. Must be prescribed by an Oncologist
3. Must be used as a single agent for a diagnosis of locally advanced or metastatic urothelial cancer and must have previously received a programmed death receptor-1 (PD-1) or programmed death ligand 1 (PD-L1) inhibitor and a platinum-containing chemotherapy
4. Recommending dosing is 1.25 mg/kg IV (up to a maximum of 125 mg for patients ≥100 kg) over 30 minutes on day 1, 8, & 15 of a 28-day cycle. Given until disease progression or unacceptable toxicity.
5. Initial approval will be for 6 months. Further approvals for 6 months at a time will require documentation of stable or improved disease.

Polivy (polatuzumab) - Medical

1. Must be prescribed by an Oncologist/Hematologist **AND**

2. Must be 18 years of age or older **AND**
3. Must have relapsed or refractory diffuse large B-cell lymphoma, not otherwise specified, or High-Grade B-Cell lymphoma after at least two prior therapies **AND**
4. Must be used in combination with bendamustine and a rituximab product **AND**
5. Dosage must not exceed 1.8 mg/kg as an IV infusion every 21 days for 6 cycles
6. Approval will be for 5 months. Polivy will not be approved for treatment beyond 6 cycles of therapy

Portrazza (necitumumab) - Medical

1. Must be prescribed by an Oncologist **AND**
2. Must be 18 years of age or older **AND**
3. Must be used in combination with gemcitabine and cisplatin for first-line treatment of patients with metastatic squamous non-small cell lung cancer
4. Patients with a diagnosis of non-squamous cell lung cancer (i.e Adenocarcinoma, Large cell carcinoma) (NSCLC) will be excluded from treatment with Portrazza
5. Recommended dosing is 800mg as an IV infusion over 60 minutes on Days 1 and 8 of each 3-week cycle
6. Initial approval will be for 6 months. Approval for additional 6 months periods will require submission of progress notes documenting stable or improved disease

HCPCS: J9295

Poteligeo (mogamulizumab-kpkc) - Medical

1. Must be 18 years of age or older **AND**
2. Poteligeo must be prescribed by a dermatologist with advanced knowledge of cutaneous T-cell lymphoma (CTCL) or an oncologist **AND**
3. Must have a diagnosis of relapsed or refractory mycosis fungoides (MF) or Sézary syndrome (SS)
    a. Must be relapsed/refractory to at least one prior systemic therapy OR
    b. Used as primary treatment for certain stages (Refer to NCCN compendia for stages that are NCCN Category 2A)
4. Maximum approved dosage is 1mg/kg as an IV infusion over at least 60 minutes on days 1, 8, 15, and 22 of the first 28-day cycle and on days 1 and 15 of each subsequent cycle

HCPCS: J9204

Provenge (sipuleucel-T) - Medical

1. A diagnosis of metastatic prostate cancer in patients who are asymptomatic or minimally symptomatic (ECOG 0 or 1) and have castrate resistant (hormone refractory) disease with a life expectancy greater than 6 months and no hepatic metastases.
2. Documentation must include:
    a. Evidence of metastases to soft tissue or bone
    b. Testosterone level < 50ug or below lowest level of normal
    c. Two sequential rising PSA levels obtained 2-3 weeks apart or other evidence of disease progression
3. Cannot be receiving simultaneous chemotherapy or immunosuppressive therapy
4. Clinical studies do not support more than 3 doses of sipuleucel-T and therefore a lifetime max of 3 doses is allowed. Approval time period will be 16 weeks.

5. The health plan will not be responsible for non-administered medication of sipuleucel-T due to storage issues, administration errors, or missed doses

HCPCS: Q2043

Sarclisa (isatuximab-irfc)- Medical

1. Must be prescribed by an Oncologist or Hematologist
2. Must be ≥ 18 years of age
3. Must have a diagnosis of relapsed or refractory multiple myeloma
4. Must have had previous treatment with at least two prior therapies including lenalidomide (Revlimid) and a proteasome inhibitor (such as Velcade [bortezomib], Kyprolis [carfilzomib], or Ninlaro [ixazomib])
5. Must be used in combination with pomalidomide (Pomalyst) and dexamethasone. Cannot be used monotherapy, if the patient is unable to use Pomalyst and dexamethasone then Sarclisa should not be used.
6. The recommended dose is 10 mg/kg as an intravenous infusion every week for 4 weeks followed by every 2 weeks until disease progression or unacceptable toxicity.

Synribo (omacetaxine mepesuccinate) - Medical

1. Must be written by an Oncologist **AND**
2. Must have a diagnosis of chronic or accelerated phase chronic myeloid leukemia (CML) **AND**
3. Must have a T315I mutation OR resistance and/or intolerance to two or more of the following agents: Gleevec (Imatanib), Sprycel (dasatanib), Tasigna (nilotinib) and Bosulif (Bosutinib) **OR**
4. Must be used as primary treatment of advanced phase CML for patients with disease progression to accelerated phase **OR**
5. Must be used as post-allogeneic hematopoietic stem cell transplant (HTC) follow-up therapy in patients with molecular relapse following complete cytogenetic response (CCyR) or for those not in CCyR
6. Synribo must be administered subcutaneously by a healthcare professional. Therefore, it will be covered under the medical benefit.
7. Recommended induction dosing is 1.25mg/m^2 subcutaneously twice daily for 14 consecutive days of a 28-day cycle. Recommended maintenance dose is 1.25mg/m2 subcutaneously twice daily for 7 consecutive days of a 28-day cycle.
8. Synribo will not be approved in combination with any other chemotherapeutic agent as current medical literature does not support this.
9. Synribo will be approved for 1 year. Continuation of therapy will not be approved if there is evidence of disease progression or unacceptable toxicity.

HCPCS: J9262

Tecentriq (atezolizumab) - Medical

1. Must be >=18 years of age **AND**
2. Must be followed by an oncologist **AND**
3. Must be used for a diagnosis of locally advanced or metastatic urothelial carcinoma
    a. Must have had disease progression during or following platinum-containing chemotherapy OR
    b. Have disease progression within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy OR
    c. Used as first-line therapy in cisplatin ineligible patients whose tumors express PD-L1

(PD-L1 stained tumor-infiltrating immune cells [IC] covering ≥ 5% of the tumor area) OR
   d. Used a first-line therapy in patients not eligible for any platinum-containing chemotherapy regardless of PD-L1 status **OR**
4. Must be used for a diagnosis of non-small cell lung cancer (NSCLC)
   a. in combination with bevacizumab, paclitaxel, and carboplatin, for the first-line treatment of adult patients with metastatic non-squamous NSCLC with no EGFR or ALK genomic tumor aberrations OR
   b. in combination with Abraxane (paclitaxel protein-bound particles for injectable suspension) and carboplatin for the first-line treatment of adults with metastatic NSCLC with no EGFR or ALK genomic tumor aberrations OR
   c. for the treatment of adult patients with metastatic NSCLC who have disease progression during or following platinum-containing chemotherapy
      i. Patient's with EGFR or ALK genomic tumor aberrations should have disease progression on FDA-approved therapy (Tarceva, Gilotrif, Iresssa or Xalkori (for ALK)) for these aberrations prior to receiving Tecentriq **OR**
5. Must be used for Triple Negative Breast Cancer (TNBC)
   a. In combination with paclitaxel protein-bound (Abraxane) for the treatment of adult patients with unresectable locally advanced or metastatic TNBC whose tumors express PD-L1 (PD-L1 IC ≥ 1% of tumor area)
6. Must be used in combination with carboplatin and etoposide, for the first-line treatment of patients with extensive-stage small cell lung cancer (ES-SCLC)
7. The use of Tecentriq following disease progression on prior anti-PD-1/PD-L1 therapy is considered experimental and investigational and will not be approved
8. Tecentriq will not be approved in combination with any other chemotherapeutic agent as current medical literature does not currently support this
9. Please refer to package insert for the FDA approved dosing regimen for each diagnosis

HCPCS: J9022

Torisel (temsirolimus) and temsirolimus (generic) - Medical

1. Prescribed by an Oncologist **AND**
2. Must be used as single agent therapy for a diagnosis of Renal Cell Carcinoma **OR**
3. Must be used as single-agent therapy for the treatment of PEComa, recurrent angiomyolipoma, and lymphangioleiomyomatosis **OR**
4. Must be used as single-agent therapy for Endometrial Carcinoma

HCPCS: J9330

Vyxeos (Daunorubicin/Cytarabine) - Medical

1. Must be 18 year of age or older **AND**
2. Must be prescribed by an oncologist or hematologist **AND**
3. Must have a diagnosis of newly diagnosed Therapy-related Acute Myeloid Leukemia (t-AML)
   a. Disease must be have occurred as a direct consequence to chemotherapy, radiation therapy, immunosuppressive therapy, or a combination of these treatments AND
   b. Used for treatment induction OR
   c. Used for re-induction after standard-dose cytarabine for patients with residual disease
      i. For patients <60 years with significant residual disease without hypocellular marrow and without core binding factor (CBF) abnormalities
      ii. For patients age ≥60 years with residual disease OR
   d. Used for post-remission therapy

i. For patients <60 years without core binding factor (CBR) abnormalities, treatment-related disease and/or poor-risk cytogenetics and/or molecular abnormalities or
ii. For patients age ≥ 60 years with complete response to previous intensive therapy **OR**

4. Must have a diagnosis of AML with Myelodysplasia-related changes (AML-MRC)
   a. Must have at least one of the following characteristics associated with myelodysplasia:
      i. AML that AML that evolves from previously documented myelodysplastic syndrome (MDS) OR
      ii. AML that demonstrates MDS-related cytogenetic abnormalities
      iii. Cytogenetic abnormalities include : [-7/del(7q)] or [del(5q)/t(5q)] or [i(17q)/t(17p)] or [–13/del(13q)] or [del(11q)] or [del(12p)/t(12p)] or [idic(X)(q13)] or [t(11;16)(q23.3;p13.3)] or [t(3;21)(q26.2;q22.1)] or [t(1;3)(p36.3;q21.2)] or [t(2;11)(p21;q23.3)] or [t(5;12)(q32;p13.2)] or [t(5;7)(q32;q11.2)] or [t(5;17)(q32;p13.2)] or [t(5;10)(q32;q21.2)] or [t(3;5)(q25.3;q35.1)] **OR**
      iv. AML with morphologically identified multilineage dysplasia, defined as dysplasia present in ≥ 50% of cells in 2 or more hematopoietic lineages AND
   b. Used for treatment induction OR
   c. Used for re-induction after standard-dose cytarabine for patients with residual disease
      i. For patients <60 years with significant residual disease without hypocellular marrow and without core binding factor (CBF) abnormalities
      ii. For patients age ≥60 years with residual disease OR
   d. Used for post-remission therapy
      i. For patients <60 years without core binding factor (CBR) abnormalities, treatment-related disease and/or poor-risk cytogenetics and/or molecular abnormalities or
      ii. For patients age ≥ 60 years with complete response to previous intensive therapy **OR**
5. A full Vyxeos course consists of 1-2 cycles of Induction and up to 2 cycles of consolidation. Second induction cycle should be administered 2-5 weeks after the first induction cycle, first consolidation dose should be administered 5-8 weeks after the start of the last induction, and the second consolidation should be administered 5-8 weeks after the start of the last induction. Vyxeos will only be approved for a maximum of 4 cycles

HCPCS: J9153

Xgeva (denosumab) - Medical

1. Must be prescribed by an oncologist or urologist AND
2. Must be used for the prevention of skeletal-related events (SRE) in patients with multiple myeloma or bone metastases from solid tumors.
   a. Must have documented radiographic (X-ray, CT, or MRI) evidence of at least one bone metastasis **OR**
3. Must be used for Giant Cell Tumor of the Bone
   a. Single agent or combined with interferon alfa/peginterferon or radiation therapy for localized disease
   b. Single agent for metastatic disease **OR**
4. Must be used for treatment of hypercalcemia of malignancy refractory to bisphosphonate therapy **OR**

5. Must have a diagnosis of Systemic Mastocytosis
    a. Used as second-line therapy for osteopenia/osteoporosis in patients with bone pain that is not responding to bisphosphonates or for patients who are not candidates for bisphosphonates because of renal insufficiency
6. Xgeva will not be authorized for non-metastatic prostate, non-metastatic breast cancer
7. Xgeva will not be authorized in combination with oral or injectable bisphosphonates
8. Dose is 120 mg SC every 4 weeks
9. The drug will be covered under the medical benefit for office administration.

HCPCS: J0897

Yervoy (ipilimumab) - Medical

1. Individual must have unresectable or metastatic melanoma **AND**
2. Must be followed by an oncologist **AND**
3. Used as a single agent for unresectable or metastatic melanoma
    a. If used as second-line or subsequent therapy, must have performance status 0-2 AND
    b. Must not have previously received therapy with Yervoy **OR**
4. In combination with Opdivo (nivolumab) in patients with unresectable or metastatic melanoma.
    a. As preferred first-line therapy
    b. As second-line or subsequent therapy, must have performance status 0-2 AND
    c. Must not have previously received therapy with a drug in the same class (PD-1 inhibitor or CTLA-4 inhibitor) **OR**
5. Must be used in combination with nivolumab (Opdivo) for patients with Renal Cell Carcinoma
    a. As first-line treatment of advanced disease in patients with intermediate or poor risk for clear cell or non-clear cell histology
    b. For relapse or stage IV disease:
        i. As first-line therapy for clear cell histology and favorable risk
        ii. As preferred first-line therapy for clear cell histology and poor/intermediate risk
        iii. As preferred subsequent therapy for clear cell histology **OR**
6. Used as adjuvant treatment of patients with cutaneous melanoma with pathologic involvement of regional lymph nodes of more than 1mm (Stage III) who have undergone complete resection, including total lymphadenectomy **OR**
7. Must have a diagnosis of metastatic colorectal cancer
    a. Must not have had previous progression on a checkpoint inhibitor AND
    b. Must be used in combination with nivolumab (Opdivo) for the treatment of adult and pediatric patients 12 years of age and older with microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) metastatic colorectal cancer that has progressed following treatment with a fluoropyrimidine, oxaliplatin, and irinotecan OR
    c. Must be used in combination with nivolumab (Opdivo) as primary treatment for patients with unresectable metachronous metastases (MSI-H/dMMR only) and previous adjuvant FOLFOX or CapeOX within the past 12 months **OR**
8. Must be used as single-agent therapy or in combination with nivolumab (Opdivo) for a diagnosis of distant metastatic Uveal Melanoma **OR**
9. Must be used as subsequent systemic therapy for patients with performance status 0-2 in combination with nivolumab for patients with Small Cell Lung Cancer who have primary progressive disease or who relapsed within 6 months following complete or partial response or stable disease with initial treatment (not recommended for relapse disease in patients on maintenance atezolizumab [Tecentriq] at time of relapse) **OR**

10. Must be used as initial or subsequent therapy in combination with nivolumab for advanced or metastatic Small Bowel Adenocarcinoma (dMMR/MSI-H only)
    a. For use as initial therapy, patient's must have had in prior oxaliplatin exposure in the adjuvant setting or contraindication **OR**
11. Must be used in combination with nivolumab (Opdivo) for tumor mutational burden (TMB) in Non-Small Cell Lung Cancer **OR**
12. Must be used in combination with nivolumab (Opdivo) as subsequent systemic therapy for Malignant Pleural Mesothelioma **OR**
13. Must be used for the treatment of brain metastases in patients with melanoma
    a. As single-agent therapy or in combination with nivolumab (Opdivo) for the treatment of recurrent brain metastases in patients with melanoma
    b. In combination with nivolumab (Opdivo) for the treatment of newly diagnosed brain metastases in select patients (e.g., patients with small asymptomatic brain metastases) and stable systemic disease or reasonable systemic treatment options
14. Must be used in combination with nivolumab (Opdivo) in patients who have been previously treated with Nexavar (sorafenib) for a diagnosis of advanced hepatocellular carcinoma
15. Liver function tests should be evaluated prior to each dose
16. Thyroid function tests and clinical chemistries should be monitored prior to each dose
17. Individuals with active autoimmune disease or those receiving systemic immunosuppression for organ transplantation will be excluded from coverage
18. The recommended dose for unresectable or metastatic melanoma is 3mg/kg administered IV over 90 minutes every 3 weeks for a total of four doses. For adjuvant melanoma, 10mg/kg administered IV over 90 minutes every 3 weeks for 4 doses followed by 10mg/kg every 12 weeks for up to 3 years or until documented disease recurrence/unacceptable toxicity. If used in combination with Opdivo, 1mg/kg administered IV every 3 weeks for a total of four doses
19. Approval will be granted for a maximum of 16 weeks or 4 doses for unresectable or metastatic melanoma, renal cell carcinoma, or MSI-H/dMMR colorectal cancer. Approval will be granted for a maximum of 3 years for adjuvant melanoma
20. Reinduction with Yervoy as a single agent will be approved for select patients with unresectable/metastatic melanoma who experienced no significant systemic toxicity during prior Yervoy therapy and who relapse after initial clinical response or progress after stable disease greater than 3 months.

HCPCS: J9228

Yescarta (axicabtagene ciloleucel) - Medical

1. Must be prescribed by a Hematologist or Oncologist at a Certified Treatment center AND
2. Must be ≥ 18 years of age AND
3. Must have a diagnosis of relapsed or refractory large B-cell lymphoma including diffuse large B-cell lymphoma (DLBCL) not otherwise specified, primary mediastinal large B-cell lymphoma, high grade B-cell lymphoma, and DLBCL arising from follicular lymphoma AND
4. Must be used after two or more lines of systemic therapy AND
5. Must not have previously received treatment with tisageniecleucel (Kymriah) or axicaptagene ciloleucel (Yescarta)
6. Yescarta will not be approved for a diagnosis of primary central nervous system lymphoma
7. Patients approved for Yescarta will also receive approval of Actemra for a period of 6 months. If severe or life-threatening cytokine-release syndrome is suspected (CRS), administer Actemra as either 12mg/kg IV over 1 hour for patients <30kg or 8mg/kg IV over 1 hour for patients ≥30kg
8. Prior authorization for Yescarta will apply regardless of the site of administration (applies to

both the inpatient and outpatient setting)
9. A maximum of 1 CAR-T infusion will be approved per patient lifetime

HCPCS: Q2041

Yondelis (trabectedin) - Medical

1. Must be prescribed by an oncologist AND
2. Must be 18 years of age or older AND
3. Must be used as single-agent therapy for a diagnosis of unresectable or metastatic liposarcoma or leiomyosarcoma
   a. Must have received a prior anthracycline-containing regimen (such as doxorubicin, epirubicin)
   OR
4. Must be used as single-agent palliative therapy for soft tissue sarcomas (see NCCN compendium for appropriate types)
5. Dose is administered at 1.5mg/m^2 body surface area as a 24-hour intravenous infusion, every 3 weeks through a central venous line
6. Initial approval will be for 6 months. Further approvals for 6 months at a time will require documentation of stable or improved disease

HCPCS: J9352

Zaltrap (ziv-aflibercept) - Medical

1. Must be prescribed by an oncologist AND
2. Must have a diagnosis of metastatic colorectal cancer (mCRC) that is resistant to or has progressed following an oxaliplatin-containing regimen AND
3. Must be used in combination with 5-fluorouracil, leucovorin, and irinotecan (FOLFIRI) OR irinotecan alone
4. Zaltrap will not be approved for patients with severe hemorrhage, patients who experience GI perforation, or for patients with compromised wound healing.
5. Zaltrap will not be authorized as monotherapy or in combination with other antibody therapy (such as Erbitux, Avastin, or Vectibix) as medical literature does not support this at the current time.
6. Recommended dosage is 4mg/kg as an IV infusion over 1 hour every 2 weeks.
7. Initial approval will be for 6 months. Recertification will require submission of progress notes demonstrating no evidence of disease progression.

HCPCS: J9400

UPDATES:

Date	Revision
03/2020	Revised
02/2020	Revised
01/2020	Revised
11/2019	Revised
10/2019	Revised
08/2019	Revised
05/2019	Revised
04/2019	Revised
03/2019	Revised
02/2019	Revised
01/2019	Revised
11/2018	Revised
10/2018	Revised
09/2018	Revised
08/2018	Revised
05/2018	Revised
04/2018	Revised
03/2018	Revised
02/2018	Revised
01/2018	Revised
11/2017	Revised
10/2017	Revised
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

Folotyn –

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

Mozobil

1. G Calandra et al. AMD3100 plus G-CSF can successfully mobilize CD34þ cells from non-Hodgkin's lymphoma, Hodgkin's disease and multiple myeloma patients previously failing mobilization with chemotherapy and/or cytokine treatment: compassionate use data. Bone Marrow Transplant. (2008)41:331-338.

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 studyof the Study Group Indolent Lymphoma. Blood. (ASH Annual Meeting Abstracts). 2008; 112:2596.