Pharmacy Management Drug Policy

SUBJECT: Oncology Clinical Review Prior Authorization (Oncology-CRPA) Medical Drugs
POLICY NUMBER: Pharmacy-64
EFFECTIVE DATE: 10/13
LAST REVIEW DATE: 05/13/2019

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.

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.

### Approval time periods

<table>
<thead>
<tr>
<th>Line of Business</th>
<th>Initial approval</th>
<th>Continued approval</th>
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<tr>
<td>Medicaid</td>
<td>6 months</td>
<td>12 months</td>
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<tr>
<td>Commercial/Exchange</td>
<td>Outpatient hospital – 6 months</td>
<td>Outpatient hospital – 6 months</td>
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<td>Home Care or Office Based- 2 years</td>
<td>Home Care or Office Based- 2 years</td>
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<tr>
<td>Medicare</td>
<td>Outpatient hospital – 6 months</td>
<td>Outpatient hospital – 6 months</td>
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<td></td>
<td>Home Care or Office Based- 2 years</td>
<td>Home Care or Office Based- 2 years</td>
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### CURRENT CRPA MEDICAL DRUGS:

**Adcetris (brentuximab vedotin) - Medical**

1. Must be prescribed by an oncologist
2. Diagnosis of:
   a. Hodgkin Lymphoma
      i. Previously untreated stage III or IV classical Hodgkin lymphoma (cHL), 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. classical hodgkin lymphoma at high risk of relapse or progression as post-autologous hematopoietic stem cell transplantation (auto-HSCT) consolidation \( OR \)
   b. Non-Hodgkin’s Lymphomas (NHL)
      i. Relapsed or refractory systemic anaplastic large cell lymphoma (ALCL) 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. Symptomatic lymphomatoid papulosis (LyP) or LyP with extensive lesions if refractory to all primary treatment options

v. Mycosis Fungoides (MF) /Sezary Syndrome (SS) (please refer to NCCN compendia for specific staging requirements)

3. 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

4. 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 follicular 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
2. May 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 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

3. May have Waldenstrom's macroglobulinemia/Lymphoplasmacytic lymphoma and
   a. 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

4. 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

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b. **Refractory CLL:** 300 mg initial dose, followed 1 week later by 2,000 mg weekly for 7 doses, followed 4 weeks later by 2,000 mg every 4 weeks for 4 doses

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

### Bavencio (avelumab)-Medical

1. Must be followed by an oncologist/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
4. 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/hematologist **AND**
2. Must have a diagnosis of relapsed or refractory peripheral T-cell lymphoma
3. The recommended dosage of Beleodaq is 1,000 mg/m² administered over 30 minutes by intravenous infusion once daily on days 1-5 of a 21-day cycle.
4. 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

### Belrapzo (bendamustine HCL) – Medical

**Applies to Managed Medicaid and Child Health plus members only**

1. Prescribed by an Oncologist or Hematologist **AND**
2. Must be ≥ 18 years of age **AND**
3. Diagnosis of Chronic Lymphocytic Leukemia (CLL) without del (17p)/TP53 mutation
   a. as first-line therapy with rituximab, ofatumumab, or obinutuzumab
   b. in combination with rituximab and with or without ibrutinib or idelalisib for relapsed or refractory disease **OR**
4. Diagnosis of Non-Hodgkin’s Lymphoma *see NCCN compendium for appropriate types and treatment regimens **OR**
5. Diagnosis of multiple myeloma
   a. Therapy for previously treated myeloma for relapse or progressive disease
   C. Therapy for previously treated myeloma

**HCPCS:**
6. Diagnosis of Waldenstrom’s macroglobulinemia/Lymphoplasmacytic lymphoma used with or without rituximab OR
7. Diagnosis of Classical Hodgkin lymphoma
   a. Subsequent systemic therapy as a single agent for relapsed or refractory disease OR
   b. Second-line or subsequent therapy (if not previously used) for relapsed or refractory disease as a component of gemcitabine/bendamustine/vinorelbine ± brentuximab vedotin OR
   c. Palliative therapy as a single agent for relapsed or refractory disease AND
8. Dose must be supported by FDA labeling, practice guidelines, or peer-reviewed literature

HCPCS: J9999 (non-facility), C9042 (facility, temporary)

Bendeka (bendamustine HCL) – Medical
Applies to Managed Medicaid and Child Health plus members only

9. Prescribed by an Oncologist or Hematologist AND
10. Must be ≥ 18 years of age AND
11. Diagnosis of Chronic Lymphocytic Leukemia (CLL) without del (17p)/TP53 mutation
   a. as first-line therapy with rituximab, ofatumumab, or obinutuzumab
   b. in combination with rituximab and with or without ibrutinib or idelalisib for relapsed or refractory disease OR
12. Diagnosis of Non-Hodgkin’s Lymphoma *see NCCN compendium for appropriate types and treatment regimens OR
13. Diagnosis of multiple myeloma
   a. Therapy for previously treated myeloma for relapse or progressive disease
   C. In combination with lenalidomide and dexamethasone OR
   D. In combination with bortezomib and dexamethasone OR
   E. As a single agent OR
14. Diagnosis of Waldenstrom’s macroglobulinemia/Lymphoplasmacytic lymphoma used with or without rituximab OR
15. Diagnosis of Classical Hodgkin lymphoma
   a. Subsequent systemic therapy as a single agent for relapsed or refractory disease OR
   b. Second-line or subsequent therapy (if not previously used) for relapsed or refractory disease as a component of gemcitabine/bendamustine/vinorelbine ± brentuximab vedotin OR
   c. Palliative therapy as a single agent for relapsed or refractory disease AND
16. Dose must be supported by FDA labeling, practice guidelines, or peer-reviewed literature

HCPCS: J9034

Besponsa (inotuzumab Ozogamicin) – Medical

1. Must be at least 18 years of age AND
2. Must be prescribed by an Oncologist AND
3. Must have a diagnosis of relapsed or refractory B-cell precursor acute lymphoblastic leukemia (ALL) with ≥5% bone marrow blasts
   a. Patients with a diagnosis of Philadelphia-chromosome positive B-cell precursor ALL are required to have disease that failed treatment with at least 1 tyrosine kinase inhibitor (including Spycel, Gleevec (imatanib), or Iclusig) and standard chemotherapy AND
   b. B-cell ALL must be CD22 positive
4. 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 × 10^9/L and absolute neutrophil counts [ANC] ≥ 1 × 10^9/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 × 10^9/L and/or ANC < 1 × 10^9/L) and resolution of any extramedullary disease.
5. 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 (ALL) with previous trial of at least one prior systemic anticancer therapy
   a. If used for Philadelphia chromosome positive disease, must be TKI intolerant/refractory **OR**
3. 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**
4. **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
5. **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 Blincyto 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

6. 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 fluoropyrimidine 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 after disease progression on or after prior therapy with bevacizumab, oxaliplatin, and a fluoropyrimidine
   b. The recommended Cyramza dose for colorectal cancer is 8mg/kg IV every 2 weeks, prior to FOLFIRI administration
5. 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 and have received at least one prior therapy OR
e. Must be used in combination with Pomalyst and dexamethasone in patients who have received at least 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

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

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**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 Blincyto will apply regardless of the site of administration (applies to both the inpatient and outpatient setting)

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**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 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

<table>
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<tr>
<th>Erwinaze (asparaginase)</th>
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<tr>
<td>1. Must be prescribed by or in consultation with an oncologist or hematologist <strong>AND</strong></td>
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<tr>
<td>2. Must have a diagnosis of acute lymphoblastic leukemia (ALL) with hypersensitivity to <em>E. coli</em> derived asparaginase (Oncaspar or Elspar) <strong>AND</strong></td>
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<tr>
<td>3. Must be used in combination with other chemotherapy</td>
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<td>4. Approval will be for 3 months. Dose should not exceed 25,000 units/m² IM/IV 3 times a week for 6 doses when substituting for pegasparagis or 25,000 units/m² IM or IV for each scheduled dose of native <em>E. coli</em> asparaginase within a treatment when substituting for <em>E. coli</em> asparaginase</td>
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<tr>
<th>Folotyn (pralatrexate) - Medical</th>
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<tr>
<td>1. Must be prescribed by an oncologist/hematologist</td>
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<tr>
<td>2. Must have a diagnosis of relapsed or refractory Peripheral T Cell Lymphoma (PTCL), transformed mycosis fungoides or blastic NK lymphoma. <strong>Excluding:</strong> 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.</td>
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<tr>
<td>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.</td>
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<tr>
<td>4. Dosage is 30mg/m² once weekly for 6 weeks (then off for 1 week) until progressive disease or unacceptable toxicity</td>
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<tr>
<td>5. Requirement of dose reduction below 20mg/m² or progressive disease should trigger discontinuation.</td>
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<td>6. Must be administered with Vitamin B12 and Folic Acid Supplementation</td>
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<td>7. Recertification required after first cycle then every two cycles thereafter.</td>
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<td>8. Continued coverage of Folotyn will require stabilization or reduction in disease. Patients will not be authorized for coverage if there is a:</td>
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<td>a. 50% increase in size of sentinel lesion <strong>OR</strong></td>
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<tr>
<td>b. New site of disease including new liver or spleen metastases or lymphadenopathy <strong>OR</strong></td>
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<tr>
<td>c. Increase in circulating tumor cells <strong>OR</strong></td>
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<td>d. Need for radiotherapy</td>
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<td>9. Please note that the FDA approval of Folotyn was based on an overall response rate of 27% and an 8% complete response</td>
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**HCPCS:** J9307

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<th>Gazyva (obinutuzumab) - Medical</th>
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<tr>
<td>1. Must be prescribed by an oncologist <strong>AND</strong></td>
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<tr>
<td>2. Used in combination with chlorambucil as first-line therapy for chronic lymphocytic leukemia/small lymphocytic lymphoma (CLL/SLL) <strong>OR</strong></td>
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<tr>
<td>3. Used in combination with chlorambucil for CLL/SLL in patients with indications for treatment who are unable to tolerate purine analogs <strong>OR</strong></td>
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<td>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 <strong>OR</strong></td>
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<td>5. In combination with bendamustine, followed by Gazyva monotherapy, for the treatment of</td>
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patients with follicular lymphoma who relapsed after, or are refractory to, a rituximab-containing regimen OR
6. 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
7. 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
8. 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
9. 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 day 1 of Cycles 2-6
10. 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
11. A maximum of 6 (28 day) cycles will be approved for a diagnosis of CLL/SLL.

**Halaven (eribulin) - Medical**

1. Prescribed by an oncologist AND
2. Must have a diagnosis of metastatic breast cancer
   a. Used as a single agent after previous failure of at least 2 chemotherapeutic regimens. (Prior therapy must have included an anthracycline and a taxane in either the adjuvant or metastatic setting) OR
   b. Used as a single agent for recurrent or metastatic HER2-negative disease
      i. with symptomatic visceral disease or visceral crisis OR
      ii. hormone receptor-negative or hormone receptor-positive and endocrine therapy refractory
   c. Used in combination with traztuzumab (Herceptin) for HER2-positive recurrent or metastatic trastuzumab-exposed disease
      i. With symptomatic visceral disease or visceral crisis
      ii. That is hormone receptor-negative or hormone receptor-positive and endocrine therapy refractory OR
3. Must have a diagnosis of Soft Tissue Sarcoma
   a. Used as single-agent therapy for:
      i. angiosarcoma OR
      ii. unresectable or progressive retroperitoneal/intraabdominal soft tissue sarcoma OR
      iii. pleomorphic rhabdomyosarcoma OR
      iv. soft tissue sarcoma of the extremity/superficial trunk, head/neck
         1. For synchronous stage IV or recurrent disease with disseminated metastases OR
      v. unresectable or metastatic liposarcoma
         1. must have received a prior anthracycline-containing regimen
OR

4. Must have a diagnosis of Uterine Sarcoma
   a. Used as a single agent
      i. For disease that is not suitable for primary surgery
      ii. Following total hysterectomy with or without bilateral salpingo-oophorectomy (TH ± BSO) for stage II-III disease
      iii. Following TH ± BSO for stage IV disease
   iv. For a radiologically isolated vaginal/pelvic recurrence with no prior radiation therapy
   v. For extrapelvic recurrence with no prior radiation therapy
   vi. For isolated or disseminated metastases

HCPCS: J9179

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

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
5. Imfinizi will not be approved in combination with any other chemotherapeutic agent as current medical literature does not currently support this
6. 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

<table>
<thead>
<tr>
<th>Requirement</th>
<th>Details</th>
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<tbody>
<tr>
<td>1.</td>
<td>Must be prescribed by a dermatologist with advanced knowledge of CTCL/PTCL or oncologist AND</td>
</tr>
<tr>
<td>2.</td>
<td>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) OR Adult T-Cell Leukemia/Lymphoma AND</td>
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<tr>
<td>3.</td>
<td>Diagnosis of Mycosis Fungoides (MF)/Sezary Syndrome (SS)</td>
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<tr>
<td>a.</td>
<td>For systemic biologic therapy as a single agent or in combination with skin-directed therapy. (please refer to NCCN compendia for specific staging requirements) OR</td>
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<tr>
<td>b.</td>
<td>As adjuvant systemic biologic therapy after total skin electron beam therapy for stage IIB MF generalized extent tumor, transformed, and/or folliculotropism disease or after chemotherapy for stage IV non-Sezary or visceral disease.</td>
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<tr>
<td>c.</td>
<td>As systemic biologic therapy for refractory or progressive stage IA-IIA or stage IIB (patch or plaque) MF</td>
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</tbody>
</table>

**HCPCS:** J9315

### Jevtana (cabazitaxel) – Medical

**Applies to Managed Medicaid and Child Health Plus members only**

<table>
<thead>
<tr>
<th>Requirement</th>
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<tbody>
<tr>
<td>1.</td>
<td>Must be prescribed by an Oncologist AND</td>
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<tr>
<td>2.</td>
<td>Must be ≥ 18 years of age</td>
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<tr>
<td>3.</td>
<td>Must have a diagnosis of prostate cancer with radiographic evidence of progressive metastatic disease AND</td>
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<tr>
<td>4.</td>
<td>Must have clinical documentation that the patient is no longer responding to a docetaxel containing regimen AND</td>
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<tr>
<td>5.</td>
<td>Must have clinical documentation that the patient has been treated with castration or hormone therapy, to which he is no longer responding or in spite of which he has progressed, or has a testosterone level less than 50ng/dl AND</td>
</tr>
<tr>
<td>6.</td>
<td>Must have a neutrophil count above 1,500 cells/mm and must NOT have severe hepatic impairment (total bilirubin &gt;3 x upper limit of normal) AND</td>
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<tr>
<td>7.</td>
<td>Must be used in combination with prednisone</td>
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<tr>
<td>8.</td>
<td>Recommended dosing is 20mg/m² administered as a one-hour IV infusion every 3 weeks in combination with daily oral prednisone. A dose of 25 mg/m² can be used in select patients at the discretion of the treating healthcare provider</td>
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**HCPCS:** J9043

### Kadcyla (ado-trastuzumab emtansine) - Medical

<table>
<thead>
<tr>
<th>Requirement</th>
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<tbody>
<tr>
<td>1.</td>
<td>Must be prescribed by an Oncologist AND</td>
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<tr>
<td>2.</td>
<td>Must be prescribed as a single agent for the diagnosis of HER2-positive metastatic breast cancer AND</td>
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<tr>
<td>3.</td>
<td>Patient must have previously received trastuzumab and a taxane (i.e. paclitaxel, docetaxel), separately or in combination.</td>
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<tr>
<td>a.</td>
<td>Must have received prior therapy for metastatic disease OR</td>
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<tr>
<td>b.</td>
<td>Developed disease recurrence during or within six months of completing adjuvant therapy.</td>
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<tr>
<td>4.</td>
<td>Approval for Kadcyla will be for 6 months at a time. Approval for further use will require</td>
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</tbody>
</table>
5. Recommended dosage is 3.6 mg/kg given as an IV infusion every 3 weeks until disease progression or unacceptable toxicity. Kadcyla should not be administered at doses greater than 3.6mg/kg.

6. Kadcyla cannot be substituted for or with trastuzumab.

7. Hepatic function, left ventricular ejection fraction, and platelet counts should be monitored upon initiation and prior to each dose.

8. Kadcyla will not be approved as first-line therapy or in combination with any other anti-neoplastic agent due to inadequate evidence to support this use.

**HCPCS:** J9354

### Keytruda (pembrolizumab) - Medical

1. Must be followed by an oncologist AND
2. Must be used for unresectable or metastatic melanoma OR
3. Must be used for the adjuvant treatment of patients with melanoma with involvement of lymph node(s) following complete resection OR
4. 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 nonsquamous 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 or cisplatin and either paclitaxel or albumin-bound paclitaxel as:
      i. Subsequent therapy for sensitizing EGFR mutation-positive tumors and prior erlotinib, afatinib, geftinib, osimertinib, or dacomitinib therapy
      ii. Subsequent therapy for ALK rearrangement-positive tumors and prior crizotinib, ceritinib, alectinib, or brigatinib therapy
      iii. Subsequent therapy for ROS1 rearrangement positive tumors and prior crizotinib or ceritinib therapy
      iv. Subsequent therapy for PD-L1 expression-positive (≥50%) tumors and EGFR, ALK negative or unknown and no prior platinum-doublet chemotherapy 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 OR
5. Must be used as a single agent for advanced and recurrent/persistent head squamous cell carcinoma (HNSCC) (non-nasopharyngeal) with disease progression on or after platinum-containing chemotherapy
   a. Newly diagnosed unresectable nodal disease with no metastases, or for patients who are unfit for surgery and performance status (PS) 3
   b. Metastatic disease at initial presentation or recurrent/persistent disease with distant metastases, or unresectable locoregional recurrence OR
6. 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 refractory disease in older adults (age >60) or those who have relapsed ≥ 3 prior lines of therapy OR

7. 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

8. Must be used for Merkel Cell Carcinoma
   a. for disseminated, clinical M1 disease with or without surgery and/or radiation therapy OR
   b. As a treatment option for patients with recurrent locally advanced disease OR

9. 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

10. Must be used for Malignant pleural Mesothelioma
    a. As a single agent for subsequent systemic therapy OR

11. 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 insability
       ii. Tumor is considered mismatch repair deficient on IHC if at least one MMR gene (MLH1, MSH2, MSH6, PMS2) is not expressed OR

12. Must have recurrent locally advanced or metastatic gastric or gastroesophageal junction (GEJ) adenocarcinoma
    a. Tumors must express PD-L1 (Combined Postive 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

13. Must have a diagnosis of metastatic anal carcinoma
   a. Used as a single agent for second-line therapy OR

14. Must have recurrent 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

15. Must have relapsed/refractory Extranodal NK/T-cell Lymphoma (Nasal type)
   a. Following additional therapy with clinical trial, combination asparaginase-based chemotherapy regimen, or best supportive care OR

16. Must have refractory Primary Mediastinal Large B-Cell Lymphoma (PMBCL) and have relapsed after 2 or more prior lines of therapy OR

17. Must have recurrent or metastatic cervical cancer with disease progression on or after chemotherapy whose tumors express PD-L1 (CPS≥1) OR

18. Must have hepatocellular carcinoma (HCC) and have been previously treated with sorafenib (Nexavar) OR

19. Must have advanced Renal Cell Carcinoma (RCC)
   a. Used as a single agent for second-line therapy

20. 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

21. 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

22. Thyroid function tests should be monitored at the start of treatment, periodically during treatment, and as indicated based on clinical evaluation.

23. 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.

24. Permanently discontinue for any life-threatening 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, persistant 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 tisagenleucel (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 tisagenieleucel (Kymria) or axicaptagene ciloleucel (Yescarta)

4. Kymria will not be approved for a diagnosis of primary central nervous system lymphoma

5. Patients approved for Kymria 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

6. Prior authorization for Kymria will apply regardless of the site of administration (applies to both the inpatient and outpatient setting)

7. 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 panobinostat in patients who have received at least two prior regimens, including bortezomib and an immunomodulatory agent OR
   e. 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 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 Macroglobulinemia/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

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: J9999 (non-facility), C9044 (facility, temporary)

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. Hemoglobin <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:** J9999 (non-facility), C9045 (facility, temporary)

### 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-asparaginase, 6 MP, etc).
4. Marqibo will not be approved in combination with other chemotherapeutic agents as current evidence does not support this use.
5. Recommended dosing is 2.25 mg/m² IV over 1 hour once every 7 days.
6. Initial approval will be for 6 months. Continued approval will require submission of progress notes demonstrating no evidence of disease progression.

**HCPCS:** J9371

### Mozobil (plerixafor injection) - Medical or Rx

1. Diagnosis of non-Hodgkin’s lymphoma or multiple myeloma who have not previously attempted a stem cell harvest in conjunction with Mozobil
2. Patient age 18 years of age or older
3. G-CSF must be administered for 4 days prior to first dose of Mozobil and every day of Mozobil treatment thereafter (maximum of 4 days of Mozobil treatment)
4. Dose should be based on actual body weight, 0.24mg/kg SC not to exceed 40mg/day (27mg/day in renal impairment)
5. Quantity limit of 4 doses or 1 course of harvesting cells while on Mozobil therapy, whichever occurs first

**HCPCS:** J2562

### 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 **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 as a single agent
3. 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/m² (up to one 4.5mg vial) on days 1, 4, and 7 in combination with Daunorubicin and Cytarabine
      ii. Consolidation: 3mg/m² 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/m² on day 1 and 3mg/m² on day 8  
   ii. Continuation: for patients without evidence of disease progression following induction, up to 8 continuous courses of 2mg/m² 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/m² on days 1, 4, and 7

### 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/m² IM or IV administered no more frequently than ever 14 days

### 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 metastatic adenocarcinoma of the pancreas AND  
4. Must have had disease progression following gemcitabine-based therapy  
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/m² intravenous infusion over 90 minutes every two weeks. Recommended starting dose is 50mg/m² 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 as a single agent or in combination with Yervoy for unresectable or metastatic melanoma  
   a. If used as second-line or subsequent therapy, must have had previous trial of BRAF-targeted therapy (if applicable) AND  
   b. If used as a single agent, must not have previously received therapy with a drug in the same class (PD-1 or PD-L1inhibitor) , either alone or in combination with Yervoy, or previous anti PD-1 therapy (either alone or in combination with Yervoy) must have 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  
   c. Must be used in combination with ipilimumab (Yervoy) for patients who progressed on
single-agent checkpoint inhibitor immunotherapy OR

4. Must be used as adjuvant treatment in patients with melanoma with lymph node involvement or metastatic disease who have undergone complete resection OR

5. 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 anti-PD-1/PD-L1 therapy not previously given
   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

6. 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

7. 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

8. Must be used in combination with ipilimumab (Yervoy) for patients with previously untreated, intermediate or poor risk advanced renal cell carcinoma OR

9. 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

10. 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

11. 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 therapy for patients who are not appropriate for intensive
       therapy OR
12. 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
13. 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
14. Must be used for patients with unresectable or metastatic hepatocellular carcinoma who have
   been previously treated with Nexavar (sorafenib)
   a. Must have laboratory confirmed diagnosis of hepatocellular carcinoma AND
   b. Must have Child-Pugh Class A or B7 disease OR
15. Must have a diagnosis of metastatic anal carcinoma
   a. Used as second-line therapy as a single agent OR
16. Must have a Brain metastases
   a. Used as treatment for recurrent limited (1-3 metastases) disease in combination with
      Yervoy (ipilimumab) for brain metastases if active against primary tumor OR
   b. Used as treatment for recurrent stable systemic disease with multiple (>3) brain
      metastases in combination with Yervoy (ipilimumab) if active against primary tumor
      OR
17. Must have Merkel Cell Carcinoma
   a. Used as treatment for disseminated, clinical M1 disease with or without surgery
      and/or radiation therapy
18. 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
19. 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
20. Monitoring for changes in renal function and thyroid function should occur.
21. Immune-mediated adverse reactions may occur. Administer corticosteroids based on the severity
    of the reaction.
22. Withhold for moderate and discontinue for severe or life-threatening pneumonitis, colitis,
    transaminase or total bilirubin elevation, or serum creatinine elevation.

HCPCS: J9299

Perjeta (pertuzumab) –Medical
Applies to Managed Medicaid and Child Health Plus members only

1. Must be prescribed by an oncologist AND
2. Must be ≥ 18 years of age AND
3. Must be prescribed for one of the following indications:
   a. as neoadjuvant or adjuvant treatment for patients with HER2-positive, locally advanced, inflammatory, or early stage breast cancer (either greater than 2 cm in diameter or node positive) as part of a complete treatment regimen for early breast cancer
      i. if used in the adjuvant setting, a pertuzumab-containing regimen must not have been used as neoadjuvant therapy
      ii. must be used in combination with:
          1. trastuzumab and paclitaxel following AC (doxorubicin and cyclophosphamide) regimen OR
          2. trastuzumab and docetaxel following AC (doxorubicin and cyclophosphamide) regimen OR
          3. TCH (docetaxel, carboplatin, and trastuzumab) regimen OR
   b. Used in combination with trastuzumab and docetaxel or paclitaxel as preferred first-line therapy for the treatment of patients with HER2-positive metastatic breast cancer who have not received prior anti-HER2 therapy or chemotherapy for metastatic disease OR
   c. May be considered in combination with trastuzumab with or without cytotoxic therapy (eg, vinorelbine or taxane) for one line of therapy beyond first-line therapy in patients with HER2-positive metastatic breast cancer who were previously treated with chemotherapy and trastuzumab in the absence of pertuzumab
4. Efficacy of pertuzumab without trastuzumab has not been proven, therefore members in which trastuzumab treatment is withheld or discontinued, will be excluded from coverage.
5. If docetaxel or paclitaxel is discontinued, treatment with Perjeta and trastuzumab may continue.
6. HER2 testing is required for all Perjeta requests. Patient must have confirmed diagnosis of HER2 positive cancer.
7. Approved dosing is 840mg (as a 60 minute IV infusion), followed by 420mg (administered as a 30-60min IV infusion) every 3 weeks thereafter
   • Initial approval will be for 6 months. Additional approval for 12 months at a time will require submission of progress notes demonstrating continued use of Herceptin in combination with Perjeta as well as no evidence of disease progression.
   • Approval will be 15 weeks in the neoadjuvant setting. Please note that the safety of Perjeta administered for greater than 6 cycles for early breast cancer has not been established. Patients approved for this indication will only be approved for a maximum of 6 cycles.
8. QL 3 vials per first 30 days, 2 vials per 30 days thereafter

HCPCS: J9036

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

**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

**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

**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/m² 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

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**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. 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 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

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**Torisel (temsirolimus) and temsirolimus (generic) - Medical**

1. Prescribed by an Oncologist **AND**
2. Diagnosis of Renal Cell Carcinoma
HCPCS: J9330  

**Treanda (bendamustine HCL) – Medical**  
**Applies to Managed Medicaid and Child Health plus members only**

1. Prescribed by an Oncologist or Hematologist **AND**
2. Must be ≥ 18 years of age **AND**
3. Diagnosis of Chronic Lymphocytic Leukemia (CLL) without del (17p)/TP53 mutation  
   a. as first-line therapy with rituximab, ofatumumab, or obinutuzumab  
   b. in combination with rituximab and with or without ibrutinib or idelalisib for relapsed or refractory disease **OR**
4. Diagnosis of Non-Hodgkin’s Lymphoma *see NCCN compendium for appropriate types and treatment regimens **OR**
5. Diagnosis of multiple myeloma  
   a. Therapy for previously treated myeloma for relapse or progressive disease  
      C. In combination with lenalidomide and dexamethasone **OR**  
      D. In combination with bortezomib and dexamethasone **OR**  
      E. As a single agent **OR**
6. Diagnosis of Waldenstrom’s macroglobulinemia/Lymphoplasmacytic lymphoma used with or without rituximab **OR**
7. Diagnosis of Classical Hodgkin lymphoma  
   d. Subsequent systemic therapy as a single agent for relapsed or refractory disease **OR**
   e. Second-line or subsequent therapy (if not previously used) for relapsed or refractory disease as a component of gemcitabine/bendamustine/vinorelbine ± brentuximab vedotin **OR**
   f. Palliative therapy as a single agent for relapsed or refractory disease **AND**
8. Dose must be supported by FDA labeling, practice guidelines, or peer-reviewed literature

HCPCS: J9033

**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 [(1;11)(p21;q23.3)] or [(t;3)(q26.2;q22.1)] or [(t;1)(p36.3;q21.2)] or
[(t;2)(q11;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 (CBF) 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. Being used for treatment of hypercalcemia of malignancy refractory to bisphosphonate therapy
5. Xgeva will not be authorized for non-metastatic prostate, non-metastatic breast cancer
6. Xgeva will not be authorized in combination with oral or injectable bisphosphonates
7. Dose is 120 mg SC every 4 weeks
8. 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
1. Must not have previously received therapy with Yervoy OR
2. In combination with Opdivo (Nivolumab) in patients with 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 a drug in the same class (PD-1 inhibitor or CTLA-4 inhibitor) OR
3. Must be used in combination with nivolumab (Opdivo) for patients with previously untreated, intermediate or poor risk advanced renal cell carcinoma OR
4. 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
5. 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
   a. Must not have had previous progression on a checkpoint inhibitor
6. Liver function tests should be evaluated prior to each dose
7. Thyroid function tests and clinical chemistries should be monitored prior to each dose
8. Individuals with active autoimmune disease or those receiving systemic immunosuppression for organ transplantation will be excluded from coverage
9. 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
10. 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
11. 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

<table>
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<tr>
<th>Yondelis (trabectedin) - Medical</th>
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<tr>
<td>1. Must be prescribed by an oncologist AND</td>
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<td>2. Must be 18 years of age or older AND</td>
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<td>3. Must have unresectable or metastatic liposarcoma or leiomyosarcoma AND</td>
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<td>4. Must have received a prior anthracycline-containing regimen (such as doxorubicin, epirubicin)</td>
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<td>5. Dose is administered at 1.5mg/m² body surface area as a 24-hour intravenous infusion, every 3 weeks through a central venous line</td>
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<td>6. Initial approval will be for 6 months. Further approvals for 6 months at a time will require documentation of stable or improved disease</td>
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<th>Zaltrap (ziv-aflibercept) - Medical</th>
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<tr>
<td>1. Must be prescribed by an oncologist AND</td>
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<tr>
<td>2. Must have a diagnosis of metastatic colorectal cancer (mCRC) that is resistant to or has progressed following an oxaliplatin-containing regimen. AND</td>
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<td>3. Must be used in combination with 5-fluorouracil, leucovorin, and irinotecan(FOLFIRI) OR irinotecan alone</td>
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<td>4. Zaltrap will not be approved for patients with severe hemorrhage, patients who experience GI perforation, or for patients with compromised wound healing.</td>
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<td>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.</td>
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<td>6. Recommended dosage is 4mg/kg as an IV infusion over 1 hour every 2 weeks.</td>
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<td>7. Initial approval will be for 6 months. Recertification will require submission of progress notes demonstrating no evidence of disease progression.</td>
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**UPDATES:**

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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**

Treanda –