Pharmacy Management Drug Policy

SUBJECT: Oncology Clinical Review Prior Authorization (Oncology-CRPA)

Clinical criteria used to make utilization review decisions are based on credible scientific evidence published in peer reviewed medical literature generally recognized by the medical community. Guidelines take into account physician society recommendations, the views of the physicians practicing in relevant clinical areas, the needs of the members in consultation with their providers, and other relevant factors to the extent practicable. Clinical criteria is reviewed and approved for use on an annual basis. Criteria are accessible to network providers, members, and prospective members upon request. Criteria may be verbally requested by calling 1 (800) 683-3781, or submitting a fax request to 1 (888) 273-8296. Requests may also be submitted in writing to P.O. Box 240, Pittsford, N.Y. 14534. Providers may also submit feedback regarding criteria by visiting www.yourcarehealthplan.com

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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.

Note: This policy is subject to frequent revisions as new medications come onto the market. Nevertheless, certain medications will be treated as Oncology CRPA drugs even though they may not yet be listed on the policy. Supportive documentation of previous drug use must be submitted for any criteria that requires trial of a preferred agent, if the preferred drug is not found in claims history.

CURRENT CRPA DRUGS:

<table>
<thead>
<tr>
<th>DRUG NAME (Rx or Medical benefit)</th>
<th>Authorization Criteria</th>
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<tbody>
<tr>
<td>Adcetris (Medical)</td>
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1. Must be prescribed by an oncologist
2. Diagnosis of:
   a. Hodgkin Lymphoma
      i. 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
   b. Systemic anaplastic large cell lymphoma
      i. failure of at least one prior multi-agent chemotherapy regimen OR
   c. 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
      Primary cutaneous ALCL with multifocal lesions /cutaneous ALCL with regional nodes as primary treatment or therapy for relapsed or refractory disease OR
      iii. Symptomatic lymphomatoid papulosis (LyP) or LyP with extensive lesions if refractory to all primary treatment options
      iv. Mycosis Fungoides (MF) /Sezary Syndrome (SS) (please refer to NCCN compendia for specific staging requirements)
3. The recommended dose 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.
4. Continue treatment until a maximum of 16 cycles, disease progression, or unacceptable toxicity.
5. In clinical trials, brentuximab was studied as monotherapy.
6. Brentuximab is contraindicated in combination with bleomycin

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Afinitor and Afinitor Disperz (Rx)

1. Prescribed by an Oncologist AND
2. 18 years of age or older AND
   a. Diagnosis of Renal Cell Carcinoma and previous failure of either Sutent or Nexavar OR
   b. Diagnosis of progressive neuroendocrine tumors of pancreatic origin (PNET) that is unresectable, locally advanced or metastatic. OR
   c. Diagnosis of lung neuroendocrine tumors, for stage IIIb (T4 due to multiple lung nodules)-IV/low- or intermediate-grade neuroendocrine carcinoma OR
   d. Diagnosis of Waldenstrom’s macroglobulinemia/lymphoplasmacytic lymphoma, as a single-agent salvage therapy for disease that does not respond to primary therapy or for progressive or relapsed disease OR
   e. Diagnosis of renal angiomyolipoma (non-cancerous kidney tumors) and tuberous sclerosis complex (TSC) not requiring immediate surgery. OR
   f. Diagnosis of PEComa, angiomylipoma, Lymphangioleiomyomatosis OR
   g. Diagnosis of advanced hormone receptor-positive, HER2-negative breast cancer (advanced HR+BC) in postmenopausal women.
      i. Must be used in combination with exemestane after failure of treatment with a nonsteroidal aromatase inhibitor (such as letrozole or anastrozole). OR
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<table>
<thead>
<tr>
<th>Requirement</th>
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<tbody>
<tr>
<td>1. Must be prescribed by an Oncologist or Hematologist</td>
<td>And</td>
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<tr>
<td>2. May have Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma (CLL/SLL)</td>
<td>And</td>
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<tr>
<td>a. Must be used as a single agent therapy for disease that is relapsed or refractory to fludarabine and alemtuzumab or</td>
<td>And</td>
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<td>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.</td>
<td>And</td>
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<tr>
<td>3. May have Waldenstrom's macroglobulinemia/Lymphoplasmacytic lymphoma and</td>
<td>And</td>
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<tr>
<td>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</td>
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<td>4. Recommended dose and schedule is 12 doses administered as follows:</td>
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<td>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</td>
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<tr>
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<tr>
<td>2. Must have a diagnosis of relapsed or refractory peripheral T-cell lymphoma</td>
<td>And</td>
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<tr>
<td>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.</td>
<td>And</td>
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<tr>
<td>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:</td>
<td>And</td>
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<tr>
<td>a. 50% increase in size of sentinel lesion OR</td>
<td>And</td>
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<td>b. New site of disease including new liver or spleen metastases or lymphadenopathy OR</td>
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<td>c. Increase in circulating tumor cells OR</td>
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<td>1. Must be prescribed by an oncologist AND</td>
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<tr>
<td>2. Must be 18 years or older with a weight of at least 45kg AND</td>
<td>And</td>
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<tr>
<td>3. Must have a diagnosis of Philadelphia chromosome-negative relapsed or refractory B-cell precursor acute lymphoblastic leukemia (ALL) with previous trial of at least one prior systemic anticancer therapy AND</td>
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4. 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. 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 5 cycles)
   a. Response is defined as 5% or fewer blasts AND platelets greater than 50,000/µL AND absolute neutrophil count (ANC) greater than 500/µL
5. 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
6. Prior authorization for Blincyto will apply regardless of the site of administration (applies to both the inpatient and outpatient setting)
7. 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
8. Blincyto will not be approved beyond a total of 5 treatment cycles

**Caprelsa (Rx) Vandetanib**

1. Must be followed by an oncologist certified with the Caprelsa REMS program AND
2. Must be 18 years old or older and have a diagnosis of symptomatic or progressive medullary thyroid cancer with unresectable (non-operative) locally advanced or metastatic disease AND
3. The following warnings/precautions should be observed when prescribing Caprelsa
4. Hypocalcemia, hypokalemia and/or hypomagnesemia should be corrected prior to initiating therapy
5. Drugs known to prolong the QT interval should be avoided
6. Given the ½ life of 19 days, ECGs should be obtained to monitor QT at baseline, at 2-4 weeks and 8-12 weeks after initiating therapy and every 3 months thereafter
7. Use of Caprelsa in patients with indolent, asymptomatic or slowly progressing disease should be carefully considered because of the treatment-related risks of this product.
8. Normal dosing is 300mg once a day
9. Quantity limit of 60/30 for 100mg tablet and 30/30 of 300mg tablet

**Cometriq (Rx)**

1. Must be followed by an oncologist AND
2. Must have a diagnosis of progressive metastatic medullary thyroid cancer AND
3. Normal dosing is 140 mg once a day. Patient should not eat for at least 2 hours before and at least 1 hour after taking Cometriq.
4. Gastrointestinal perforations, fistula formation, and severe, sometimes fatal hemorrhage has occurred with the use of Cometriq. Do not administer in patients with severe hemorrhage.
5. Quantity limit of 120 cap/30 days for 140mg capsule kit, 60 cap/30 days for 100mg capsule kit, 90 cap/30 days for 60mg capsule kit.
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### Cyramza (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 platinum-based chemotherapy
   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 10 mg/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 after disease progression on or after prior therapy with bevacizumab, oxaliplatin, and a fluoropyrimidine
   b. The recommended Cyramza dose for colorectal cancer is 8 mg/kg IV every 2 weeks, prior to FOLFIRI administration
5. Initial approval will be for 3 months for a diagnosis of gastric cancer/gastro-esophageal junction adenocarcinoma or NSCLC. Initial approval will be 6 months for a diagnosis of metastatic colorectal cancer. Continued approval will require submission of progress notes demonstrating stable disease without progression.

### Erivedge (Rx)

1. Individual must have a diagnosis of metastatic basal cell carcinoma OR
2. A diagnosis of locally advanced basal cell carcinoma that has recurred following surgery OR
3. A diagnosis of locally advanced basal cell carcinoma and is not a candidate for surgery or radiation. (i.e. diagnosis of Gorlin syndrome or limitations because of location of tumor or cumulative prior radiotherapy dose) AND
4. Must be followed by an oncologist or dermatologist
5. Recommended dosing is 150 mg PO daily until disease progression or unacceptable toxicity.
6. Pregnancy statuses should be determined within 7 days prior to initiation of treatment in females with reproductive potential.
7. Quantity limit of 30 per 30 days.
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**Farydak (Rx)**

1. Must be prescribed by an oncologist AND
2. Must be 18 years of age or older AND
3. Must have a diagnosis of Multiple Myeloma and have received at least 2 prior regimens including Velcade (bortezomib) AND an immunomodulatory agent (Revlimid, Pomalyst, Thalidomide) AND
4. Must be used in combination with Velcade (bortezomib) and dexamethasone
5. Recommended dose is 20mg, taken orally once every other day for 3 doses per week (on Days 1, 3, 5, 8, 10 and 12) of weeks 1 and 2 of each 21-day cycle for 8 cycles. Consideration can be given to continue treatment for an additional 8 cycles for patients with clinical benefit
6. Initial approval will be for 24 weeks. Approval for an additional 24 weeks will require documentation of stable/improved disease without signs of progression.

    Signs of progression include:
    a. At least 25 percent increase from lowest response value in any of the following:
       i. Serum M protein (absolute increase must be ≥0.5 g/dL)
       ii. Urine M protein (absolute increase must be ≥200 mg/24 hrs)
       iii. Bone marrow plasma cell percentage (absolute increase must be ≥10 percent)
    b. Difference in the kappa and lambda FLC (absolute increase must be >10 mg/dL (The FLC criteria should only be used for patients with unmeasurable M protein in the serum and urine) OR
    c. Increase in the size or development of new bone lesions or soft tissue plasmacytomas OR
    d. Development of a serum calcium >11.5 mg/dL without other cause
7. Further approval will not be given if there is unresolved severe or medically significant toxicity.
   Coverage will not be approved beyond 48 weeks of therapy
8. QL of 6 capsules per 21 days

**Firmagon (Medical)**

1. Must be prescribed by a Urologist or Oncologist AND
2. Must have a diagnosis of advanced prostate cancer AND
3. Initial dosing of 240mg SC (given as 2 x 120mg injections) and maintenance dosing of 80mg every 28 days.

**Folotyn (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.
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<thead>
<tr>
<th>Rule</th>
<th>Details</th>
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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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<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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<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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<tr>
<td>a. 50% increase in size of sentinel lesion OR</td>
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<td>b. New site of disease including new liver or spleen metastases or lymphadenopathy OR</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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**Gazyva (Medical)**

1. Must be prescribed by an oncologist **AND**
2. Must be used in combination with chlorambucil for the treatment of patients with previously untreated chronic lymphocytic leukemia (CLL)
3. Recommended dosage:
   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
4. A maximum of 6 (28 day) cycles will be approved.

**Gilotrif (Rx)**

1. Prescribed by an oncologist **AND**
2. Must be prescribed for the first-line treatment of patients with metastatic non-small lung cancer (NSCLC) whose tumors have epidermal growth factor receptor (EGFR) mutations.
3. Recommended dosage is 40mg orally once daily
4. Gilotrif used in combination with other chemotherapeutic and targeted therapies is considered experimental/investigational and will not be covered.
5. QL 30/30 days.
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### Halaven (Medical)
1. Diagnosis of metastatic breast cancer
2. Prescribed by an oncologist
3. 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
4. Can be used without previous chemotherapeutic failure in the following instances:
   a. hormone receptor-positive, human epidermal growth factor receptor 2 (HER2)-negative with visceral crisis
   b. HER2-negative and either hormone receptor-negative or hormone receptor-positive and endocrine therapy refractory
   c. Progressive disease with no clinical benefit after three consecutive endocrine therapy regimens or with symptomatic visceral disease
5. Halaven will only be approved as monotherapy. Requests for combination therapy with other chemotherapeutic agents are considered experimental/investigational
6. Recommended dosing is 1.4 mg/m2 administered IV on days 1 and 8 of a 21 day cycle

### Hycamtin (Rx)
1. Must be prescribed by an Oncologist AND
2. Diagnosis of carcinoma of the cervix in combination with cisplatin in patients not amenable to curative treatment with surgery and/or radiation therapy. OR
3. Diagnosis of metastatic carcinoma of the ovary after failure of initial or subsequent chemotherapy OR
4. Diagnosis of Small Cell Lung Cancer in patients with a prior complete or partial response to previous therapy AND a duration of at least 45 days must have passed from the end of the firstline treatment to the start of treatment with Hycamtin.

### Ibrance (Rx)
1. Must be prescribed by an oncologist AND
2. Must be 18 years of age or older AND
3. Must have a diagnosis of advanced (stage 3 or 4) estrogen receptor-positive, human epidermal growth factor receptor 2-negative (ER+/HER2-) breast cancer AND
   a. Must have either locally recurrent disease that is not amenable to surgery or evidence of metastatic disease AND
4. Used in combination with letrozole for patients who have not previously received endocrine therapy for advanced disease
   a. Patients with previous neo-adjuvant or adjuvant therapy will still qualify for the above as long as there has been no previous treatment for advanced disease.
   b. Patients who are currently stable on endocrine therapy will be approved for Ibrance plus letrozole as long as there is no evidence of progression on current endocrine therapy. OR
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5. Used in combination with fulvestrant for patients who had progression of disease during prior endocrine therapy  
   a. Patients with previous trial and failure to fulvestrant will be excluded from treatment  
6. Recommended dose is 125mg orally once daily for the first 21 days of a 28 day treatment cycle  
7. Quantity limit of 21 capsules per 28 days

<table>
<thead>
<tr>
<th>Iclusig (Rx)</th>
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| 1. Member must have a diagnosis of T315I-positive chronic myeloid leukemia (CML) OR  
2. Must have a diagnosis of T315I-positive Philadelphia chromosome positive acutelymphoblastic leukemia (Ph+ ALL). OR  
3. Must have CML or Ph+ ALL AND must have had failure or intolerance to all other tyrosine kinase inhibitor (TKI) therapies (Gleevec, Tasigna, Sprycel, Bosulif)  
4. Recommended dosage is 45mg taken orally once daily with or without food.  
5. Arterial/venous thrombosis, hepatotoxicity, and heart failure have occurred in Iclusig-treated patients. Interrupt and consider discontinuation of Iclusig if these occur.  
6. QL of 30 tablets/30 days for 45mg tablet, 60tablets/30days for 15mg tablet. |

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<tr>
<th>Imbruvica (Rx)</th>
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| 1. Must be prescribed by an Oncologist AND  
2. Must have a diagnosis of mantle cell lymphoma (MCL) and have received at least one prior therapy OR  
3. Must have a diagnosis of relapsed or refractory Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma (CLL/SLL) OR  
4. Must have a diagnosis of CLL with 17p deletion OR  
5. Must have a diagnosis of Waldenstrom’s Macroglobulinemia/Lymphoplasmacytic Lymphoma that is progressive or relapsed or does not respond to primary therapy.  
6. Imbruvica must be used as a single agent  
7. Approval will be for 12 months at a time. Continued approval will require the submission of progress notes demonstrating stable disease and no evidence of disease progression.  
8. Approved dosing is 560 mg (four 140mg capsules) taken orally once daily.  
9. QL 120 capsules/30 days. |

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<th>Inlyta (Rx)</th>
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| 1. Individual must have a diagnosis of advanced renal cell carcinoma (RCC) AND  
2. Must have experienced failure with at least one prior systemic therapy AND  
3. Must be followed by an oncologist. AND  
4. Patients with untreated brain metastasis or recent active gastrointestinal bleeding will be excluded. |
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5. The recommended starting dose is 5mg twice daily. Dose increase or reduction is recommended based on individual safety and tolerability.
6. Blood pressure should be well-controlled prior to initiating INLYTA. Patients should be monitored for hypertension and treated as needed with standard anti-hypertensive therapy.
7. Monitoring of thyroid function, liver enzymes, and for proteinuria should occur before the initiation of Inlyta and periodically throughout treatment.
8. Quantity limit of 120/30 for 5mg tablet and 540/30 for 1 mg tablet.
9. Please note: for applicable lines of businesses, a split-fill program will apply to new starts only. An override to bypass the split-fill program will be provided for existing users that have been maintained on Inlyta.

Istodax (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) OR Adult T-Cell Leukemia/Lymphoma AND
   a. Patient must have failed at least one prior systemic therapy OR
3. Diagnosis of Mycosis Fungoides (MF)/Sezary Syndrome (SS)
   a. 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
   b. As adjuvant systemic biologic therapy after total skin electron beam therapy for stage IIB MF generalized extent tumor, transformed, and/or folliculotropic disease or after chemotherapy for stage IV non-Sezary or visceral disease.
   c. As systemic biologic therapy for refractory or progressive stage IA-IIA or stage IIB (patch or plaque) MF

Jakafi (Rx)

1. Must be written by an Oncologist AND
2. Must have diagnosis of intermediate or high-risk myelofibrosis, including primary myelofibrosis, post-polycythemia vera myelofibrosis, and post-essential thrombocythemia myelofibrosis OR
3. Must have a diagnosis of polycythemia vera and had an inadequate response to or are intolerant of hydroxyurea
4. A complete blood count should be performed prior to initiating therapy with Jakafi and monitored every 2-4 weeks until doses are stabilized.
5. Serious bacterial, mycobacterial, fungal and viral infections (such as PML, tuberculosis, and herpes zoster) can occur. Active serious infections should have resolved before starting therapy with Jakafi. Observe patients receiving Jakafi for signs and symptoms of infection and initiate appropriate treatment promptly.
6. Patients who meet criteria for approval for treatment with Jakafi will be approved for 12 months. Recertification will require documentation of stable disease.
7. Quantity limit of 60 tablets per 30 days
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<td>1. Must be prescribed by an Oncologist AND</td>
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<tr>
<td>2. 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. 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. Must have received prior therapy for metastatic disease OR</td>
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<tr>
<td>b. Developed disease recurrence during or within six months of completing adjuvant therapy.</td>
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<td>4. Approval for Kadcyla will be for 6 months at a time. Approval for further use will require documentation of stable disease without progression.</td>
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<td>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.</td>
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<td>6. Kadcyla cannot be substituted for or with trastuzumab.</td>
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<td>7. Hepatic function, left ventricular ejection fraction, and platelet counts should be monitored upon initiation and prior to each dose.</td>
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<td>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.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Keytruda (Medical)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Must be used for unresectable or metastatic melanoma AND</td>
</tr>
<tr>
<td>2. Must be &gt;=18 years of age AND</td>
</tr>
<tr>
<td>3. Must be followed by an oncologist AND</td>
</tr>
<tr>
<td>4. Patients with autoimmune disease or those requiring immunosuppression, and patients who experienced Grade 4 toxicity requiring corticosteroids or Grade 3 toxicity requiring corticosteroids (&gt;10 mg/day prednisone equivalents) for greater than 12 weeks after treatment with ipilimumab will be excluded from coverage</td>
</tr>
<tr>
<td>5. Keytruda will not be approved in combination with any other chemotherapeutic agent as current medical literature does not currently support this.</td>
</tr>
<tr>
<td>6. The recommended dose is 2 mg/kg administered IV over 30 minutes every 3 weeks until disease progression or unacceptable toxicity.</td>
</tr>
<tr>
<td>7. Thyroid function tests should be monitored at the start of treatment, periodically during treatment, and as indicated based on clinical evaluation.</td>
</tr>
<tr>
<td>8. Withhold Keytruda for Grade 2 pneumonitis, Grade 2 or 3 colitis, Grade 3 nephritis, Grade 3 hyperthyroidism, symptomatic hypophysitis, AST or ALR &gt;3 and &lt;=5 times ULN, total bilirubin &gt;1.5 and &lt;=3 times ULN, or any other Grade 3 treatment-related adverse reaction. Patients may resume Keytruda if adverse reactions recover to Grade 0-1.</td>
</tr>
</tbody>
</table>
SUBJECT: Oncology Clinical Review Prior Authorization (Oncology-CRPA)

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9. 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

10. Initial approval will be for 6 months. Continued approval will require submission of progress notes demonstrating stable disease without progression.

**Kryprolis (Medical)**

1. Must be prescribed by an Oncologist **AND**
2. Must be prescribed as a single chemotherapeutic agent or in combination with lenalidomide and dexamethasone for previously treated relapsed, refractory, or progressive multiple myeloma:
   a. Must have received at least 2 prior therapies including:
      i. Velcade (bortezomib) **AND**
      ii. An immunomodulatory agent [i.e. Thalomid (thalidomide) or Revlimid (lealidomide)] **AND**
   b. Must have demonstrated disease progression on or within 60 days of completion of the last therapy.
3. Used in combination with lenalidomide and dexamethasone for transplant candidates with progressive solitary plasmacytoma or smoldering myeloma (asymptomatic) that has progressed to active (symptomatic) myeloma as:
   a. primary chemotherapy **OR**
   b. salvage therapy on or off clinical trials for disease relapse after 6 months following primary chemotherapy with the same regimen
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
   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.

**Lenvima (Rx)**

1. Must be prescribed by an oncologist or endocrinologist **AND**
2. Must be 18 years of age or older **AND**
3. Must have a diagnosis of locally recurrent or metastatic, progressive, differentiated (papillary, follicular, Hurthle) thyroid cancer that is refractory to radioactive iodine. Patients are considered refractory to iodine if they meet one of the following criteria:
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a. At least one measurable lesion without iodine uptake on any iodine-131 scan
b. At least one measurable lesion that had progressed according to the Response Evaluation Criteria In Solid Tumors (RECIST) criteria within 12 months after iodine-131 therapy despite iodine-131 avidity at the time of treatment
c. Patient exceeded total lifetime dose of RAI>600 mCi

4. The recommended dosage is 24mg orally, given once daily. In patients with severe renal or hepatic impairment, the dose is 14mg once daily

5. QL will vary based on the dose pack prescribed:
   a. 24mg pack= 90 capsules/30 days
   b. 20mg pack= 60 capsules/30 days
   c. 14mg pack =60 capsules/30 days
   d. 10mg pack= 30 capsules/30 days

6. Please note: for applicable lines of businesses, a split-fill program will apply to new starts only. An override to bypass the split-fill program will be provided for existing users that have been maintained on Lenvima.

**Lynparza (Rx)**

1. Must be prescribed by an oncologist AND
2. Must have a diagnosis of BRCA mutated (gBRCAm, as detected through laboratory testing) advanced ovarian cancer AND
3. Must have been treated with three or more prior chemotherapy regimens AND
4. Initial approval will be 6 months. Documentation of response and/or stable disease will be required for further approval (granted for 6 months at a time)
5. Lynparza will not be approved as:
   a. Maintenance therapy for platinum-sensitive gBRCA mutation-positive ovarian cancer
   b. First- or second-line treatment of gBRCA mutation-positive ovarian cancer
   c. Treatment of any other gBRCA mutation-positive cancer /tumor
   d. Treatment of wild-type BRCA tumors, including ovarian cancer

6. The recommended dosage is 400mg by mouth twice daily
7. QL 480 capsules/30 days

**Marqibo (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, 6MP, etc).
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<table>
<thead>
<tr>
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</tr>
</thead>
</table>

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.

<table>
<thead>
<tr>
<th>Mekinist (Rx)</th>
</tr>
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</table>
1. Must be followed by an oncologist AND
2. Individual must have unresectable or metastatic melanoma AND
   a. Patient must have BRAF V600E or V600K mutation positive melanoma as detected by an FDA approved test AND
   b. Mekinist will be approved as a single agent or in combination with dabrafenib (Tafinlar). OR
3. Mekinist will not be approved in combination with any other anti-neoplastic agents (such as Yervoy, or Zelboraf).
4. Mekinist will not be approved for patients who have received prior BRAF inhibitor therapy such as Zelboraf (vemurafenib).
5. The recommended dosing of Mekinist is 2mg orally once daily taken at least 1 hour before or at least 2 hours after a meal.
6. Quantity limit of 30 tablets/30 days for the 2 mg and the 1 mg tablets. QL of 90 tablets/30 days of the 0.5 mg tablet.

<table>
<thead>
<tr>
<th>Mozobil (Rx or Medical)</th>
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</table>
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, which ever occurs first

<table>
<thead>
<tr>
<th>Nexavar (Rx)</th>
</tr>
</thead>
</table>
1. Prescribed by an Oncologist AND
2. Diagnosis of renal cell carcinoma OR
3. Diagnosis of unresectable hepatocellular carcinoma OR
4. Diagnosis of differentiated thyroid carcinoma (DTC) (Follicular, Hurthle cell, Medullary cell, or Papillary carcinoma) OR
SUBJECT: Oncology Clinical Review Prior Authorization (Oncology-CRPA)

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5. Diagnosis of soft tissue sarcoma – GIST and previous failure of sunitinib (Sutent) or imatinib (Gleevec) OR
6. Diagnosis of soft tissue sarcoma – angiosarcoma, as a single agent OR
7. Diagnosis of soft tissue sarcoma – desmoid tumors (aggressive fibromatosis) as initial treatment or treatment of recurrence for:
   a. Gross residual disease following surgery OR
   b. Unresectable disease OR
   c. Disease for which surgery would be unacceptably morbid OR
8. Diagnosis of osteosarcoma.
   a. Second-line therapy as a single agent with growth factor support.
9. Quantity limit of 120/30 DS or 136/34 DS
10. Please note: for applicable lines of businesses, a split-fill program will apply to new starts only. An override to bypass the split-fill program will be provided for existing users that have been maintained on Nexavar

<table>
<thead>
<tr>
<th>Opdivo (Medical)</th>
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</thead>
<tbody>
<tr>
<td>1. Must be &gt;=18 years of age AND</td>
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<tr>
<td>2. Must be followed by an oncologist AND</td>
</tr>
<tr>
<td>3. Must be used for unresectable or metastatic melanoma OR</td>
</tr>
<tr>
<td>4. Must be used for metastatic non-small cell lung cancer (NSCLC- including adenocarcinoma, squamous cell carcinoma, and large cell carcinoma) with progression on or after platinum-based chemotherapy</td>
</tr>
<tr>
<td>5. 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</td>
</tr>
<tr>
<td>6. Opdivo will not be approved in combination with any other chemotherapeutic agent as current medical literature does not currently support this.</td>
</tr>
<tr>
<td>7. The recommended dose is 3mg/kg as an IV infusion over 60 minutes every 2 weeks.</td>
</tr>
<tr>
<td>8. Monitoring for changes in renal function and thyroid function should occur.</td>
</tr>
<tr>
<td>9. Immune-mediated adverse reactions may occur. Administered corticosteroids based on the severity of the reaction.</td>
</tr>
<tr>
<td>10. Withhold for moderate and discontinue for severe or life-threatening pneumonitis, colitis, transaminase or total bilirubin elevation, or serum creatinine elevation.</td>
</tr>
<tr>
<td>11. Initial approval will be for 6 months. Continued approval will require submission of progress notes demonstrating stable disease without progression.</td>
</tr>
</tbody>
</table>
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### Perjeta (Medical)

1. Must be prescribed by an oncologist AND
2. Must be prescribed for one of the following indications:
   a. Used in combination with trastuzumab and docetaxel or paclitaxel 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
   b. Used in combination with trastuzumab and docetaxel as neoadjuvant 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. OR
      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 previously treated with chemotherapy and trastuzumab in the absence of pertuzumab
3. Efficacy of pertuzumab without trastuzumab has not been proven, therefore members in which trastuzumab treatment is withheld or discontinued, will be excluded from coverage.
4. If docetaxel or paclitaxel is discontinued, treatment with Perjeta and trastuzumab may continue.
5. HER2 testing is required for all Perjeta requests. Patient must have confirmed diagnosis of HER2 positive cancer.
6. Approved dosing is 840mg (as a 60 minute IV infusion), followed by 420mg (administered as a 30-60min IV infusion) every 3 weeks thereafter
   a. Initial approval will be for 6 months. Recertification will require submission of progress notes demonstrating continued use of Herceptin in combination with Perjeta as well as no evidence of disease progression.
   b. 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.
7. QL 3 vials per first 30 days, 2 vials per 30 days thereafter.

### Pomalyst (Rx)

1. Must be prescribed by an oncologist AND
2. Must have a diagnosis of multiple myeloma AND
3. Must have received at least 2 prior therapies including bortezomib (Velcade) and an immunomodulatory agent (such as lenalidomide or thalidomide) AND
4. Must have documented disease progression on or within 60 days of completion of the last therapy AND
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5. Must be used in combination with dexamethasone or as a single-agent for steroid-intolerant patients.
6. Recommended dosing is 4 mg daily on days 1-21 of repeated 28-day cycles until disease progression.
7. Pomolyst will only be available through a restricted program called the Pomolyst REMS program. Pregnancy must be excluded prior to the start of treatment and two reliable methods of contraception should be used throughout treatment.
8. QL of 23 tablets per 30 days.

Provenge (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. Can not 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

Purixan (Rx)

1. Will be authorized for a diagnosis of acute lymphoblastic leukemia (ALL) for:
   a. Children who are unable to swallow oral pills OR
   b. Children or adults who require a daily dosage that cannot be obtained from 50mg tablets
2. Requests for the use of Purixan for other indications will be evaluated based on the off-label policy for medical necessity
   a. In addition, there must be documentation as to why the individual cannot utilize oral tablets (Swallowing disorder, unique dosing, etc)
3. Quantity limit of 100 ml per 30 days.
Pharmacy Management Drug Policy

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Revlid (Rx)

1. Must be written by oncologist AND
2. Diagnosis of Myelodysplastic Syndrome (MDS)
   a. First line with 5q deletion cytogenic abnormality OR
   b. First line in lower risk patients with symptomatic anemia, no 5q deletion with or without other cytogenetic abnormalities, and serum erythropoietin levels greater than 500 mU/mL and with a low probability of response to immunosuppressive therapy OR
   c. Second line after failure of EPO without 5q deletion cytogenic abnormality OR
3. Diagnosis of Multiple Myeloma
   a. Primary chemotherapy for asymptomatic myeloma that has progressed to symptomatic myeloma (in combination with dexamethasone w/ or w/o bortezomib for transplant patients or in combination with low-dose dexamethasone or MPL regimen for nontransplant candidates) OR
   b. Primary treatment for patients with systemic light chain amyloidosis (in combination with dexamethasone) OR
   d. Maintenance therapy as a single agent for active myeloma responding to primary myeloma therapy or stable/responsive disease following stem cell transplant OR
   e. Salvage therapy for disease relapse after 6 months following primary chemotherapy (in combination with dexamethasone w/ or w/o bortezomib for transplant patients or in combination with low-dose dexamethasone or MPL regimen for nontransplant candidates) OR
   f. Salvage therapy for disease relapse or progressive/refractory disease (as a single agent for steroid-intolerant patients or in combination with dexamethasone w/ or w/o bortezomib or cyclophosphamide or in combination with bendamustine and dexamethasone) OR
4. Diagnosis of Non Hodgkin’s Lymphoma – See NCCN compendium for appropriate types and treatment regimens
5. Quantity limit 30/30 DS or 34/34 DS

Soltamox (RX)

1. Must be used for one of the following indications:
   a. As adjuvant treatment for axillary node-negative and axillary node-positive breast cancer
   b. For metastatic breast cancer
   c. For ductal carcinoma in situ (DCIS) following breast surgery and radiation therapy to reduce the risk of invasive breast cancer.
   d. For breast cancer prophylaxis in women who are at high risk for developing disease. High risk is defined as women at least 35 years of age with a 5-year predicted risk of disease greater than or equal to 1.67% (calculated by the Gail model).
2. Must have documentation of an inability to swallow tablets.
3. QL 300ml/ 30 days.
Pharmacy Management Drug Policy

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<table>
<thead>
<tr>
<th>Sprycel (Rx)</th>
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<tbody>
<tr>
<td>1. Must be written by an Oncologist <strong>AND</strong></td>
</tr>
<tr>
<td>2. Indicated as first-line therapy for patients with Philadelphia chromosome positive <strong>chronic phase</strong> chronic myeloid leukemia (Ph+ CP-CML) <strong>OR</strong></td>
</tr>
<tr>
<td>3. Indicated for patients with intolerance or resistance to previous therapy (including Gleevec) in <strong>all stages</strong> of Chronic Myeloid Leukemia (CML) <strong>OR</strong></td>
</tr>
<tr>
<td>4. Indicated for patients with intolerance or resistance to at least one previous therapy in Philadelphia chromosome-positive Acute Lymphoblastic Leukemia (ALL)</td>
</tr>
<tr>
<td>5. Treatment for progressive gastrointestinal stromal tumors (GIST) with PDGFRA D842V mutation when patient is no longer receiving benefit from imatinib (Gleevec) or sunitinib (Sutent)</td>
</tr>
<tr>
<td>6. Quantity limit 60/30 DS or 68/34 DS</td>
</tr>
<tr>
<td>7. <strong>Please note:</strong> for applicable lines of businesses, a split-fill program will apply to new starts only. An override to bypass the split-fill program will be provided for existing users that have been maintained on Sprycel</td>
</tr>
</tbody>
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<thead>
<tr>
<th>Stivarga (Rx)</th>
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<tbody>
<tr>
<td>1. Must be seen by an oncologist <strong>AND</strong></td>
</tr>
<tr>
<td>2. May have a diagnosis of metastatic colorectal cancer (CRC)</td>
</tr>
<tr>
<td>a. KRAS testing must have been completed <strong>AND</strong></td>
</tr>
<tr>
<td>Must have previously been treated with fluoropyrimidine-, oxaliplatin-, AND irinotecan- based chemotherapy, <strong>AND</strong> an anti-VEGF therapy (i.e Avastin), If CRC is KRAS wild type, an anti-EGFR (ie Erbitux, Vectibix) must also have been tried.</td>
</tr>
<tr>
<td>3. May have a diagnosis of locally advanced, unresectable or metastatic gastrointestinal stromal tumor (GIST) and previously been treated with Gleevec (imatinib) and Sutent (sunitinib)</td>
</tr>
<tr>
<td>4. Stivarga will not be approved in combination with any other chemotherapeutic agent as current medical literature does not currently support this.</td>
</tr>
<tr>
<td>5. Recommended dose is 160 mg orally, once daily for the first 21 days of each 28 day cycle and Stivarga should be administered with a low-fat (less than 30%) meal.</td>
</tr>
<tr>
<td>6. Hepatic function should be monitored prior to and during treatment. If hepatotoxicity occurs, interrupt and then reduce or discontinue Stivarga.</td>
</tr>
<tr>
<td>7. Initial Stivarga approval will be for 6 months. Further approval will require evidence of continued benefit without progression of disease.</td>
</tr>
<tr>
<td>8. QL 84 tablets per 30 days.</td>
</tr>
</tbody>
</table>
## Sutent (Rx)

1. Must be written by oncologist **AND**
2. Diagnosis of GIST (gastrostomal tumor) and failure or intolerance to Gleevec **OR**
3. Diagnosis of Renal Cell Carcinoma **OR**
4. Diagnosis of progressive neuroendocrine tumors of pancreatic origin (PNET) that is unresectable, locally advanced or metastatic. **OR**
5. Diagnosis of lung neuroendocrine tumors **OR**
6. Diagnosis of soft tissue sarcoma – angiosarcoma (useful as a single agent) **OR**
7. Diagnosis of soft tissue sarcoma – solitary fibrous tumor/hemangiopericytoma (single-agent therapy) **OR**
8. Diagnosis of thyroid carcinoma – Follicular, Hurthle cell, and Papillary cell carcinoma:
   a. Treatment of clinically progressive or symptomatic metastatic disease in patients with nonradioiodine-responsive tumors at sites other than central nervous system **OR**
9. Diagnosis of thyroid carcinoma – Medullary carcinoma:
   a. Treatment of disseminated symptomatic disease if clinical trials or Caprelsa are not available or appropriate, or if there is progression on Caprelsa.
10. Quantity limit of 30/30 DS or 34/34 DS

## Sylatron (Rx)

1. Must be prescribed by an oncologist or dermatologist with advanced knowledge of melanoma
2. Diagnosis of melanoma with microscopic or gross nodal involvement within 84 days of definitive surgical including complete lymphadenectomy. **OR**
3. Diagnosis of Chronic Myelogenous Leukemia (CML)
   a. Primary treatment as a single agent for newly diagnosed CML in rare patients unable to tolerate imatinib, dasatinib, nilotinib, bosutinib, or ponatinib.
   b. Follow-up therapy in rare patients unable to tolerate imatinib, dasatinib, nilotinib, bosutinib, or ponatinib with:
      - BCR-ABL 1 transcript levels >10% at 3 or 6 months
      - Partial, minor, or no cytogenetic response or in cytogenic relapse at 12 months
      - Partial cytogenetic response or in a cytogenetic relapse at 18 months.
   c. Posttransplant follow-up treatment in patients with
      - Molecular relapse (polymerase chain reaction positive) following complete cytogenetic remission
      - Cytogenetic relapse or those who are not in cytogenetic remission.
4. Diagnosis of giant cell tumor of the bone:
   a. As a single agent or combined with denosumab or radiation therapy for localized disease
   b. Single agent for metastatic disease
   c. Those with autoimmune hepatitis or hepatic decompensation (Child-Pugh > 6; Class B or C) will be excluded from coverage
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<table>
<thead>
<tr>
<th>Synribo (Medical)</th>
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<tbody>
<tr>
<td>1. Must be written by an Oncologist <strong>AND</strong></td>
</tr>
<tr>
<td>2. Must have a diagnosis of chronic or accelerated phase chronic myeloid leukemia (CML) <strong>AND</strong></td>
</tr>
<tr>
<td>3. Must have resistance and/or intolerance to two or more of the following agents: Gleevec (Imatanib), Sprycel (dasatanib), Tasigna (nilotinib) and Bosulif (Bosutinib).</td>
</tr>
<tr>
<td>4. Synribo must be administered subcutaneously by a healthcare professional. Therefore, it will be covered under the medical benefit.</td>
</tr>
<tr>
<td>5. 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.</td>
</tr>
<tr>
<td>6. Synribo will not be approved in combination with any other chemotherapeutic agent as current medical literature does not support this.</td>
</tr>
<tr>
<td>7. Synribo will be approved for 1 year. Continuation of therapy will not be approved if there is evidence of disease progression or unacceptable toxicity.</td>
</tr>
</tbody>
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<thead>
<tr>
<th>Tafinlar (Rx)</th>
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<tbody>
<tr>
<td>1. Must be followed by an oncologist <strong>AND</strong></td>
</tr>
<tr>
<td>2. Individual must have unresectable or metastatic melanoma <strong>AND</strong></td>
</tr>
<tr>
<td>a. Must be used as a single agent for the treatment of patients with BRAF V600E mutation as detected by an FDA-approved test. <strong>OR</strong></td>
</tr>
<tr>
<td>b. Must be used in combination with trametinib (Mekinist) for the treatment of patients with BRAF V600E or V600K mutations. <strong>OR</strong></td>
</tr>
<tr>
<td>3. Must have Non-Small Cell Lung Cancer (NSCLC)</td>
</tr>
<tr>
<td>a. Used as a single agent for patients with BRAF V600E mutation <strong>OR</strong></td>
</tr>
<tr>
<td>4. Must have a diagnosis of recurrent Central Nervous system Cancer with limited (1-3) metastatic or multiple (&gt;3) Metastatic Lesions</td>
</tr>
<tr>
<td>a. Used as a single agent for brain metastases if active against primary tumor (melanoma) for brain</td>
</tr>
<tr>
<td>5. Tafinlar will not be approved in combination with any other anti-neoplastic agents (such as Yervoy or Zelboraf)</td>
</tr>
<tr>
<td>6. Dermatologic evaluations should be performed prior to initiation of therapy and every two months.</td>
</tr>
<tr>
<td>7. Patients with wild-type BRAF melanoma will be excluded</td>
</tr>
<tr>
<td>8. Quantity limit of 300/30 days (50mg strength) and 120/30 days (75mg strength).</td>
</tr>
</tbody>
</table>
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### Tarceva (Rx)

1. Prescribed by an Oncologist AND
2. First line treatment of pancreatic cancer (used in combination with gemcitabine) OR
3. Single agent therapy or in combination with cetuximab for the treatment of of recurrent chordoma (bone cancer). OR
4. Non-small cell lung cancer (used as monotherapy) after failure of at least 1 chemotherapy regimen OR
5. First-line therapy for recurrence or metastases in patients with a known EGFR mutation:
   a. As a single agent
   b. Added to current chemotherapy if EGFR mutation is discovered during chemotherapy. OR
6. Indicated for maintenance therapy in patients with non small cell lung cancer who have stable disease after receiving chemotherapy.
7. Tarceva used in combination with other targeted therapies is considered experimental/investigational and will not be covered.
8. Quantity limit of 30/30 or 34/34 DS
9. Please note: for applicable lines of businesses, a split-fill program will apply to new starts only. An override to bypass the split-fill program will be provided for existing users that have been maintained on Tarceva.

### Targretin (RX)

1. Must be prescribed for the treatment of cutaneous T-cell lymphoma that is refractory to at least one prior systemic therapy. OR
2. Prescribed for a diagnosis of Mycosis Fungoides (MF) OR
3. Prescribed for a diagnosis of Sezary Syndrome (SS) OR
4. Prescribed for a diagnosis of primary cutaneous anaplastic large cell lymphoma (ALCL) OR
5. Prescribed for a diagnosis of symptomatic lymphomatoid papulosis (LyP)
6. QL of 300 capsules/30 days
7. Please note: for applicable lines of businesses, a split-fill program will apply to new starts only. An override to bypass the split-fill program will be provided for existing users that have been maintained on Targretin.

### Tasigna (Rx)

1. Must be written by an oncologist AND
2. Diagnosis of chronic or accelerated phase Philadelphia chromosome positive chronic myelogenous leukemia (CML) either as initial therapy or after previous failure of imatinib (Gleevec) OR
3. Diagnosis of GIST
4. Treatment for progressive disease when patient is no longer receiving benefit from imatinib (Gleevec) or sunitinib (Sutent)
5. Quantity limit 120/30 DS or 136/34 DS
SUBJECT: Oncology Clinical Review Prior Authorization (Oncology-CRPA)

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<tr>
<th>Torisel (Medical)</th>
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<tbody>
<tr>
<td>1. Prescribed by an Oncologist AND</td>
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<tr>
<td>2. Diagnosis of Renal Cell Carcinoma</td>
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<tr>
<th>Treanda (Medical)</th>
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<tbody>
<tr>
<td>1. Prescribed by an Oncologist or Hematologist AND</td>
</tr>
<tr>
<td>2. Diagnosis of Chronic Lymphocytic Leukemia (CLL)</td>
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<tr>
<td>a. as first-line therapy with or without rituximab for stage II-IV disease</td>
</tr>
<tr>
<td>b. with or without rituximab for relapsed or refractory disease OR</td>
</tr>
<tr>
<td>3. Diagnosis of Non-Hodgkin’s Lymphoma *see NCCN compendium for appropriate types and treatment regimens OR</td>
</tr>
<tr>
<td>4. Diagnosis of multiple myeloma</td>
</tr>
<tr>
<td>a. Salvage therapy on or off clinical trials as a single agent or in combination with lenalidomide and dexamethasone for disease relapse or for progressive or refractory disease OR</td>
</tr>
<tr>
<td>5. Diagnosis of Waldenstrom’s macroglobulinemia/Lymphoplasmacytic lymphoma used with or without rituximab OR</td>
</tr>
<tr>
<td>6. Diagnosis of Classical Hodgkin lymphoma</td>
</tr>
<tr>
<td>a. As second-line or salvage therapy as a single agent with or without radiation therapy (RT) prior to autologous stem cell rescue for progressive disease or relapsed disease OR</td>
</tr>
<tr>
<td>7. Diagnosis of Lymphocyte-predominant Hodgkin lymphoma</td>
</tr>
<tr>
<td>a. As second-line or salvage therapy as a single agent or in combination with rituximab with or without radiation therapy (RT) prior to autologous stem cell rescue for progressive or relapsed disease.</td>
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<th>Tykerb (Rx)</th>
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<tr>
<td>1. Prescribed by an Oncologist AND</td>
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<tr>
<td>2. Diagnosis of advanced or metastatic breast cancer</td>
</tr>
<tr>
<td>1. a. Used in combination with trastuzumab (Herceptin) or capecitabine (Xeloda) with the following criteria: (level 2A per NCCN) Treatment of patients with advanced or metastatic breast cancer whose tumors are HER2 positive</td>
</tr>
<tr>
<td>2. Patient must have failed the following treatment options: an anthracycline (doxorubicin, epirubicin), a taxane (paclitaxel, docetaxel) and trastuzumab (Herceptin)</td>
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<tr>
<td>3. Initial approval will be for 90 days. Recertification will require documentation of continued use of Xeloda or Herceptin OR</td>
</tr>
<tr>
<td>3. Used in combination with letrozole (Femara) for the treatment of patients with advanced breast cancer whose tumor are both HER2 positive and hormone positive (ER positive and/or PR positive) OR</td>
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<tr>
<td>4. Diagnosis of central nervous system cancers</td>
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<tr>
<td>a. In combination with capecitabine if active against primary tumor (breast) as treatment for brain metastases in patients with recurrent disease.</td>
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<tr>
<td>Quantity limit of 180/30 or 204/34 DS</td>
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### Valchlor(Rx)
1. Must be prescribed by an oncologist or dermatologist
2. Used for a diagnosis of stage 1A or 1B mycosis fungoides-type cutaneous T-cell lymphoma
3. Must have had prior treatment with skin-directed therapy (topical corticosteroids, carmustine, local radiation, topical retinoids, phototherapy, topical imiquimod)
4. Quantity limit 60 grams

### Votrient (Rx)
1. Must be written by oncologist **AND**
2. Diagnosis of advanced Renal Cell Carcinoma **OR**
3. Diagnosis of advanced soft tissue sarcoma with previous receipt of chemotherapy **OR**
4. Diagnosis of uterine sarcoma as a single agent
   a. with inoperable disease limited to the uterus
   b. for local recurrence confined to the vagina
   c. for extrapelvic recurrence with no prior radiation therapy
   d. for disseminated metastases.
   e. following TH/BSO for stage IV disease
5. Quantity limit of 120/30 days
6. **Please note:** for applicable lines of businesses, a split-fill program will apply to new starts only. An override to bypass the split-fill program will be provided for existing users that have been maintained on Votrient

### Xalkori (Rx)
1. Must be followed by an oncologist **AND**
2. Individual must have locally advanced or metastatic non-small cell lung cancer (NSCLC) **AND**
   Patient must have NSCLC that is anaplastic lymphoma kinase (ALK) positive or ROS1 positive as detected by an FDA-approved test. **OR**
3. Diagnosis of soft tissue sarcoma – inflammatory myofibroblastic tumor (IMT) with ALK translocation
4. Single-agent therapy
5. The recommended dose of Xalkori is 250mg taken orally twice daily.
6. Patients should be monitored for pulmonary symptoms indicative of pneumonitis.
7. Liver function should be monitored once a month and as clinically indicated.
8. Treatment should be permanently discontinued for any occurrence of pneumonitis, severe QTc prolongation, or moderate to severe ALT or AST/Bilirubin elevation.
9. Efficacy of Xalkor in combination with Tarceva has not been proven, therefore patients approved for coverage of Xalkori will be excluded from coverage of Tarceva.
10. Quantity limit of 60 per 30 days.
If the member's subscriber contract excludes coverage for a specific service it is not covered under that contract. In such cases, medical 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.

### Xgeva (Medical)

1. Prescribed by an oncologist or urologist
2. Being used for the prevention of skeletal-related events (SRE) in patients with bone metastases from solid tumors.
   a. Must have documented radiographic (X-ray, CT, or MRI) evidence of at least one bone metastasis **OR**
3. Being 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 approved for prevention of SREs in patients with multiple myeloma
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.

### Xtandi (Rx)

1. Must be prescribed by a urologist or oncologist **AND**
2. Must have a diagnosis of castration-resistant prostate cancer with radiographic evidence of progressive metastatic disease. **OR**
3. Must be used as a single agent for second-line hormonal therapy for relapse or metastases following medical or surgical androgen deprivation therapy (ADT). In combination with ADT:
   a. As part of neoadjuvant/concomitant/adjuvant ADT to enhance effectiveness of radiation therapy
      In androgen deprivation therapy-naïve patients for a minimum of 7 days in patients with overt metastases who are at risk of developing symptoms associated with androgen flare.
   c. Following inadequate testosterone suppression with ADT alone.
4. Must have had trial and failure/intolerance to Abiraterone (Zytiga).
5. Xtandi will not be approved in combination with other chemotherapeutic agents as medical literature does not support this at the current time.
6. Approval will be for 1 year at a time. Continuation of therapy will not be approved if there is evidence of disease progression or unacceptable toxicity.
7. Xtandi will not be approved in patients who have a history of seizure or have predisposing factors for seizure because safety and efficacy in these patients has not been established.
SUBJECT: Oncology Clinical Review Prior Authorization (Oncology-CRPA)

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| 8. | Quantity limit of 120/30 days. |
| 9. | Please note: for applicable lines of businesses, a split-fill program will apply to new starts only. An override to bypass the split-fill program will be provided for existing users that have been maintained on Xtandi |

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<th>Yervoy (Medical)</th>
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<th>Zaltrap (Medical)</th>
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Zelboraf (Rx)

1. Must be used for unresectable or metastatic melanoma that is BRAF V600E mutation positive as detected by an FDA approved test. (Patients with wild-type BRAF melanoma will be excluded) OR OR
2. Used for brain metastases if active against the primary tumor (BRAF V600E melanoma) for recurrent disease. OR
3. Must have NSCLC with BRAF mutations AND
4. Must be followed by an oncologist
5. The recommended dosing of Zelboraf is 960mg given twice daily.
6. Dermatologic evaluations should be performed prior to initiation of therapy and every two months.
7. LFTs and bilirubin should be monitored prior to initiation of treatment and monthly.
8. Electrolytes and ECG should be monitored prior to initiation of therapy, 15 days after treatment initiation, monthly during the first 3 months of treatment, and every 3 months thereafter.
9. Patients with wild-type BRAF melanoma will be excluded
10. Individuals who are approved for coverage of Zelboraf will be excluded from coverage of Yervoy.
11. Quantity limit of 240/30 days.

Zolinza (Rx)

1. Prescribed by a dermatologist with advanced knowledge of CTCL or oncologist AND
2. Diagnosis of cutaneous T-cell Lymphoma:
   1. Patient must have failed at least 2 other therapies OR
3. Diagnosis of multiple myeloma:
   1. As salvage therapy in combination with bortezomib for disease relapse or for progressive or refractory disease OR
4. Diagnosis of Non-Hodgkins Lymphoma – Mycosis Fungoides (MF)/Sezary Syndrome (SS)
   As adjuvant systemic biologic therapy after total skin electron beam therapy for stage IIB MF generalized extend tumor, transformed, and/or folliculotropic disease or after chemotherapy for stage IV non-Sezary or visceral disease
5. As systemic biologic therapy for refractory or progressive stage IA-IIA or stage IIB (patch or plaque) MF
6. As systemic biologic therapy as a
**Pharmacy Management Drug Policy**

**SUBJECT: Oncology Clinical Review Prior Authorization (Oncology-CRPA)**

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| a. Single agent or in combination with skin-directed therapy for stage III MF with blood involvement |
| b. Single agent or in combination with skin-directed therapy for I-IIA MF with histologic evidence of folliculotropic or large cell transformed or stage IIB MF with limited extent tumor disease |
| c. Single agent or in combination with denileukin diftitox, systemic retinoids, interferons, or photopheresis for stage I-IIB with histologic evidence of folliculotropic or large cell transformed MF, stage IIB MF with generalized extent tumor, transformed, and/or folliculotropic disease, or SS |

8. Quantity limit 120/30 DS or 136/34 DS

**Zydelig (Rx)**

1. Must be prescribed by an oncologist/hematologist AND
2. Must be prescribed for one of the following diagnoses:
   a. In combination with rituximab for relapsed chronic lymphocytic leukemia (CLL) in patients unable to tolerate standard chemotherapy due co-morbidities (i.e. co-existing medical conditions, reduced renal function as measured by creatinine clearance <60mL/min, or NCI CTCAE Grade ≥ 3 neutropenia or grade ≥ 3 thrombocytopenia resulting from myelotoxic effects of prior therapy with cytotoxic agents.)
   b. Relapsed follicular B-cell non-Hodgkin lymphoma (FL) in patients who have received at least two prior systemic therapies.
   c. Relapsed small lymphocytic lymphoma (SLL) in patients who have received at least two prior systemic therapies.
3. Recommended starting dose is 150mg twice daily.
4. Patients with a history of serious allergic reactions, including anaphylaxis and toxic epidermal necrolysis will be excluded.
5. QL 60 tablets/30 days

**Zykadia (Rx)**

1. Must be prescribed by an oncologist AND
2. Must have a diagnosis of ALK positive metastatic non-small cell lung cancer (NSCLC) as demonstrated by an FDA approved test AND
3. Must have progressed on or are intolerant to crizotinib (Xalkori)
   - Recommended dosage is 750mg once daily. Zykadia should not be administered within 2 hours of a meal.
4. Initial approval will be for 6 months. Additional approval will require submission of progress notes demonstrating stable/improved disease.
5. QL of 150 capsules/30 days.
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<td>1. Must be prescribed by a urologist or oncologist</td>
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<tr>
<td>2. Must have a diagnosis of castration-resistant prostate cancer with radiographic evidence of progressive metastatic disease</td>
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<tr>
<td>3. Must be used in combination with prednisone</td>
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<tr>
<td>4. The safety of Zytiga in patients with LVEF&lt;50% or NYHA Class III or IV heart failure has not been established and therefore will not be approved.</td>
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<tr>
<td>5. Patients with moderate base line hepatic impairment (Child-Pugh Class B) should be started at a reduced dose of 250mg once daily</td>
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<tr>
<td>6. Quantity limit of 120/30</td>
</tr>
<tr>
<td>7. Please note: for applicable lines of businesses, a split-fill program will apply to new starts only. An override to bypass the split-fill program will be provided for existing users that have been maintained on Zytiga</td>
</tr>
</tbody>
</table>

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

Afinitor–

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

Mozobil

Nexavar –

Tarceva–
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| 3. | Treanda – |
| 5. | Xalxori – |
| 7. | Drugs 2010; 70(2):167-179 |
| 8. | Zelboraf – |