Pharmacy Management Drug Policy

SUBJECT: Oncology Clinical Review Prior Authorization (Oncology-CRPA) Rx Drugs
POLICY NUMBER: Pharmacy-33
EFFECTIVE DATE: 10/13
LAST REVIEW DATE: 10/18/2018

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 applicable to drugs that are included on a specific drug formulary. If a drug referenced in this policy is non-formulary, please reference the Coverage Exception Evaluation Policy for All Lines of Business Formularies policy for review guidelines.
2. 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.
3. 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.
4. 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.
5. 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.

6. 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.

<table>
<thead>
<tr>
<th>Approval time periods</th>
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<tbody>
<tr>
<td>Line of Business</td>
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<tr>
<td>Medicaid</td>
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<td>Commercial/Exchange</td>
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CURRENT CRPA DRUGS:

<table>
<thead>
<tr>
<th>DRUG NAME (Rx benefit)</th>
<th>Authorization Criteria</th>
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<tbody>
<tr>
<td>Afinitor and Afinitor Disperz (everolimus and everolimus tablets of oral suspension) - Rx</td>
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<tr>
<td>1. Prescribed by an Oncologist AND</td>
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<tr>
<td>2. 18 years of age or older AND</td>
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<tr>
<td>a. Diagnosis of Renal Cell Carcinoma and previous failure of either Sutent or Nexavar OR</td>
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<tr>
<td>b. Diagnosis of progressive neuroendocrine tumors of pancreatic origin (PNET) or progressive neuroendocrine tumors (NET) of gastrointestinal (GI) or lung origin that are unresectable, locally advanced or metastatic OR</td>
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<tr>
<td>c. 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</td>
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<tr>
<td>d. Diagnosis of renal angiomyolipoma (non-cancerous kidney tumors) and tuberous sclerosis complex (TSC) not requiring immediate surgery. OR</td>
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<tr>
<td>e. Diagnosis of PEComa, angiomyolipoma, Lymphangioleiomyomatosis</td>
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<tr>
<td>f. Diagnosis of advanced hormone receptor-positive, HER2-negative breast cancer (advanced</td>
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HR+BC) in postmenopausal women.
   i. Must be used in combination with exemestane, fulvestrant, or tamoxifen after failure of treatment with a nonsteroidal aromatase inhibitor (such as letrozole or anastrozole).

g. Diagnosis of Classical Hodgkin Lymphoma
   i. As subsequent systemic therapy as a single agent for refractory or relapsed disease OR
   ii. As palliative therapy as a single agent for older adults (age >60) OR

h. Diagnosis of osteosarcoma (bone cancer)
   i. Used as second-line therapy in combination with sorafenib OR

i. Diagnosis of Thymoma/Thymic Carcinoma
   i. Used as second-line therapy as a single agent OR

j. Diagnosis of Neuroendocrine tumors of the gastrointestinal tract, lung, and thymus
   i. Refer to NCCN Compendia for approved scenarios OR

k. Diagnosis of Neuroendocrine Tumors of the Pancrease as a single agent for the management of progressive locoregional advanced disease and/or distant metastatic disease OR

l. Diagnosis of Gastrointestinal Stromal Tumors (GIST)
   i. Used in combination with either imatinib (Gleevec), sunitinib (Sutent), or regorafenib (Stivarga) for disease progression after single-agent therapy with imatinib, sunitinib, or regorafenib. OR

m. Diagnosis of Papillary, Follicular, or Hurthle Cell Thyroid Carcinoma
   i. Consider if clinical trials or other systemic therapies are not available or appropriate for treatment of progressive and/or symptomatic iodine-refractory unresectable locoregional recurrent or persistant disease or disetant metastatic disease OR

n. Diagnosis of endometrial carcinoma
   i. Refer to NCCN compendia for approved scenarios OR

3. 1 year of age or older AND
   a. Diagnosis of subependymal giant cell astrocytoma (SEGA) associated with tuberous sclerosis complex (TSC) which cannot be treated with surgery OR

4. 2 years of age or older AND
   a. Diagnosis of tuberous sclerosis complex (TSC)-associated partial-onset seizures (Afinitor Disperz only)

5. Afinitor will not be covered for the treatment of patients with functional carcinoid tumors

6. Quantity limit of 30/30 DS or 34/34 DS

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### Alocensa (alectinib) - Rx

1. Must be prescribed by an Oncologist AND
2. Must have a diagnosis of anaplastic lymphoma kinase (ALK)-positive, metastatic non-small cell lung cancer (NSCLC) as demonstrated by laboratory testing AND
3. Must have progressed on or are intolerant to crizotinib (Xalkori)
4. Recommended dosage is 600mg twice daily, administered with food
5. Initial approval will be for 6 months. Additional approval will require submission of progress notes demonstrating stable/improved disease
6. QL 240 capsules/30 days

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### Alunbrig (brigatinib) - Rx
### Pharmacy Management Drug Policy

**Oncology CRPA Rx Drugs**

1. Must be followed by an Oncologist **AND**
2. Must be ≥ 18 years of age **AND**
3. Individual must have ALK positive metastatic non-small cell lung cancer (NSCLC) **AND**
4. Must have progressed on or be intolerant to crizotinib (Xalkori)
5. The recommended dosage of Alunbrig is 90 mg once daily for the first 7 days and if tolerated, increase to 180mg orally once daily

### Bosulif (bosutinib) - Rx

1. Must be written by an oncologist **AND**
2. Indicated for the treatment of adult patients with chronic, accelerated, or blast phase
   Philadelphia chromosome positive (Ph+) chronic myeloid leukemia (CML) with resistance or intolerance to prior therapy
   a. as a single agent **OR**
3. Indicated as a single agent for newly-diagnosed chronic phase Ph+ chronic myelogenous leukemia (CML) **OR**
4. As primary treatment of CML in accelerated or blast phase
   a. As a single agent for accelerated phase CML or
   b. In combination with induction for myeloid blast phase CML or
   c. In combination with induction or steroids for lymphoid blast phase CML **OR**
5. Indicated for post-transplant follow-up treatment in patients with: molecular relapse (polymerase chain reaction positive) following complete cytogenetic remission or cytogenetic relapse or those who are not in cytogenetic remission **OR**
6. Indicated for relapsed/refractory Philadelphia chromosome-positive ALL
   a. As a single agent or
   b. In combination with an induction regimen not previously given
7. Recommended dosage is 500mg once daily with food for Ph+ CML with resistance or intolerance to prior therapy. Recommended dosage is 400mg once daily for Newly–diagnosed chronic phase Ph+ CML. Escalate dose to 600mg daily in patients who do not reach complete hematologic response by week 8 or complete cytogenetic response by week 12 and do not have Grade 3 or greater adverse reactions
8. Approval will be for 1 year at a time. Further approval will require documentation of stable disease and the absence of disease progression.
9. Quantity limit 30/30 days for 500mg and 400mg tablets and 120/30days for 100mg tablets

### Braftovi (encorafenib) -- Rx

1. Must be followed by an oncologist **AND**
2. Must be 18 year of age or older **AND**
3. Must be used for unresectable or metastatic melanoma that is BRAF V600E mutation positive as detected by an FDA approved test **AND**
4. Must be used in combination with Mektovi (binimetinib) **AND**
5. Based on comparable FDA labeling and NCCN recommendations regarding safety and efficacy, Braftovi will only be authorized if there is a proven contraindication to the following FDA approved treatment regimens: Tafinlar/Mekinist and Zelboraf/Cotellic. Braftovi will not be approved for patients who have experienced progression on prior BRAF/MEK targeted therapy.
6. The recommended dose of Braftovi is 450mg orally once daily in combination with Mektovi
7. Other than Mektovi, Braftovi will not be approved or in combination with any other anti-neoplastic agents (such as Yervoy, Mekinist, Tafinlar, Opdivo, Keytruda, Zelboraf, or Cotellic) and Braftovi will not be approved in patients with wild-type BRAF melanoma
8. Quantity Limit 180/30 days for 75mg capsule and 120/30 days for 50mg capsules
9. **Please note:** for applicable lines of businesses (Commercial, Exchange, Child Health Plus), 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 Braftovi

### Cabometyx (cabozantinib) – Rx

1. Must be >18 years of age AND
2. Must be prescribed by an oncologist AND
3. Must have a diagnosis of advanced renal cell carcinoma (RCC) OR
4. Must have a diagnosis of Non-Small Cell Lung Cancer (NSCLC) with RET gene arrangements as demonstrated by an FDA approved test
5. Drug will be approved for 6 months at a time. Additional coverage will require submission of progress notes documenting stable or improved disease
6. QL 30 tablets/30 days
7. **Please note:** for applicable lines of businesses (Commercial, Exchange, Child Health Plus), 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 Cabometyx

### Calquence (acalebrutinib) – Rx

1. Must be 18 years of age or older AND
2. Must be prescribed by an Oncologist/Hematologist AND
3. Must have a diagnosis of Mantle Cell Lymphoma and have received at least one prior therapy
   a. Patients who have prior treatment with a BTK inhibitor (i.e. Imbruvica) will be excluded from coverage
4. Approved dosing is 100mg by mouth every 12 hours
5. QL 60 capsules/30 days

### Caprelsa (vandetanib) - Rx

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-operable) 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 (cabozantinib) - Rx
1. Must be followed by an oncologist AND
2. Must have a diagnosis of progressive metastatic medullary thyroid cancer OR
3. Must have a diagnosis of kidney cancer OR
   a. Must be used as subsequent therapy as a single agent for relapse or for surgically unresectable stage IV disease with predominant clear cell histology that progressed on prior tyrosine kinase inhibitor therapy [axitinib (Inlyta), pazopanib (Votrient), sorafenib (Nexavar), or sunitinib (Sutent)]
4. Must have a diagnosis of non-small cell lung cancer (NSCLC)
   a. Indicated for patients with RET gene rearrangements
5. Gastrointestinal perforations, fistula formation, and severe, sometimes fatal hemorrhage has occurred with the use of Cometriq. Do not administer in patients with severe hemorrhage.
6. 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.

Copiktra (duvelisib) - Rx

1. Must be 18 years of age or older AND
2. Must be prescribed by a hematologist or Oncologist AND
3. Must have a diagnosis of relapsed or refractory chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL) after at least 2 prior therapies
   a. Patients will be excluded from coverage of Copiktra if they have had any of the following:
      i. Prior exposure to a PI3K inhibitor (i.e Zydelig) or a BTK inhibitor (I.e Imbruvica) OR
      ii. Prior autologous transplant within 6 months or prior allogeneic transplant OR
4. Must have relapsed or refractory follicular lymphoma (FL) after at least two prior systemic therapies
   a. Must be refractory to rituximab and either chemotherapy or radioimmunotherapy
      i. Refractory disease is defined as less than a partial remission or relapse within 6 months after the last dose AND
   b. Patients will be excluded from coverage of Copiktra if they have had any of the following:
      i. Prior exposure to a PI3K inhibitor (i.e Zydelig) or a BTK inhibitor (I.e Imbruvica) OR
      ii. Grade 3b Follicular lymphoma OR
      iii. Large cell transformation, OR
      iv. Prior allogeneic transplant
5. Dose must not exceed 25mg orally twice daily
6. QL 60 capsules per 30 days

Cotellic (cobimetinib) - Rx

1. Must be followed by an oncologist AND
2. Patient must have BRAF V600E or V600K mutation positive unresectable or metastatic melanoma as detected by an FDA approved test AND
3. Must be used in combination with Zelboraf (vemurafenib)
4. Cotellic will not be approved in patients with wild-type BRAF melanoma or in combination with any other anti-neoplastic agents (such as Yervoy, Mekinist, Tafinlar, Opdivo, Keytruda)
5. Cotellic will not be approved for patients who have experienced progression on prior BRAF targeted therapy such as Zelboraf (vemurafenib), Tafinlar (Dabrafenib), or Mekinist (Trametinib)
   a. If patients are currently receiving Zelboraf and the request is to add Cotellic, approval will be granted as long as there has been no progression while on Zelboraf
6. Recommended dose is 60mg orally once daily for the first 21 days of each 28-day cycle until disease progression or unacceptable toxicity
7. QL 63 tablets/28 days.

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<tr>
<th><strong>Erivedge (vismodegib) - Rx</strong></th>
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<tbody>
<tr>
<td>1. Individual must have a diagnosis of metastatic basal cell carcinoma OR</td>
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<tr>
<td>2. A diagnosis of locally advanced basal cell carcinoma that has recurred following surgery OR</td>
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<td>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</td>
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<td>4. Must be followed by an oncologist or dermatologist</td>
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<td>5. Recommended dosing is 150mg PO daily until disease progression or unacceptable toxicity.</td>
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<td>6. Pregnancy statues should be determined within 7 days prior to initiation of treatment in females with reproductive potential.</td>
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<td>7. Erivedge will not be approved for patients that have previously failed treatment with a hedgehog pathway inhibitor (Odomzo)</td>
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<td>8. Quantity limit of 30 per 30 days.</td>
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<tr>
<th><strong>Erleada (apalutamide) - Rx</strong></th>
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<tr>
<td>1. Must be prescribed by a urologist or oncologist AND</td>
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<tr>
<td>2. Must have a diagnosis of non-metastatic, castration-resistant prostate cancer</td>
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<tr>
<td>a. Patient must also receive a gonadotropin-releasing hormone (GnRH) analog (goserelin (Zoladex), histrelin (Vantas), leuprolide ( Eligard, Lupron Depot), triptorelin (Trelstar)) concurrently or should have had bilateral orchiectomy</td>
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<td>3. Recommended dosing is 240mg (four 60mg tablets) administered orally once daily</td>
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<td>4. Quantity limit of 120/30 days</td>
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<tr>
<th><strong>Farydak (Panobinostat) - Rx</strong></th>
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<tr>
<td>1. Must be prescribed by an oncologist AND</td>
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<tr>
<td>2. Must be 18 years of age or older AND</td>
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<tr>
<td>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</td>
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<tr>
<td>4. Must be used in combination with Velcade (bortezomib) and dexamethasone</td>
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<tr>
<td>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</td>
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<td>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:</td>
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<td>a. At least 25 percent increase from lowest response value in any of the following:</td>
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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

**Gilotrif (afatinib) - 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)
   a. Tumor must have a known sensitizing EGFR mutation [Exon 19 deletion or Exon 21 (L858R) substitution] as detected by an FDA approved test OR
3. Must be prescribed for the treatment of patients with metastatic, squamous NSCLC progressing after platinum-based chemotherapy
4. Recommended dosage is 40mg orally once daily
5. Gilotrif used in combination with other targeted therapies is considered experimental/investigational and will not be covered.
   QL 30/30 days.

**Hycamtn (topotecan HCl) - 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 first line treatment to the start of treatment with Hycamtn.
5. Quantity limit of 35 capsules per 30 days

**Ibrance (palbociclib) - 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
   b. Used in combination with an aromatase inhibitor (anastrozole, letrozole, exemestane) for patients who have not previously received endocrine therapy for advanced disease
   i. 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.

ii. Patients who are currently stable on endocrine therapy will be approved for Ibrance plus an aromatase inhibitor as long as there is no evidence of progression on current endocrine therapy OR

c. Used in combination with fulvestrant for patients who had progression of disease during prior endocrine therapy OR

4. Must have a diagnosis of well-differentiated/dedifferentiated Liposarcoma (WD-DDLS) for Retroperitoneal Sarcomas
   a. Must be used as a single agent

5. Recommended dose is 125mg orally once daily for the first 21 days of a 28 day treatment cycle
6. Quantity limit of 21 capsules per 28 days

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<tr>
<th><strong>Iclusig (ponatinib) - Rx</strong></th>
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<tbody>
<tr>
<td>1. Member must have a diagnosis of T315I-positive chronic myeloid leukemia (CML) OR</td>
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<tr>
<td>2. Must have a diagnosis of T315I-positive Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ ALL). OR</td>
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<tr>
<td>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)</td>
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<td>4. Recommended dosage is 45mg taken orally once daily with or without food.</td>
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<td>5. Arterial/venous thrombosis, hepatotoxicity, and heart failure have occurred in Iclusig-treated patients. Interrupt and consider discontinuation of Iclusig if these occur.</td>
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<td>6. QL of 30 tablets/30 days for 45mg tablet, 60 tablets/30 days for 15mg tablet.</td>
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<tr>
<th><strong>Idhifa (Enasidenib) - Rx</strong></th>
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<tr>
<td>1. Must be ≥ 18 years of age AND</td>
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<tr>
<td>2. Must be prescribed by an Oncologist or Hematologist AND</td>
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<tr>
<td>3. Must have a diagnosis of relapsed or refractory Acute Myeloid Leukemia (AML) with an Isocitrate Dehydrogenase-2 (IDH2) mutation</td>
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<tr>
<td>4. Initial approval will be for 6 months. Further approval will require documentation of stable or improved disease</td>
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<td>5. QL 30 tablets/30 days</td>
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<tr>
<th><strong>Imbruvica (ibrutinib) - Rx</strong></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 mantle cell lymphoma (MCL) and have received at least one prior therapy</td>
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<tr>
<td>a. Can be used in combination with rituximab as pre-treatment in order to limit the number of cycles of less aggressive induction therapy with RHyperCVAD regimen OR</td>
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<td>b. Second-line as a single agent OR</td>
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<tr>
<td>3. Must have a diagnosis of Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma (CLL/SLL) (with or without 17p deletion)</td>
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<td>a. Preferred first-line therapy as a single agent OR</td>
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<tr>
<td>b. Therapy as a single agent for relapsed or refractory disease OR</td>
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<tr>
<td>c. In combination with bendamustine and rituximab for CLL/SLL without del (17p)/TP53 mutation OR</td>
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<tr>
<td>4. Must have a diagnosis of Waldenstrom’s Macroglobulinemia/Lymphoplasmacytic Lymphoma</td>
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Proprietary of the Insurance Plan
Pharmacy Management Drug Policy
Oncology CRPA Rx Drugs

a. Used as a single agent or in combination with rituximab as primary therapy OR
b. Used as a single agent or in combination with rituximab as therapy for previously treated disease that does not respond to primary therapy or for progressive or relapsed disease OR
5. Must have a diagnosis of marginal zone lymphoma (MZL) and require systemic therapy and have received at least one prior anti-CD20-based therapy OR
6. Must have chronic graft versus host disease (cGVHD) after failure of one or more lines of systemic therapy OR
7. Must have Gastric MALT Lymphoma
   a. Second-line or subsequent therapy for recurrent or progressive disease in patients with indications for treatment OR
8. Must have nongastric MALT Lymphoma
   a. Second-line or subsequent therapy for refractory or progressive disease in patients with indications for treatment OR
9. Must have Hairy Cell Leukemia
   a. Single-agent therapy in patients with indication for treatment for progression
10. 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.
11. Approved dosing is 560 mg taken orally once daily for MCL and MZL and 420mg taken orally once daily for CLL/SLL, WM, and cGVHD
12. QL for Imbruvica 70mg Capsule and 140mg, 280mg, 420 mg, and 560 mg tablet: 30 tablets/30 days. QL for Imbruvica 140mg Capsule: 120 capsules/30 days.

**Inlyta (axitinib) - Rx**

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.
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 (Commercial, Exchange, Child Health Plus), 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

**Iressa (gefitinib) - Rx**

1. Must be prescribed by an oncologist AND
2. Must be prescribed for patients with recurrent or metastatic non-small cell lung cancer (NSCLC)
   a. Must be used as first-line therapy OR
b. As subsequent therapy for metastatic disease following progression on a first-line cytotoxic regimen in patients with performance status 3-4 AND  
3. Tumor must have a known sensitizing EGFR mutation [Exon 19 deletion or Exon 21 (L858R) substitution] as detected by an FDA approved test.  
4. Recommended dose is 250 mg orally, once daily with or without food  
5. QL 30/30 days

### Jakafi (ruxolitinib) - 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

### Kisqali and Kisqali Femara Co-Pack (ribociclib and ribociclib/letrozole)

1. Must be prescribed by an oncologist AND  
2. Must be 18 years of age or older AND  
3. Must have a diagnosis of hormone receptor (HR)-positive, human epidermal growth factor receptor 2-negative (ER+/HER2-) advanced (stage 3 or 4) or metastatic breast cancer AND  
   a. Kisqali must be used in combination with an aromatase inhibitor (anastrozole, exemestane, or letrozole) for pre/perimenopausal or postmenopausal women who have not previously received endocrine therapy for advanced disease  
      i. 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  
      ii. Patients who are currently stable on endocrine therapy will be approved for Kisqali plus an aromatase inhibitor as long as there is no evidence of progression on current endocrine therapy OR  
   b. Kisqali must be used in combination with fulvestrant for postmenopausal women as initial endocrine based therapy or following disease progression on endocrine therapy  
4. Recommended dose is 600mg of Kisqali orally (three 200mg tablets) taken once daily with or without food for 21 consecutive days followed by 7 days off treatment  
5. Quantity limit of Kisqali : 63 capsules per 28 days  
6. Quantity limit of Kisqali Femara Co-Pack:  
   a. Kisqali Femara 200mg Co-pack: 49 tablets/28 days  
   b. Kisqali Femara 400mg Co-pack: 70 tablets/28 days  
   c. Kisqali Femara 600mg Co-pack: 91 tablets/28 days
<table>
<thead>
<tr>
<th><strong>Lenvima (leqvatinib) - Rx</strong></th>
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<tbody>
<tr>
<td>1. Must be prescribed by an oncologist or endocrinologist AND</td>
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<tr>
<td>2. Must be 18 years of age or older AND</td>
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<tr>
<td>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: 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&gt;600 mCi OR</td>
</tr>
<tr>
<td>4. Must have a diagnosis of Renal Cell Cancer (RCC) a. Must be used in combination with everolimus (Afinitor) for advanced RCC following one prior anti-angiogenic therapy [such as axitinib (Inlyta), pazopanib (Votrient), sorafenib (Nexavar), sunitinib (Sutent), or bevacizumab (Avastin)] OR</td>
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<tr>
<td>5. Must have a diagnosis of unresectable hepatocellular carcinoma (HCC)</td>
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<tr>
<td>6. Used as first-line treatment</td>
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<tr>
<td>7. QL will vary based on the dose pack prescribed: a. 24mg pack= 90 capsules/30 days b. 20mg pack= 60 capsules/30 days c. 18mg pack = 90 capsules/30 days d. 14mg pack =60 capsules/30 days e. 12 mg pack = 90 capsules/30 days f. 10mg pack= 30 capsules/30 days g. 8 mg pack = 60 capsules/30 days h. 4mg pack = 30 capsules/30 days</td>
</tr>
<tr>
<td>8. Please note: for applicable lines of businesses (Commercial, Exchange, Child Health Plus), 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.</td>
</tr>
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<thead>
<tr>
<th><strong>Lonsurf (trifluridine and tipiracil) - Rx</strong></th>
</tr>
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<tbody>
<tr>
<td>1. Must be 18 years of age or older AND</td>
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<tr>
<td>2. Must be prescribed by an oncologist AND</td>
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<tr>
<td>3. Must have a diagnosis of metastatic colorectal cancer AND</td>
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<tr>
<td>4. KRAS testing must have been completed AND</td>
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<tr>
<td>5. Must be used for subsequent therapy as a single agent after a. First progression (KRAS/NRAS mutant only) or second progression for disease previously treated with FOLFOXIRI (fluorouracil, leucovorin, oxaliplatin, and irinotecan) regimen with or without bevacizumab i. If RAS wild-type, an anti-EGFR therapy (ie Erbitux, Vectibix) must have been tried and failed b. Second progression for disease previously treated with irinotecan- and oxaliplatin-based therapy</td>
</tr>
</tbody>
</table>
Pharmacy Management Drug Policy  
Oncology CRPA Rx Drugs

c. Progression for disease that progressed through all available regimens,
6. Lonsurf will not be approved in combination with any other chemotherapeutic agent as current medical literature does not currently support this
7. Recommended dosage is 35mg/m²/dose orally twice daily on Days 1-5 and days 8-12 of each 28 day cycle. Lonsurf should be taken within 1 hour after completion of morning and evening meals
8. Lonsurf will be approved for 3 months at a time. Further approval will require documentation of stable or improved disease
9. QL of 80 per 28 days for the 20mg/8.19mg tablets and QL of 100 per 28 days for the 15mg/6.14mg tablets

<table>
<thead>
<tr>
<th>Lynparza Capsules (olaparib) - Rx</th>
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<tbody>
<tr>
<td>1. Must be prescribed by an oncologist AND</td>
</tr>
<tr>
<td>2. Must have a diagnosis of BRCA mutated (gBRCAm, as detected through laboratory testing) advanced ovarian cancer AND</td>
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<tr>
<td>3. Must have been treated with three or more prior chemotherapy regimens AND</td>
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<tr>
<td>4. The recommended dosage is 400mg by mouth twice daily</td>
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<tr>
<td>5. QL 480 capsules/30 days</td>
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<table>
<thead>
<tr>
<th>Lynparza Tablets (olaparib) - Rx</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Must be prescribed by an oncologist AND</td>
</tr>
<tr>
<td>2. Must be ≥ 18 years of age AND</td>
</tr>
<tr>
<td>3. Must be used for a diagnosis of BRCA-mutated advanced ovarian cancer and have been treated with three or more prior lines of chemotherapy OR</td>
</tr>
<tr>
<td>4. Must be used as maintenance therapy for patients with recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer who have completed 2 or more lines of platinum-based therapy and are in a complete or partial response to platinum-based chemotherapy OR</td>
</tr>
<tr>
<td>5. Must be used for BRCA mutated, HER2 negative metastatic breast cancer in patients who have been treated with chemotherapy in the neoadjuvant, adjuvant or metastatic setting.</td>
</tr>
<tr>
<td>a. Patients with hormone receptor positive breast cancer should have been treated with a prior endocrine therapy or be considered inappropriate for endocrine therapy</td>
</tr>
<tr>
<td>6. Lynparza tablets will not be approved as first-line treatment of BRCA-mutation positive ovarian cancer</td>
</tr>
<tr>
<td>7. The recommended dosage is 300mg by mouth twice daily</td>
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<tr>
<td>8. QL 120 tablet/30days</td>
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<thead>
<tr>
<th>Mekinist (trametinib) - Rx</th>
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<tbody>
<tr>
<td>1. Must be followed by an oncologist AND</td>
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<tr>
<td>2. Individual must have unresectable or metastatic melanoma AND</td>
</tr>
<tr>
<td>a. Patient must have BRAF V600E or V600K mutation positive melanoma as detected by an FDA approved test AND</td>
</tr>
<tr>
<td>b. Mekinist will be approved as a single agent or in combination with dabrafenib (Tafinlar) OR</td>
</tr>
<tr>
<td>3. Used as adjuvant treatment in combination with dabrafenib (Tafinlar) for patients with BRAF-V600 mutation positive melanoma</td>
</tr>
<tr>
<td>a. Refer to NCCN guidelines for approvable scenarios OR</td>
</tr>
<tr>
<td>4. Used in combination with dabrafenib (Tafinlar) for recurrent or metastatic Non-Small Cell Lung</td>
</tr>
</tbody>
</table>
Cancer (NSCLC)
   a. Must have BRAF V600E mutation-positive tumors OR
   b. Used as first-line or subsequent therapy OR
5. Must have a diagnosis of recurrent central nervous system cancer secondary to metastatic melanoma
   a. Used as a single agent for brain metastases if active against primary tumor (melanoma) OR
6. Used in combination with dabrafenib (Tafinlar) for the treatment of patients with locally advanced or metastatic anaplastic thyroid cancer (ATC) with BRAF V600E mutation and with no satisfactory locoregional treatment options
7. Mekinist will not be approved in combination with any other anti-neoplastic agents (such as Yervoy, or Zelboraf)
8. Mekinist will not be approved for patients who have received prior BRAF inhibitor therapy such as Zelboraf (vemurafenib)
9. The recommended dosing of Mekinist is 2mg orally once daily taken at least 1 hour before or at least 2 hours after a meal.
10. 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.

Mektovi (binimetinib) -- Rx
1. Must be followed by an oncologist AND
2. Must be 18 year of age or older
3. Patient must have BRAF V600E or V600K mutation positive unresectable or metastatic melanoma as detected by an FDA approved test AND
4. Must be used in combination with Braftovi (encorafenib)
5. Based on comparable FDA labeling and NCCN recommendations regarding safety and efficacy, Mektovi will only be authorized if there is a proven contraindication to the following FDA approved treatment regimens: Tafinlar/Mekinist and Zelboraf/Cotellic. Mektovi will not be approved for patients who have experienced progression on prior BRAF/MEK targeted therapy.
6. Other than Braftovi, Mektovi will not be approved or in combination with any other anti-neoplastic agents (such as Yervoy, Mekinist, Tafinlar, Opdivo, Keytruda, Zelboraf, or Cotellic) and Mektovi will not be approved in patients with wild-type BRAF melanoma
7. Recommended dose is 45 mg (3 tablets) orally twice daily in combination with Braftovi (encorafenib)
8. Quantity Limit 180 tablets/30 days
9. Please note: for applicable lines of businesses (Commercial, Exchange, Child Health Plus), 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 Mektovi

Mozobil (plerixafor injection) – Rx or Medical
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

**Nerlynx (neratinib) - Rx**

1. Must be prescribed by an oncologist AND
2. Must have a diagnosis of early-stage HER2-positive breast cancer
   a. Must be used for extended adjuvant treatment following Herceptin-based (trastuzumab-based) therapy AND
3. Recommended dosing is 240mg (6 tablets) orally once daily with food.
4. Approval will be for 12 months. FDA labeling does not support the use of Nerlynx beyond a duration of 12 month
5. QL 180 tablets/30 day
6. Please note: for applicable lines of businesses (Commercial, Exchange, Child Health Plus), 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 Nerlynx

**Nexavar (sorafenib) - Rx**

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
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 (Commercial, Exchange, Child Health Plus), 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

**Ninlaro (ixazomib) - Rx**

1. Must be prescribed by an Oncologist or Hematologist AND
2. Must be prescribed in combination with Revlimid (lenalidomide) and dexamethasone for the treatment of patients with multiple myeloma who have relapsed, been refractory, or intolerant to at least one prior therapy.
3. Recommended starting dose is 4mg taken orally on days 1, 8, and 15 of a 28-day cycle. Dose should be taken at least one hour before or at least two hours after food
4. Patients refractory to prior lenalidomide or proteasome inhibitor (Kyprolis [carfilzomib], Velcade [bortezomib]) therapy will be excluded from coverage of Ninlaro
Pharmacy Management Drug Policy  
Oncology CRPA Rx Drugs

a. Refractory is defined as the absence of improvement on therapy (best response of stable disease or disease progression).
b. Patients who have previously shown progression on Lenalidomide or a proteasome inhibitor will be allowed if they initially showed improvement of disease while on therapy

5. QL 3 capsules/28 days

Odomzo (sonidegib) - Rx

1. Member must be followed by an oncologist or dermatologist AND
2. Must have a diagnosis of locally advanced basal cell carcinoma (BCC) AND
3. Must have BCC that has recurred following surgery or radiation therapy OR is not a candidate for surgery or radiation therapy
4. Recommended dosage is 200mg orally once daily taken on an empty stomach at least 1 hour before or 2 hours after a meal
5. Pregnancy status in females of reproductive potential, serum creatine kinase (CK) levels, and renal function tests should be verified prior to initiating ODOMZO in all patient.
6. Odomzo will not be approved for patients that have previously failed treatment with a hedgehog pathway inhibitor (Erivedge)
7. Quantity limit 30 per 30 days

Pomalyst (pomalidomide) - 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
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. Pomalyst will only be available through a restricted program called the Pomalyst 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 21 tablets per 28st days.

Purixan (6-mercaptopurine) - Rx

1. Must be prescribed by an oncologist AND
2. 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
3. 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.
**Revlimid (lenalidomide) - Rx**

1. Must be written by oncologist or hematologist AND
2. Diagnosis of Myelodysplastic Syndrome (MDS)
   a. First line with 5q deletion cytogenetic 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 cytogenetic abnormality OR
3. Diagnosis of Multiple Myeloma
   a. Primary therapy for active (symptomatic) myeloma or for disease relapsed after 6 months following primary induction therapy with the same regimen - See NCCN compendium for appropriate treatment regimens 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. Therapy for previously treated myeloma for relapse or progressive disease - See NCCN compendium for appropriate treatment regimens OR
4. Diagnosis of Classic Hodgkin Lymphoma
   a. As subsequent systemic therapy as a single agent for relapsed or refractory disease in patients age ≥ 18 years OR
   b. As palliative therapy as a single agent for relapsed or refractory disease in older adults (age >60 years) OR
5. Diagnosis of Non-Hodgkin’s Lymphoma – See NCCN compendium for appropriate types and treatment regimens
6. Quantity limit 30/30 DS or 34/34 DS

**Rubraca (rucaparib) - Rx**

1. Must be prescribed by an oncologist AND
2. Must be 18 years of age AND
3. Must have a diagnosis of BRCA mutated (gBRCAm, as detected through laboratory testing) advanced ovarian cancer and have been treated with 2 or more prior chemotherapy regimens OR
4. Must be used for maintenance treatment of patients with recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in complete or partial response to platinum-based chemotherapy
5. 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)
6. Rubraca will not be approved as:
   a. First-line treatment of BRCA mutation-positive ovarian cancer
   b. Treatment of any other BRCA mutation-positive cancer /tumor
   c. Treatment of wild-type BRCA tumors, including ovarian cancer
7. The recommended dosage is 600mg orally twice daily with or without food.
8. QL 120 tablets/30 days

**Rydapt (midostaurin) - Rx**

1. Must be prescribed by or in consultation with an oncologist or hematologist AND
2. Must be ≥ 18 years of age AND
3. Must have newly diagnosed AML that is FLT3 mutation positive in combination with standard
cytarabine and daunorubicin induction and cytarabine consolidation OR
4. Aggressive systemic mastocytosis, systemic mastocytosis with associated hematological neoplasm, or mast cell leukemia
5. Rydapt will not be approved as single agent therapy for AML
6. Ryadapt will be approved open-ended for a diagnosis of systemic mastocytosis or mast cell leukemia. It will be approved for 6 months for a diagnosis of FLT3+ AML. Further approval will require continued response to therapy and continued use of Ryadapt in combination with standard induction or consolidation therapy
7. QL 240 capsules/30 days

Soltamox (tamoxifen citrate) - 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.

Sprycel (dasatinib) - Rx
1. Must be written by an Oncologist AND
2. Indicated as first-line therapy for patients with Philadelphia chromosome positive chronic phase chronic myeloid leukemia (Ph+ CP-CML) OR
3. Indicated for patients with intolerance or resistance to previous therapy (including Gleevec) in all stages of Chronic Myeloid Leukemia (CML) OR
4. Indicated for patients with intolerance or resistance to at least one previous therapy in Philadelphia chromosome-positive Acute Lymphoblastic Leukemia (ALL)
5. Treatment for progressive gastrointestinal stromal tumors (GIST) with PDGFRα D842V mutation when patient is no longer receiving benefit from imatinib (Gleevec) or sunitinib (Sutent)
6. Quantity limit 60/30 DS or 68/34 DS
7. Please note: for applicable lines of businesses (Commercial, Exchange, Child Health Plus), 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

Stivarga (regorafenib) - Rx
1. Must be seen by an oncologist AND
2. May have a diagnosis of metastatic colorectal cancer (CRC)
   a. KRAS testing must have been completed AND
   b. Must have previously been treated with fluoropyrimidine-, oxaliplatin-, AND irinotecan-based chemotherapy, AND an anti-VEGF therapy (i.e Avastin). If CRC is KRAS wild type, an anti-EGFR (i.e Erbitux, Vectibix) must also have been tried.
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)
4. Stivarga will not be approved in combination with any other chemotherapeutic agent as current
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.
6. Hepatic function should be monitored prior to and during treatment. If hepatotoxicity occurs, interrupt and then reduce or discontinue Stivarga.
7. Initial Stivarga approval will be for 6 months. Further approval will require evidence of continued benefit without progression of disease.
8. QL 84 tablets per 28 days

### Sutent (sunitinib malate) - Rx

1. Must be written by oncologist AND
2. Diagnosis of GIST (gastrostromal 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 or Cometriq are not available or appropriate, OR if there is progression on Capresla or Cometriq.
10. Quantity limits:
    a. 12.5mg: 90 capsules per 30 days
    b. 25mg, 37.5mg, 50mg: 30 capsules per 30 days

### Sylatron (peginterferon alfa-2b) - 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 cytogenetic 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
### Tafinlar (dabrafenib) - Rx

1. Must be followed by an oncologist AND
2. Individual must have unresectable or metastatic melanoma AND
   - a. Must be used as a single agent for the treatment of patients with BRAF V600E mutation as detected by an FDA-approved test OR
   - b. Must be used in combination with trametinib (Mekinist) for the treatment of patients with BRAF V600E or V600K mutations OR
3. Used as adjuvant treatment in combination with trametinib (Mekinist) for patients with BRAF-V600 mutation positive melanoma
   - a. Refer to NCCN guidelines for approvable scenarios OR
4. Used for recurrent or metastatic Non-Small Cell Lung Cancer (NSCLC)
   - a. Must have BRAF V600E mutation-positive tumors AND
   - b. Used as first-line or subsequent therapy AND
   - c. Used in combination with trametinib (Mekinist) or as a single agent if the combination is not tolerated OR
   - d. Used as a single agent for patients with BRAF V600E mutation OR
5. Must have a diagnosis of recurrent Central Nervous system cancer secondary to metastatic melanoma
   - a. Used as a single agent for brain metastases if active against primary tumor (melanoma) OR
6. Used in combination with trametinib (Mekinist) for the treatment of patients with locally advanced or metastatic anaplastic thyroid cancer (ATC) with BRAF V600E mutation and with no satisfactory locoregional treatment options
7. Tafinlar will not be approved in combination with any other anti-neoplastic agents (such as Yervoy or Zelboraf)
8. Dermatologic evaluations should be performed prior to initiation of therapy and every two months
9. Patients with wild-type BRAF melanoma will be excluded
10. Quantity limit of 300/30 days (50mg strength) and 120/30 days (75mg strength)

### Tagrisso (osimertinib) - 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 metastatic epidermal growth factor receptor (EGFR) T790M mutation-positive non-small cell lung cancer (NSCLC), as detected by laboratory testing
   - a. Must have progressed on or after EGFR TKI therapy (Such as Tarceva, Gilotrif, or Iressa) OR
4. Must have a diagnosis of metastatic NSCLC with tumors that have epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 L858R mutations, as detected by laboratory testing
   - a. As first-line treatment
5. Recommended dosage is 80mg orally once daily, with or without food
### Tarceva (erlotinib) – 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. Single agent therapy for recurrence or metastases in patients with a known sensitizing EGFR mutation [Exon 19 deletion or Exon 21 (L858R) substitution] as detected by an FDA approved test as:
   a. First-line therapy **OR**
   b. Maintenance **OR**
   c. Second or greater line treatment after progression following at least one chemotherapy regimen **OR**
5. Tarceva used in combination with other targeted therapies is considered experimental/investigational and will not be covered.
6. Quantity limit of 30/30 or 34/34 DS
7. Please note: for applicable lines of businesses (Commercial, Exchange, Child Health Plus), 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 Capsules(bexarotene) - 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 (Commercial, Exchange, Child Health Plus), 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

### Targretin gel(bexarotene) - Rx

1. Must be prescribed by an oncologist **AND**
2. Must be used for the treatment of cutaneous lesions in patients with cutaneous T-Cell lymphoma (CTCL) Stage IA and IIB, who have refractory or persistent disease after other therapies or who have not tolerated other therapies **OR**
3. Used as first-line topical therapy for chronic or smoldering T-Cell Leukemia/Lymphoma **OR**
4. Used as a single agent or in combination with other limited/localized skin-directed therapies for Mycosis Fungoides (MF)/Sezary Syndrom (SS) OR
   a. Refer to NCCN compendia for a list of approvable uses **OR**
5. Used as topical therapy for primary cutaneous marginal zone or follicle center cutaneous B-Cell lymphoma
6. Targretin gel will not be approved for a diagnosis of psoriasis or AIDS-related Kaposi’s sarcoma

### Tasigna (nilotinib) - Rx

1. Must be written by an oncologist **AND**
2. Diagnosis of chronic or accelerated phase Philadelphia chromosome positive chronic myelogenous leukemia (CML)
### Pharmacy Management Drug Policy

#### Oncology CRPA Rx Drugs

<table>
<thead>
<tr>
<th>Prescription Requirements</th>
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</thead>
<tbody>
<tr>
<td>a. As initial therapy for adult and pediatric patients ≥ 1 years of age OR</td>
</tr>
<tr>
<td>b. After resistance or intolerance to prior therapy that included imatinib for adults ≥ 18 years of age OR</td>
</tr>
<tr>
<td>c. After resistance or intolerance to prior tyrosine-kinase inhibitor (TKI) therapy in pediatric patients ≥ 1 years OR</td>
</tr>
</tbody>
</table>

#### 3. Diagnosis of Philadelphia chromosome-positive acute lymphoblastic leukemia (ALL)

- a. Used for patients who achieve complete response to induction therapy following allogeneic hematopoietic stem cell transplant for consolidation OR
- b. As therapy for relapsed/refractory disease with F317L/V/I/C, T315A, or V299L mutations as a single agent or in combination with an induction regimen not previously used

#### 4. Diagnosis of GIST

- a. Used as treatment for progressive disease when patient is no longer receiving benefit from imatinib (Gleevec), sunitinib (Sutent), or regorafenib (Cyramza)

#### 5. Quantity limit 120/30 DS or 136/34 DS

### Tibsovo (ivosidenib) - Rx

<table>
<thead>
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<th>Requirement</th>
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<tbody>
<tr>
<td>1. Must be ≥ 18 years of age AND</td>
</tr>
<tr>
<td>2. Must be prescribed by an Oncologist or Hematologist AND</td>
</tr>
<tr>
<td>3. Must have a diagnosis of relapsed or refractory Acute Myeloid Leukemia (AML) with an Isocitrate Dehydrogenase-1 (IDH1) mutation</td>
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<tr>
<td>4. Initial approval will be for 6 months. Further approval will require documentation of stable or improved disease</td>
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<tr>
<td>5. QL 60 tablets/30 days</td>
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<tr>
<td>6. Please note: for applicable lines of businesses (Commercial, Exchange, Child Health Plus), 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 Tibsovo</td>
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### Tykerb (lapatinib) - Rx

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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>
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<tr>
<td>a. Used in combination with trastuzumab (Herceptin) or capecitabine (Xeloda) with the following criteria: (level 2A per NCCN)</td>
</tr>
<tr>
<td>1. 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>
</tr>
<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>
</tr>
<tr>
<td>4. Diagnosis of central nervous system cancers</td>
</tr>
<tr>
<td>a. In combination with capecitabine if active against primary tumor (breast) as treatment for brain metastases in patients with recurrent disease.</td>
</tr>
<tr>
<td>5. Quantity limit of 180/30 or 204/34 DS</td>
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### Valchlor (methlorethamine) - Rx

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<tbody>
<tr>
<td>1. Must be prescribed by an oncologist or dermatologist</td>
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<tr>
<td>2. Used for a diagnosis of stage 1A or 1B mycosis fungoides-type cutaneous T-cell lymphoma</td>
</tr>
</tbody>
</table>
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

### Venclexta (venetoclax) - Rx

1. Must be prescribed by an Oncologist **AND**
2. Must have a diagnosis of Chronic Lymphocytic Leukemia (CLL) or small lymphocytic lymphoma (SLL) with or without 17p deletion  
   a. Used in combination with rituximab or as a single agent and must have received at least one prior therapy **OR**
3. Must have a diagnosis of Mantle Cell Lymphoma  
   a. As second-line therapy to achieve a complete response after a partial response to induction therapy or for relapse or progressive therapy
4. 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 (same as Imbruvica)
5. Quantity Limits:
   a. Starting pack: 42 tab/28 days
   b. 50mg tab: 224/28 days
   c. 100mg tab: 112tab/28 days

### Verzenio (abemaciclib) - 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 or4) or metastatic hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative breast cancer  
   a. Used in combination with an aromatase inhibitor (ie. anastrozole, letrozole, exemestane) as initial endocrine-based therapy **OR**
   b. Used in combination with fulvestrant for women with disease progression following endocrine therapy **OR**
   c. Used as monotherapy for patients with disease progression following endocrine therapy and prior chemotherapy in the metastatic setting
4. Recommended dose is 150mg twice daily when used in combination with fulvestrant or an aromatase inhibitor and 200mg twice daily when used as monotherapy
5. Quantity limit of 60 tablets per 30 days
6. **Please note:** for applicable lines of businesses (Commercial, Exchange, Child Health Plus), 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 Verzenio

### Votrient (pazopanib) - Rx
### Pharmacy Management Drug Policy
#### Oncology CRPA Rx Drugs

| 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 (Commercial, Exchange, Child Health Plus), 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 (crizotinib) - Rx |
| 1. Must be followed by an oncologist AND |
| 2. Individual must have locally advanced or metastatic non-small cell lung cancer (NSCLC) AND |
| 3. Patient must have NSCLC that is anaplastic lymphoma kinase (ALK) positive or ROS1 positive as detected by an FDA-approved test. OR |
| 4. Diagnosis of soft tissue sarcoma – inflammatory myofibroblastic tumor (IMT) with ALK translocation |
| 5. single-agent therapy |
| 6. The recommended dose of Xalkori is 250mg taken orally twice daily. |
| 7. Patients should be monitored for pulmonary symptoms indicative of pneumonitis. |
| 8. Liver function should be monitored once a month and as clinically indicated. |
| 9. Treatment should be permanently discontinued for any occurrence of pneumonitis, severe QTc prolongation, or moderate to severe ALT or AST/Bilirubin elevation. |
| 10. 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. |
| 11. Quantity limit of 60 per 30 days. |

| Xermelo (telotristate ethyl)- Rx |
| 1. Must be prescribed by an oncologist, hematologist, or endocrinologist AND |
| 2. Must be 18 years of age or older AND |
| 3. Must have a diagnosis of metastatic neuroendocrine tumor and carcinoid syndrome associated diarrhea AND |
| 4. Must have continued diarrhea symptoms despite at least a 3 month trial of somatostatin analogue therapy (octreotide or lanreotide) AND |
| 5. Xermelo must be prescribed in combination with a somatostatin analogue therapy |
| 6. QL 90 tablets/30 day |

| Xtandi (en zalutamide) - Rx |
| 1. Must be prescribed by a urologist or oncologist AND |
| 2. Must have a diagnosis of castration-resistant prostate cancer |
| 3. 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. |
| 4. 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.

5. Quantity limit of 120/30 days.

6. *Please note:* for applicable lines of businesses (Commercial, Exchange, Child Health Plus), 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

### Yonsa (abiraterone acetate)- 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 **AND**
3. Must be used in combination with methylprednisolone **AND**
4. Must have had previous trial and intolerance to Zytiga **AND**
5. The safety of Yonsa in patients with LVEF<50% or NYHA Class III or IV heart failure has not been established and therefore will not be approved.
6. Recommended dosage is 500mg (four 125mg tablets) administered once daily in combination with methylprednisolone 4mg administered orally twice daily

7. Patients with moderate base line hepatic impairment (Child-Pugh Class B) should be started at a reduced dose of 125mg once daily. Dose should be increased to 500mg twice a day for patients on CYP3A4 inducers for the co-administration period. Reduce dose back to the previous dose and frequency once concomitant strong CYP3A4 inducer is discontinued

8. Quantity limit of 120/30days. A QL of 240/30 days will be allowed if documentation is received that a strong CYP3A4 inducer must be co-administered

9. *Please note:* for applicable lines of businesses (Commercial, Exchange, Child Health Plus), 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 Yonsa

### Zejula (niraparib) - Rx

1. Must be prescribed by an Oncologist **AND**
2. Must be ≥ 18 year of age **AND**
3. Must have a diagnosis of recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in a complete or partial response to platinum-based chemotherapy
   a. Must have completed 2 or more lines of platinum-based therapy and are in a complete or partial response (platinum-sensitive disease) to most recent platinum-based regimen
4. Recommended dosage is 300mg once daily with or without food
5. QL 90 capsules/30 days
6. *Please note:* for applicable lines of businesses (Commercial, Exchange, Child Health Plus), 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 Zejula

### Zelboraf (vemurafenib) - Rx

10. 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**
11. Used for brain metastases if active against the primary tumor (BRAF V600E melanoma) for recurrent disease. **OR**
12. Must have NSCLC with BRAF mutations **AND**
13. Must be followed by an oncologist
14. The recommended dosing of Zelboraf is 960mg given twice daily.
15. Dermatologic evaluations should be performed prior to initiation of therapy and every two months.
16. LFTs and bilirubin should be monitored prior to initiation of treatment and monthly.
17. 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.
18. Patients with wild-type BRAF melanoma will be excluded
19. Individuals who are approved for coverage of Zelboraf will be excluded from coverage of Yervoy.
20. Quantity limit of 240/30 days.

**Zolinza (vorinostat) - 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. Quantity limit 120/30 DS or 136/34 DS

**Zydelig (idelalisib) - 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 (ceritinib) - 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
   a. Used as first line therapy **OR**
   b. Subsequent therapy following disease progression on first-line therapy with Xalkori, or for patients who are intolerant to Xalkori, except in cases of symptomatic systemic disease with an isolated lesion **OR**
   c. Continuation of therapy if used first line, except in cases of asymptomatic progression with rapid radiologic progression of threatened organ function or symptomatic systemic progression with multiple lesions **OR**
3. Must have a diagnosis of recurrent or metastatic NSCLC disease in patients with ROS1 arrangement-positive tumors
a. As first-line therapy OR
4. Used for inflammatory myofibroblastic tumor (IMT) with ALK translocation
   a. As a single agent OR
5. Recommended dosage is 450mg once daily with food
6. Initial approval will be for 6 months. Additional approval will require submission of progress notes demonstrating stable/improved disease.
7. QL of 90 capsules/30 days.

**Zytiga (abiraterone acetate) - Rx**

10. Must be prescribed by a urologist or oncologist
11. Must have a diagnosis of castration-resistant prostate cancer with radiographic evidence of progressive metastatic disease OR
12. Must have a diagnosis of high risk castration-sensitive prostate cancer AND
13. Must be used in combination with prednisone
14. The safety of Zytiga in patients with LVEF<50% or NYHA Class III or IV heart failure has not been established and therefore will not be approved.
15. Patients with moderate base line hepatic impairment (Child-Pugh Class B) should be started at a reduced dose of 250mg once daily
16. Quantity limit of 120/30days for 250mg tablet, 60/30 days for 500mg tablet
17. **Please note:** for applicable lines of businesses (Commercial, Exchange, Child Health Plus), 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

**UPDATES:**

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<th>Date</th>
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<td>10/18</td>
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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-

Mozobil-

Nexavar-

Zelboraf-

Zelboraf-