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: 4/2/2020

If the member's subscriber contract excludes coverage for a specific service or prescription drug, it is not covered under that contract. In such cases, medical or drug policy criteria are not applied. Medical or drug policies apply to commercial, SafetyNet, and Health Care Reform products only when a contract benefit for the specific service exists.

POLICY:

The oncology drug Clinical Review Prior-Authorization (CRPA) process is designed to ensure that newly approved (FDA) prescription drugs are used appropriately in cases where a drug poses potential efficacy, quality, toxicity, or utilization concerns for the members and the Health Plan. In addition, this policy may be used for medications that have significant concerns about safety or inappropriate use, but do not warrant a stand-alone policy. The FLRx Pharmacy Management clinical team reviews the oncology drugs falling into these categories under the process of Clinical Review Prior Authorization (CRPA). A Letter of Medical Necessity (LOMN), Exception Form, or Prior Authorization Form completion is required for consideration of drug coverage under this policy.

Prior Authorization criteria listed in this policy is based on FDA labeled indication or NCCN level of evidence 1 or 2A. For requests that do not meet the policy criteria defined below, please refer to the Off-Label Use of FDA Approved Drugs policy.

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 approved 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.
    b. Recertifications will be evaluated for the regimen that is currently being prescribed (monotherapy, combination therapy, etc). If this differs from the initial review, the request will be reviewed based on the level of evidence that is available for the current regimen.
    c. 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

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Approval time periods

Line of Business	Initial approval	Continued approval
Medicaid	2 years	2 years
Commercial/Exchange	2 years	2 years

CURRENT CRPA DRUGS:

DRUG NAME (Rx benefit)
Authorization Criteria
Afinitor and Afinitor Disperz (everolimus and everolimus tablets for oral suspension) - Rx
1. Prescribed by an Oncologist **AND** 2. Must be ≥ 18 years of age **AND** 3. **For Afinitor 2.5 mg, 5 mg, and 7.5 mg, there must be a contraindication to use of generic everolimus tablets in these strengths AND** 4. Diagnosis of Renal Cell Carcinoma a. As a single agent or in combination with lenvatinib (Lenvima) as subsequent therapy for clear cell histology **OR**

   b. as single-agent systemic therapy for non-clear cell histology OR
   c. in combination with lenvatinib (Lenvima) as systemic therapy for non-clear cell histology (useful in certain circumstances) OR
   d. in combination with bevacizumab (Avastin) as systemic therapy for non-clear cell histology (useful under certain circumstances) **OR**
5. 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**
6. Diagnosis of Waldenstrom's macroglobulinamia/lymphoplasmacytic lymphoma, as a single-agent salvage therapy for disease that does not respond to primary therapy or for progressive or relapsed disease **OR**
7. Diagnosis of renal angiomyolipoma (non-cancerous kidney tumors) and tuberous sclerosis complex (TSC) not requiring immediate surgery. **OR**
8. Diagnosis of PEComa, angiomyolipoma, Lymphangioleiomyomatosis (LAM) **OR**
9. Diagnosis of advanced hormone receptor-positive, HER2-negative breast cancer (advanced HR+, HER2- BC) in postmenopausal women.
   a. Must be used in combination with exemestane, fulvestrant, or tamoxifen after failure of treatment with a nonsteroidal aromatase inhibitor (such as letrozole or anastrozole). **OR**
10. Diagnosis of Classical Hodgkin Lymphoma
   a. As subsequent systemic therapy as a single agent for refractory or relapsed disease **OR**
   b. As palliative therapy as a single agent for older adults (age >60) **OR**
11. Diagnosis of osteosarcoma (bone cancer)
   a. Used as second-line therapy in combination with sorafenib **OR**
12. Diagnosis of Thymoma/Thymic Carcinoma
   a. Used as second-line therapy as a single agent **OR**
13. Diagnosis of Gastrointestinal Stromal Tumors (GIST)
   a. Used in combination with either imatinib (Gleevec), sunitinib (Sutent), or regorafenib (Stivarga) for disease progression after single-agent therapy with imatanib, sunitinib, or regorafenib. **OR**
14. Diagnosis of Papillary, Follicular, or Hurthle Cell Thyroid Carcinoma
   a. 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 persistent disease or distant metastatic disease **OR**
15. Diagnosis of endometrial carcinoma
   a. Refer to NCCN compendia for approved scenarios **OR**
16. Diagnosis of subependymal giant cell astrocytoma (SEGA) associated with tuberous sclerosis complex (TSC) which cannot be treated with surgery **AND**
   a. 1 year of age or older **OR**
17. Diagnosis of tuberous sclerosis complex (TSC)-associated partial-onset seizures (Afinitor Disperz only) **AND**
   a. 2 years of age or older
18. Afinitor will not be covered for the treatment of patients with functional carcinoid tumors
19. Quantity limit of 30/30 DS for all strengths. Requests for everolimus 5 mg at a quantity of 60/30 require adequate justification as to why Afinitor 10 mg cannot be used (approval of generic everolimus will load approval for brand Afinitor 10 mg).
20. Approval will be for 1 year at a time. Recertification will require documentation of stable disease without progression, and depending on diagnosis, which may be BSA-based, review of dosing regimen to ensure dosing efficiency.

Alecensa (alectinib) - Rx

1. Must be prescribed by an Oncologist **AND**
2. Must be ≥ 18 years of age **AND**
3. Must have a diagnosis of anaplastic lymphoma kinase (ALK)-positive, metastatic non-small cell lung cancer (NSCLC)
4. Recommended dosage is 600mg twice daily, administered with food
5. Initial approval will be for 6 months. Additional approval every 6 months will require submission of progress notes demonstrating stable/improved disease
6. QL 240 capsules/30 days

Alunbrig (brigatinib) - Rx

1. Must be followed by an Oncologist **AND**
2. Must be ≥ 18 years of age **AND**
3. Must have a diagnosis of anaplastic lymphoma kinase (ALK)-positive, metastatic non-small cell lung cancer (NSCLC)
4. The recommended dosage of Alunbrig is 90 mg once daily for the first 7 days and if tolerated, increase to 180mg orally once daily

Ayvakit (avapritinib) – Rx

1. Must be prescribed by an oncologist **AND**
2. Must be ≥ 18 years of age **AND**
3. Must have a diagnosis of unresectable or metastatic GIST (gastrointestinal stromal tumor)
    a. With platelet-derived growth factor receptor alpha (PDGFRA) exon 18 mutation, including PDGFRA D842V mutations, as primary treatment, postoperative treatment, or continued treatment for limited progression **OR**
    b. With disease progression after therapy with Gleevec (imatinib), Sutent (sunitinib), and Stivarga (regorafenib)
4. QL 30 tablets/30 days
5. *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 Ayvakit

Balversa (erdafitinib) – Rx

1. Must be prescribed by an Oncologist **AND**
2. Must be ≥ 18 years of age **AND**
3. Must be used as a single agent for locally advanced or metastatic urothelial carcinoma
    a. Must have susceptible FGFR3 or FGFR2 genetic alterations as demonstrated by laboratory testing
        i. FGFR3 gene mutations include: R248C, S249C, G370C, Y373C
        ii. FGFR gene fusions include: FGFR3-TACC3, FGFR3BAIAP2L1, FGFR2-BICC1, FGFR2-CASP7 **AND**
    b. Must have progressed during or following at least one line of prior platinum-containing chemotherapy (including within 12 months of neoadjuvant or adjuvant platinum-containing chemotherapy)
4. Recommended initial dosage is 8 mg orally once daily with a dose increase to 9 mg daily based upon laboratory parameters and tolerability
5. Initial approval will be for a period of 6 months. Subsequent 6-month approvals will require demonstration of improved or stable disease
6. Quantity limits:
    a. 5mg: 28 tab/28 days

b. 4mg: 56 tab/28 days
c. 3mg: 84 tab/28 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 Balversa

Bosulif (bosutinib) - Rx

1. Must be written by an oncologist **AND**
2. Must be ≥ 18 years of age **AND**
3. Must have a diagnosis of chronic, accelerated, or blast phase Philadelphia chromosome positive (Ph+) chronic myeloid leukemia (CML) with resistance or intolerance to prior therapy
    a. Used as a single agent **OR**
4. Must have a diagnosis of newly-diagnosed chronic phase Ph+ chronic myelogenous leukemia (CML)
    a. Used as a single agent **OR**
5. As primary treatment of CML in accelerated or blast phase
    a. As a single agent for accelerated phase CML **OR**
    b. As single agent or in combination with induction therapy for myeloid blast phase CML **OR**
    c. In combination with induction or steroids for lymphoid blast phase CML **OR**
6. Indicated for post- allogenic hematopoietic stem cell transplant (HCT) in CML patients
    a. Used for at least 1 year in patients with prior accelerated or blast phase with complete cytogenetic response **OR**
    b. As follow up therapy in patients with molecular relapse following complete cytogenetic response **OR**
    c. As follow up therapy in patients with relapse or those not in complete cytogenetic response **OR**
7. Indicated for relapsed/refractory Philadelphia chromosome-positive ALL
    a. As a single agent **OR**
    b. In combination with an induction regiment not previously given
8. 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
9. Approval will be for 1 year at a time. Further approval will require documentation of stable disease and the absence of disease progression.
10. 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 years of age **AND**
3. Must have a diagnosis of unresectable or metastatic melanoma that is BRAF V600E or V600K mutation positive **AND**
    a. Must be used in combination with Mektovi (binimetinib) **OR**
4. Must be used for unresectable advanced or metastatic colorectal cancer that is BRAF V600E mutation positive
    a. As subsequent therapy in combination with either Erbitux (cetuximab) or Vectibix (panitumumab) for disease not previously treated with Erbitux or Vectibix, with or without Mektovi (binimetinib) **AND** for disease that was previously treated with:
        i. oxaliplatin-based therapy without irinotecan **OR**

ii. irinotecan-based therapy without oxaliplatin **OR**
iii. FOLFOXIRI (fluorouracil, leucovorin, oxaliplatin, and irinotecan) regimen **OR**
iv. a fluoropyrimidine without irinotecan or oxaliplatin followed by FOLFOX (fluorouracil, leucovorin, and oxaliplatin) or CapeOX (capecitabine and oxaliplatin) with or without bevacizumab

5. The recommended dose of Braftovi is 450mg orally once daily in combination with Mektovi
6. Braftovi will not be approved in patients with wild-type BRAF melanoma
7. Quantity Limit 180/30 days for 75mg capsule and 120/30 days for 50mg capsules
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 Braftovi

Brukinsa (zanubrutinib) - Rx

6. Must be prescribed by an oncologist/hematologist **AND**
7. Must be ≥ 18 years of age **AND**
8. Must have a diagnosis of mantle cell lymphoma and have received at least one prior therapy
9. Patients who have had prior treatment with a BTK inhibitor (i.e Imbruvica, Calquence) will be excluded from coverage
10. QL 120 capsules/30 days

Cabometyx (cabozantinib tablets) – Rx

11. Must be prescribed by an oncologist **AND**
12. Must be ≥ 18 years of age **AND**
13. Must have a diagnosis of advanced renal cell carcinoma (RCC) **OR**
14. Must have a diagnosis of Non-Small Cell Lung Cancer (NSCLC) with RET gene arrangements as demonstrated by an FDA approved test **OR**
15. Must have a diagnosis of hepatocellular carcinoma (HCC) and have been previously treated with Nexavar (sorafenib)
16. Drug will be approved for 6 months at a time. Additional coverage will require submission of progress notes documenting stable or improved disease
17. QL 30 tablets/30 days
18. *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 (acalabrutinib) – Rx

1. Must be prescribed by an oncologist/hematologist **AND**
2. Must be ≥ 18 years of age **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 will be excluded from coverage **OR**
4. Must have a diagnosis of CLL (chronic lymphocytic leukemia) or SLL (small lymphocytic leukemia)
    a. Used as a single agent or in combination with Gazyva (obinutuzumab)
5. Approved dosing is 100 mg by mouth every 12 hours
6. 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 of age **AND**
3. Must have a diagnosis of symptomatic or progressive medullary thyroid cancer with unresectable (non-operable) locally advanced or metastatic disease **OR**
4. Must have a diagnosis of Hurthle cell carcinoma, papillary carcinoma, or follicular carcinoma
    a. For unresectable locoregional recurrent disease or distant metastatic disease
    b. Consider if clinical trials or other systemic therapies are not available or appropriate for treatment of progressive and/or symptomatic iodine-refractory **OR**
5. Must have a diagnosis of Non-Small Cell Lung Cancer (NSCLC) with RET gene arrangements as demonstrated by an FDA approved test
6. The following warnings/precautions should be observed when prescribing Caprelsa
    a. Hypocalcemia, hypokalemia and/or hypomagnesemia should be corrected prior to initiating therapy
    b. Drugs known to prolong the QT interval should be avoided
    c. 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
    d. 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.
7. Normal dosing is 300mg once a day
8. Quantity limit of 60/30 for 100mg tablet and 30/30 of 300mg tablet

Cometriq (cabozantinib capsules) - Rx

1. Must be followed by an oncologist **AND**
2. Must be ≥ 18 years of age **AND**
3. Must have a diagnosis of progressive metastatic medullary thyroid cancer **OR**
4. Must have a diagnosis of Hurthle cell carcinoma, papillary carcinoma, or follicular carcinoma
    a. For unresectable locoregional recurrent disease or distant metastatic disease
    b. Consider if clinical trials or other systemic therapies are not available or appropriate for treatment of progressive and/or symptomatic iodine-refractory **OR**
5. Must have a diagnosis of Non-Small Cell Lung Cancer (NSCLC) with RET gene arrangements as demonstrated by an FDA approved test
6. Gastrointestinal perforations, fistula formation, and severe, sometimes fatal hemorrhage has occurred with the use of Cometriq. Do not administer in patients with severe hemorrhage.
7. 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 prescribed by a hematologist or oncologist **AND**
2. Must be ≥ 18 years of age **AND**
3. Must have a diagnosis of relapsed or refractory chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL) and Copiktra used as a single agent
    a. Patients will be excluded from coverage of Copiktra if they have had <u>any</u> of the following:
        i. Prior exposure ot a PI3K inhibitor (i.e Zydelig) **OR**
        ii. Prior autologous transplant within 6 months or prior allogeneic transplant **OR**
4. Must have relapsed or refractory folicular 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
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. Must be ≥ 18 years of age **AND**
3. Must have a diagnosis of BRAF V600E or V600K mutation positive unresectable or metastatic melanoma as detected by an FDA approved test **AND**
    a. 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 if 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.

Daurismo (glasdegib)- Rx

1. Must be prescribed by an oncologist or hematologist **AND**
2. Must be ≥ 18 years of age **AND**
3. Must have a diagnosis of acute myeloid leukemia (AML)
    a. Must be newly diagnosed **AND**
    b. Must be ≥ 75 years of age OR have significant comorbid conditions (defined as severe cardiac disease, ECOG performance status ≥ 2, or baseline creatinine >1.3 mg/dL or another comorbidity) **AND**
    c. Must be used in combination with low-dose cytarabine (LDCA)
4. Recommended dosage is 100mg orally, once daily in combination with cytarabine 20mg subcutaneously twice daily on days 1-10 of each 28-day cycle
5. Initial approval will be for 6 months. Subsequent approval for 6 months at a time will required documentation of stable/improved disease
6. QL of 30 tablets per 30 days for 100mg tablets and QL of 60 tablets per 30 days for 25 mg tablets
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 Daurismo

Erivedge (vismodegib) - Rx

1. Must be prescribed by an oncologist or dermatologist **AND**
2. Must be ≥ 18 years of age **AND**
3. Individual must have a diagnosis of metastatic basal cell carcinoma **OR**

4. Must have a diagnosis of locally advanced basal cell carcinoma that has recurred following surgery **OR**
5. Must have 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)
6. Recommended dosing is 150mg PO daily until disease progression or unacceptable toxicity.
7. Pregnancy statues should be determined within 7 days prior to initiation of treatment in females with reproductive potential.
8. Erivedge will not be approved for patients that have previously failed treatment with a hedgehog pathway inhibitor (Odomzo)
9. Quantity limit of 30 per 30 days.

Erleada (apalutamide) - Rx

1. Must be prescribed by a urologist or oncologist **AND**
2. Must be ≥ 18 years of age **AND**
3. Must have a diagnosis of non-metastatic, castration-resistant prostate cancer
    a. Must have had serious side effects with Nubeqa **AND**
    b. If patient has not had a bilateral orchiectomy, must also use an LHRH agonist or antagonist in combination **OR**
4. Must have a diagnosis of metastatic, castration-sensitive prostate cancer
    a. Must have had serious side effects or drug failure with abiraterone acetate 250 mg **AND**
    b. If patient has not had a bilateral orchiectomy, must also use an LHRH agonist or antagonist in combination
5. Recommended dosing is 240mg (four 60mg tablets) administered orally once daily
6. Quantity limit of 120/30 days

Farydak (panobinostat) - Rx

1. Must be prescribed by an oncologist **AND**
2. Must be ≥ 18 years of age **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**
    a. Must be used in combination with Velcade (bortezomib) and dexamethasone **OR**
    b. Must be used in combination with Revlimid (lenalidomide) and dexamethasone **OR**
    c. Must be used in combination with Kyprolis (carfilzomib)
4. 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
5. 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) **OR**
    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

6. 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
7. QL of 6 capsules per 21 days

Gilotrif (afatinib) - Rx

1. Prescribed by an oncologist **AND**
2. Must be ≥ 18 years of age **AND**
3. Must have a diagnosis of metastatic non-small cell lung cancer (NSCLC)
   a. Must be used as first line therapy
   b. Tumor must have a known sensitizing EGFR mutation [Exon 19 deletion or Exon 21 (L858R) substitution] as detected by an FDA approved test **OR**
4. Must have a diagnosis of metastatic, squamous NSCLC with progression after platinum-based chemotherapy
5. Recommended dosage is 40mg orally once daily
6. Gilotrif used in combination with other targeted therapies is considered experimental/investigational and will not be covered.
7. QL 30/30 days.

Hycamtin (topotecan HCl) - Rx

1. Must be prescribed by an Oncologist **AND**
2. Must be ≥ 18 years of age **AND**
3. Must have a diagnosis of carcinoma of the cervix in combination with cisplatin in patients not amenable to curative treatment with surgery and/or radiation therapy **OR**
4. Must have a diagnosis of metastatic carcinoma of the ovary after failure of initial or subsequent chemotherapy **OR**
5. Must have a diagnosis of relapsed 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 Hycamtin.
6. Quantity limit of 35 capsules per 30 days

Ibrance tablets (palbociclib) - Rx

1. Must be prescribed by an oncologist **AND**
2. Must be ≥ 18 years of age **AND**
3. Must have a diagnosis of advanced or metastatic (stage 3 or 4) estrogen receptor-positive, human epidermal growth factor receptor 2-negative (ER+/HER2-) breast cancer **AND**
   a. For post-menopausal women or pre-menopausal women treated with ovarian ablation/suppression **AND**
   b. Used in combination with an aromatase inhibitor (anastrozole, letrozole, exemestane) or fulvestrant for patients who have progressed on endocrine therapy for advanced disease
      i. Patients with previous neo-adjuvant or adjuvant therapy will still qualify for the above if 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 if there is no evidence of progression on current endocrine therapy
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 tablets per 28 days

Iclusig (ponatinib) - Rx

1. Must be prescribed by an oncologist or a hematologist AND
2. Must be ≥ 18 years of age **AND**
3. Must have a diagnosis of T315I-positive chronic myeloid leukemia (CML) **OR**
4. Must have a diagnosis of CML **AND** must have had failure or intolerance to all other tyrosine kinase inhibitor (TKI) therapies (Gleevec, Tasigna, Sprycel, Bosulif) **OR**
5. Must have a diagnosis of Ph+ ALL
    a. For patients with T3151-positive disease **OR**
    b. Used as a single agent for relapsed/refractory disease **OR**
    c. Used in combination with an induction regimen not previously given for relapsed/refractory disease **OR**
    d. Used as maintenance therapy in combination with vincristine and prednisone with or without methotrexate and mercaptopurine
6. Recommended dosage is 45mg taken orally once daily with or without food.
7. Arterial/venous thrombosis, hepatotoxicity, and heart failure have occurred in Iclusig-treated patients. Interrupt and consider discontinuation of Iclusig if these occur.
8. QL of 30 tablets/30 days for 45mg tablet, 60tablets/30days for 15mg tablet.

Idhifa (enasidenib) - Rx

1. Must be prescribed by an Oncologist or Hematologist **AND**
2. Must be ≥ 18 years of age **AND**
3. Must have a diagnosis of relapsed or refractory Acute Myeloid Leukemia (AML) with an Isocitrate Dehydrogenase-2 (IDH2) mutation
4. Initial approval will be for 6 months. Further approval will require documentation of stable or improved disease
5. QL 30 tablets/30 days

Imbruvica (ibrutinib) - Rx

1. Must be prescribed by an oncologist/hematologist **AND**
2. Must be ≥ 18 years of age **AND**
3. Must have a diagnosis of mantle cell lymphoma (MCL) and have received at least one prior therapy **AND**
    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**
    b. Second-line as a single agent **OR**
4. Must have a diagnosis of Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma (CLL/SLL) (with or without 17p deletion) **AND**
    a. Used as a single agent for first-line therapy or for relapsed/refractory disease **OR**
5. Must have a diagnosis of Waldenstrom's Macroglobulinemia/Lymphoplasmacytic Lymphoma
    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**
6. Must have a diagnosis of nodal or splenic marginal zone lymphoma (MZL) **AND**
    a. Used as second-line or subsequent therapy for refractory or progressive disease
7. Must have a diagnosis of chronic graft versus host disease (cGVHD) after failure of one or more lines of systemic therapy **OR**
8. Must have a diagnosis of B-cell Lymphoma (diffuse large B-cell, high-grade B-cell, AIDS-related B-cell) and not a candidate for transplant **AND**

a. Used as second line or subsequent therapy for partial response, no response, relapsed, progressive, or refractory disease **OR**

9. Must have a diagnosis of gastric MALT lymphoma or non-gastric MALT lymphoma **AND**
    a. Used a second-line or subsequent therapy for recurrent or progressive disease **OR**
10. Must have a diagnosis of follicular lymphoma **AND**
    a. Used as a single agent as second line or subsequent therapy for refractory or progressive disease **OR**
11. Must have a diagnosis of Hairy Cell Leukemia **AND**
    a. Used as single agent therapy **AND**
12. **Requests for Imbruvica 140mg tablets or 280mg tablets will NOT be approved unless there is a contraindication to Imbruvica 140mg capsules**
13. 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.
14. 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
15. 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. Must be followed by an oncologist **AND**
2. Must be ≥ 18 years of age **AND**
3. Individual must have a diagnosis of advanced (relapsed or stage 3) renal cell carcinoma (RCC)
    a. If clear cell histology:
        i. First line therapy in combination with Keytruda (pembrolizumab) or Bavencio (avelumab)
        ii. Used as single agent as subsequent therapy
    b. If non-clear cell histology:
        i. Used as single agent for systemic therapy **OR**
4. Can be considered for Thyroid Carcinoma (Hurthle Cell Carcinoma, Follicular Carcinoma, Papillary Carcinoma) 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 persistent disease or distant metastatic disease **AND**
5. Patients with untreated brain metastasis or recent active gastrointestinal bleeding will be excluded.
6. The recommended starting dose is 5mg twice daily. Dose increase or reduction is recommended based on individual safety and tolerability.
7. 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.
8. Monitoring of thyroid function, liver enzymes, and for proteinuria should occur before the initiation of Inlyta and periodically throughout treatment.
9. Quantity limit of 120/30 for 5mg tablet and 540/30 for 1 mg tablet.
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 Inlyta

Inrebic (fedratinib) – Rx

1. Must be prescribed by an oncologist/hematologist **AND**
2. Must be ≥ 18 years of age **AND**
3. Must have a diagnosis of intermediate or high-risk myelofibrosis, including primary and secondary (post-polycythemia vera or post-essential thrombocytopenia), for non-transplant

candidates and platelets ≥50K
    a. Must have had serious side effects or drug failure with Jakafi **OR**
4. Must have a diagnosis of MF (myelofibrosis)-accelerated phase or MF-blast phase/acute myeloid leukemia, for the improvement of splenomegaly and other disease related symptoms
5. Recommended dose is 4 x 100 mg capsules once daily with or without food
6. Quantity limit of 120 capsules per 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 Inrebic

Iressa (gefitinib) - Rx

8. Must be prescribed by an oncologist **AND**
9. Must be ≥ 18 years of age **AND**
10. Must be prescribed for patients with recurrent, advanced, or metastatic non-small cell lung cancer (NSCLC)
    a. Tumor must have known sensitizing EGFR mutation [Exon 19 deletion or Exon 21 (L858R) substitution] as detected by an FDA approved test **AND**
    b. Must be used as single agent for first-line therapy
11. Recommended dose is 250 mg orally, once daily with or without food
12. Quantity limit of 30 tablets per 30 days

Jakafi (ruxolitinib) - Rx

1. Must be written by an Oncologist/Hematologist **AND**
2. Must be ≥ 18 years of age and have diagnosis of intermediate or high-risk myelofibrosis, including primary myelofibrosis, post-polycythemia vera myelofibrosis, and post-essential thrombocythemia myelofibrosis **OR**
3. Must be ≥ 18 years of age and have a diagnosis of polycythemia vera and had an inadequate response to or are intolerant of hydroxyurea **OR**
4. Must be ≥ 12 years of age and have a diagnosis of steroid-refractory acute graft-versus-host disease
5. Patients who meet criteria for approval for treatment with Jakafi will be approved for 12 months. Recertification will require documentation of stable disease.
6. 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 **AND**
3. There is a proven contraindication to the following FDA approved drugs: Ibrance AND Verzenio
    a. Exception – Kisqali will be authorized for treatment of advanced or metastatic (stage 3 or 4) hormone receptor-positive, human epidermal growth factor receptor 2negative (HR+/HER2-) breast cancer (in combination with an aromatase inhibitor) in **perimenopausal** women as initial endocrine-based therapy
4. For individuals with a diagnosis of advanced or metastatic (stage 3 or 4) hormone receptor-positive, human epidermal growth factor receptor 2-negative (HR+/HER2-) breast cancer **AND** Verzenio and Ibrance is contraindicated, the following criteria is applicable:
    a. For post-menopausal women or pre-menopausal women treated with ovarian ablation/suppression **AND**
    b. Used in combination with an aromatase inhibitor (anastrozole, letrozole, exemestane) or fulvestrant 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 if 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 if there is no evidence of progression on current endocrine therapy

5. 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
6. Quantity limit of Kisqali: 63 capsules per 28 days
7. 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

Lenvima (lenvatinib) - Rx

1. Must be prescribed by an oncologist or endocrinologist **AND**
2. Must be ≥ 18 years of age **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:
   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 **OR**
4. Must have a diagnosis of medullary thyroid carcinoma with recurrent or distant metastases
   a. If clinical trials, Caprelsa (vandetanib), or Cometriq (cabozantinib) are not available or appropriate **OR**
   b. If there is progression on Caprelsa (vandetanib) or Cometriq (cabozantinib)
5. Must have a diagnosis of metastatic anaplastic thyroid carcinoma
   a. Used as single agent as first line therapy or second line therapy
6. Must have a diagnosis of advanced 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**
7. Must have a diagnosis of unresectable hepatocellular carcinoma (HCC)
   a. Used as first-line treatment **OR**
8. Must have a diagnosis of advanced endometrial cell carcinoma that is not microsatellite instability high (MSI-H) or mismatch repair deficient (dMMR)
   a. Must be used in combination with Keytruda (pembrolizumab) **AND**
   b. Must have disease that has progressed following at least one prior systemic therapy **AND**
   c. Must not be a candidate for curative surgery or radiation
9. 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 capsuels/30 days

h. 4mg pack = 30 capsules/30 days

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 Lenvima

Lonsurf (trifluridine and tipiracil) - Rx

1. Must be prescribed by an oncologist **AND**
2. Must be ≥ 18 years of age **AND**
3. Must have a diagnosis of metastatic colorectal cancer **AND**
    a. KRAS testing must have been completed **AND**
    b. Must be used for subsequent therapy as a single agent after 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 **OR**
    c. Progression for disease that progressed through all available regimens besides Stivarga (regorafenib) **OR**
4. Must have a diagnosis of metastatic gastric or gastroesophageal junction adenocarcinoma previously treated with at least 2 prior lines of chemotherapy that included a fluoropyrimidine, a platinum, either a taxane or irinotecan, and if appropriate, HERT2/neu-targeted therapy
    a. Used as a single agent
5. Lonsurf will not be approved in combination with any other chemotherapeutic agent as current medical literature does not currently support this
6. Recommended dosage is 35mg/m^2/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
7. Lonsurf will be approved for 3 months at a time. Further approval will require documentation of stable or improved disease
8. 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

Lorbrena (lorlatinib) – Rx

1. Must be prescribed by an oncologist **AND**
2. Must be ≥ 18 years of age **AND**
3. Must have a diagnosis of ALK positive metastatic non-small cell lung cancer (NSCLC) as demonstrated by an FDA approved test
    a. Used as a single agent **AND**
    b. Must have progressed on Xalkori (crizotinib) and at least one other ALK inhibitor (Alcensa (alectinib), Alunbriq (brigatinib), or Zykadia (ceritinib)) **OR**
    c. Must have progressed on Alcensa (alectinib), Alunbriq (brigatinib), or Zykadia (ceritinib) as the first ALK inhibitor therapy for metastatic disease **OR**
4. Must have a diagnosis of recurrent, advanced, or metastatic NSCLC with ROS1 rearrangement-positive tumors
    a. As subsequent therapy following disease progression on Zykadia (ceritinib) or Xalkori (crizotinib)
5. Recommended dosage is 100 mg orally once daily
6. QL of 30 tablets/30 days for 100mg tablets and QL of 90 tablets/30 days for 25 mg tablets
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 Lorbrena

Lynparza Tablets (olaparib tablets) - Rx

1. Must be prescribed by an oncologist **AND**
2. Must be ≥ 18 years of age **AND**
3. Must have a diagnosis of BRCA-mutation positive advanced ovarian cancer and have been treated with three or more prior lines of chemotherapy
    a. Used as a single agent **OR**
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**
5. Must be used as maintenance therapy for patients with deleterious or suspected deleterious germline or somatic BRCA-mtuated (gBRCAm or sBRCAm) advanced epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in complete or partial response to first-line platinum-based chemotherapy **OR**
6. 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.
    a. Patients with hormone receptor positive breast cancer should have been treated with a prior endocrine therapy or be considered inappropriate for endocrine therapy **OR**
7. Must have a diagnosis of pancreatic adenocarcinoma
    a. Used as maintenance therapy for metastatic disease with deleterious or suspected deleterious germline BRCA-mutated (gBRCAm) mutations which has not progressed during >16 weeks of first-line, platinum-based chemotherapy
8. Lynparza tablets will not be approved as first-line treatment of BRCA-mutation positive ovarian cancer
9. The recommended dosage is 300mg by mouth twice daily
10. QL 120 tablet/30days

Mekinist (trametinib) - Rx

1. Must be prescribed by an oncologist **AND**
2. Must be ≥ 18 years of age **AND**
3. Individual must have unresectable or metastatic melanoma
    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 in BRAF inhibitor naïve patients or in combination with Tafinlar (dabrafenib) **OR**
4. Used as adjuvant treatment in combination with Tafinlar (dabrafenib) for patients with BRAF-V600E or V600K mutation positive melanoma
    a. Refer to NCCN guidelines for approvable scenarios **OR**
5. Used in combination with Tafinlar (dabrafenib) 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**
    c. Used as subsequent therapy after progression on first-line systemic therapy with a non-BRAF targeted regimen **OR**
6. Must have a diagnosis of recurrent brain metastases secondary to metastatic melanoma
    a. Used in combination with Tafinlar (dabrafenib) **OR**
7. Must have a diagnosis of locally advanced or metastatic anaplastic thyroid cancer (ATC) with BRAF V600E mutation and with no satisfactory locoregional treatment options
    a. Used in combination with Tafinlar (dabrafenib) as first-line or second-line therapy **OR**

8. Must have a diagnosis of BRAF-V600E or V600K mutation positive, unresectable advanced or metastatic colorectal cancer
    a. In patients not previously treated with Erbitux (cetuximab) or Vectibix (panitumumab) **AND**
    b. In combination with Tafinlar (dabrafenib) and Erbitux (cetuximab) or Vectibix (panitumumab) **AND**
    c. Must have been previously treated with:
        i. Oxaliplatin-based therapy without irinotecan **OR**
        ii. Irinotecan-based therapy without oxaliplatin **OR**
        iii. A fluoropyrimidine without irinotecan or oxaliplatin followed by FOLFOX (fluorouracil, leucovorin, and oxaliplatin) or CapeOX (capecitabine and oxaliplatin) with or without bevacizumab
9. Mekinist will not be approved in combination with any other anti-neoplastic agents (such as Yervoy, or Zelboraf)
10. Mekinist will not be approved for patients who have received prior BRAF inhibitor therapy such as Zelboraf (vemurafenib)
11. The recommended dosing of Mekinist is 2mg orally once daily taken at least 1 hour before or at least 2 hours after a meal.
12. 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 years of age **AND**
3. Must have a diagnosis of BRAF V600E or V600K mutation positive, unresectable or metastatic melanoma
    a. Must be used in combination with Braftovi (encorafenib) **OR**
4. Must have a diagnosis of BRAF v600E mutation positive, unresectable advanced or metastatic colorectal cancer
    a. Used as subsequent therapy in combination with Braftovi (encorafenib) **AND** either Erbitux (cetuximab) or Vectibix (panitumumab) for disease not previously treated with Erbitux or Vectibix **AND** must have been previously treated with:
        i. Oxaliplatin-based therapy without irinotecan **OR**
        ii. irinotecan-based therapy without oxaliplatin **OR**
        iii. FOLFOXIRI (fluorouracil, leucovorin, oxaliplatin, and irinotecan) regimen **OR**
        iv. a fluoropyrimidine without irinotecan or oxaliplatin followed by FOLFOX (fluorouracil, leucovorin, and oxaliplatin) or CapeOX (capecitabine and oxaliplatin) with or without bevacizumab
5. 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
6. Recommended dose is 45 mg (3 tablets) orally twice daily in combination with Braftovi (encorafenib)
7. Quantity Limit 180 tablets/30 days
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 Mektovi

Mozobil (plerixafor injection) – Rx or Medical

1. Must be prescribed by an oncologist **AND**
2. Must be ≥ 18 years of age **AND**
3. Must have diagnosis of non-Hodgkin's lymphoma or multiple myeloma and have not previously attempted a stem cell harvest in conjunction with Mozobil
4. 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)
5. Dose should be based on actual body weight, 0.24mg/kg SC not to exceed 40mg/day (27mg/day in renal impairment)
6. Quantity limit of 4 doses or 1 course of harvesting cells while on Mozobil therapy, whichever occurs first

Nerlynx (neratinib) - Rx

1. Must be prescribed by an oncologist **AND**
2. Must be ≥ 18 years of age **AND**
3. Must have a diagnosis of early-stage HER2-positive breast cancer
    a. Used for extended adjuvant treatment following Herceptin-based (trastuzumab-based) therapy **OR**
4. Must have a diagnosis of advanced or metastatic HER2+ breast cancer following 2+ anti-HER2 based regimens in metastatic setting
    a. Used with capecitabine
5. Recommended dosing is 240mg (6 tablets) orally once daily with food.
6. Approval will be for 12 months. For a diagnosis of early stage of HER2+ breast cancer, FDA labeling does not support use beyond 1 year. For a diagnosis of metastatic or advanced HER2+ breast cancer following 2+ anti-HER2 based regimens, treatment is until disease progression or unacceptable toxicity.
7. QL 180 tablets/30 day
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 Nerlynx

Nexavar (sorafenib) - Rx

1. Prescribed by an oncologist **AND**
2. Must be ≥ 18 years of age **AND**
3. Must have a diagnosis of advanced renal cell carcinoma **OR**
4. Must have a diagnosis of unresectable hepatocellular carcinoma
    a. Used as single agent for patients with unresectable disease and not candidate for transplant **OR**
    b. Used as single agent as subsequent treatment after progression on first line Lenvima (lenvatinib) **OR**
5. Must have a diagnosis of differentiated thyroid carcinoma (DTC)
    a. If follicular, papillary, or Hurthle carcinoma
        i. Used for unresectable locoregional recurrent or persistent disease, or distant metastatic disease
    b. If medullary carcinoma
        i. Used if clinical trials, Caprelsa (vandetanib), or Cometriq (cabozantinib) are not available or appropriate **OR**
        ii. Used if there is progression on Caprelsa (vandetanib) or Cometriq (cabozantinib)
6. Must have a diagnosis of soft tissue sarcoma

a. If angiosarcoma, solitary fibrous tumor, or hemangiopericytoma
    i. Used as single agent therapy
b. If gastrointestinal stromal tumor (GIST)
    i. Used after disease progression with Sutent (sunitinib) or Stivarga (regorafenib) or Gleevec (imatinib) **OR**
c. If desmoid tumor (aggressive fibromatosis), used for primary, recurrent or progressive disease as treatment for
    i. Gross residual disease following surgery **OR**
    ii. Unresectable disease **OR**
    iii. Disease for which surgery would be unacceptably morbid **OR**

7. Must have a diagnosis of osteosarcoma
    a. Used as single agent for second-line therapy **OR**
8. Must have a diagnosis of Acute Myeloid Leukemia (AML) with FLT3-ITD mutation
    a. Used in combination with azacitidine or decitabine
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 ≥ 18 years of age **AND**
3. Must have a diagnosis of relapsed or previously treated multiple myeloma **AND**
    a. Must have received at least one prior therapy **AND**
    b. Used in combination with Revlimid (lenalidomide) and dexamethasone **OR**
    c. Used in combination with cyclophosphamide and dexamethasone **OR**
    d. Used in combination with dexamethasone **OR**
    e. Used in combination with Pomalyst (pomalidomide) after receiving at least 2 prior therapies including an immunomodulatory agent (such as Revlimid (lenalidomide)) and a proteasome inhibitor (such as Velcade (bortezomib), Kyprolis (carfilzomib)) with disease progression on or within 60 days of completion of last therapy
4. Must have a diagnosis of relapsed/refractory systemic light chain amyloidosis
    a. Used with or without dexamethasone
5. 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
6. Patients refractory (without response) to prior lenalidomide or proteasome inhibitor (Kyprolis [carfilzomib], Velcade [bortezomib]) therapy will be excluded from coverage of Ninlaro
    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
7. QL 3 capsules/28 days

Nubeqa (darolutamide) - Rx

1. Must be prescribed a urologist or oncologist **AND**
2. Must be ≥ 18 years of age **AND**
3. Must have a diagnosis of non-metastatic, castration-resistant prostate cancer
    a. Patient must also use an LHRH agonist or antagonist in combination or have had bilateral orchiectomy
4. Recommended dosing is 600mg (two 300mg tablets) orally twice daily. Take Nubeqa with Food

5. Quantity Limit 120 tablets/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 Nubeqa.

Odomzo (sonidegib) - Rx

1. Member must be followed by an oncologist or dermatologist **AND**
2. Must be ≥ 18 years of age **AND**
3. Must have a diagnosis of locally advanced basal cell carcinoma (BCC) **AND**
4. Must have BCC that has recurred following surgery or radiation therapy **OR** is not a candidate for surgery or radiation therapy
5. Recommended dosage is 200mg orally once daily taken on an empty stomach at least 1 hour before or 2 hours after a meal
6. 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 patients.
7. Odomzo will not be approved for patients that have previously failed treatment with a hedgehog pathway inhibitor (Erivedge)
8. Quantity limit 30 per 30 days

Piqray (alpelisib) - Rx

1. Must be prescribed by an oncologist **AND**
2. Must be ≥ 18 years of age **AND**
3. Must have a diagnosis of advanced or metastatic hormone receptor-positive, human epidermal growth factor receptor 2-negative (HR+/HER2-) breast cancer
    a. In postmenopausal women or in premenopausal women treated with ovarian ablation/suppression with LHRH agonist **AND**
    b. Disease must be PIK3CA-mutated following progression on or after an endocrine-based regimen **AND**
    c. Must be used in combination with fulvestrant
4. QL:
    a. 300mg/day pack and 250mg/day pack: 56 tablets/28 days
    b. 200mg/day pack: 28 tablets/28 days
5. *Please note:* for applicable lines of businesses (Commercial, Exchange, Child Health Plus), a split-fill program will apply to new starts only for Piqray 300mg/day and Piqray 250mg/day doses. An override to bypass the split-fill program will be provided for existing users that have been maintained on Piqray

Pomalyst (pomalidomide) - Rx

1. Must be prescribed by an oncologist **AND**
2. Must be ≥ 18 years of age **AND**
3. Must have a diagnosis of multiple myeloma
    a. Must have received at least 2 prior therapies including a proteasome inhibitor (such as bortezomib, carfilzomib, ixazomib) and an immunomodulatory agent (such as lenalidomide or thalidomide) **AND** have documented disease progression on or within 60 days of completion of the last therapy **AND**
        i. Used as single agent for steroid intolerant patients **OR** in combinations listed in NCCN **OR**
    b. Must have received at least 2 prior therapies including a proteasome inhibitor (such as bortezomib, carfilzomib, ixazomib) and an immunomodulatory agent (such as lenalidomide or thalidomide) **AND**

i. in one of the following combinations: with dexamethasone and Darzalex (daratumumab), with dexamethasone and Empliciti (elotuzumab), or with Sarclisa (isatuximab-irfc) and dexamethasone

4. Must have a diagnosis of AIDS-related Kaposi Sarcoma
   a. Used as subsequent systemic therapy given with antiretroviral therapy (ART) that has progressed/not responded to first line systemic therapy, and has progressed on alternate first line systemic therapy **OR**
5. Must have a diagnosis of relapsed/refractory systemic light chain amyloidosis
   a. Used in combination with dexamethasone
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 28 days.

Purixan (6-mercaptopurine) - Rx

1. Must be prescribed by an oncologist **AND**
2. Must have 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. Must be ≥ 18 years of age **AND**
3. Must have a diagnosis of Myelodysplastic Syndrome (MDS)
   a. First line with 5q deletion cytogenic abnormality **OR**
   b. First line in lower risk patients with symptomatic anemia, without 5q deletion, with or without other cytogenetic abnormalities, and serum erythropoietin levels > 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**
4. Must have a 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 for active myeloma responding to primary myeloma therapy or stable/responsive disease following stem cell transplant
      i. As single agent or in combination with bortezomib **OR**
   e. Therapy for previously treated myeloma for relapse or progressive disease - See NCCN compendium for appropriate treatment regimens **OR**
5. Must have a diagnosis of Classic Hodgkin Lymphoma
   a. As subsequent systemic therapy as a single agent for relapsed or refractory disease in patients age

6. Must have a diagnosis of chronic lymphocytic leukemia (CLL) or small lymphocytic leukemia (SLL)
   a. Have relapsed and refractory disease with or without del(17p)/TP53 mutation, used with or without rituximab **OR**
   b. Have disease without del(17p)/TP53 mutation **AND**
      i. As post first-line chemoimmunotherapy maintenance therapy **OR**
      ii. As post second-line chemoimmunotherapy maintenance therapy following complete or partial response to treatment for relapsed/refractory disease
7. Must have a diagnosis of Primary Cutaneous Lymphomas
   a. Therapy for Mycosis Fungoides/Sezary syndrome – see NCCN compendium for appropriate types and treatment regimens **OR**
   b. Therapy for primary cutaneous anaplastic large cell lymphoma (ALCL)
      i. For relapsed/refractory disease, used as a single agent **OR**
8. Must have a diagnosis of B-Cell Lymphoma – see NCCN compendium for appropriate types and treatment regimens **OR**
9. Must have a diagnosis of Non-Hodgkin's Lymphoma – See NCCN compendium for appropriate types and treatment regimens
10. Quantity limit 30/30 DS or 34/34 DS

Rozlytrek (entrecetinib) – Rx

1. Must be prescribed by an oncologist/hematologist **AND**
2. Must have a diagnosis of recurrent, advanced or metastatic non-small cell lung cancer (NSCLC)
   a. With ROS1-postive tumor **AND**
      i. Must be ≥ 18 years of age, used for first line therapy as single agent **OR**
   b. With NTRK gene fusion-positive tumor **AND**
      i. As first line therapy **OR**
      ii. As subsequent therapy following progression on first-line therapy with a non-NTRK-targeted regimen **OR**
3. Must have a diagnosis of unresectable or metastatic solid tumors with a neurotrophic receptor tyrosine kinase (NTRK) gene fusion without a known acquired resistance mutation
   a. Must be ≥ 12 years of age **AND**
   b. Must have progressed following treatment or have no satisfactory alternative treatments
4. Recommended dosage is 600mg once daily for adults with ROS1-positive NSCLC and NTRK gene fusion-positive solid tumors. Recommended dosage for pediatric patients be ≥ 12 years of age with NTRK gene fusion-positive solid tumors is based on BSA (600mg once daily for BSA >1.50m^2, 500mg daily for BSA 1.11-1.50m^2, 400mg once daily for BSA 0.91 to 1.10 m^2)
5. QL of 90/30 for 200mg capsules, 30/30 for 100 mg capsules
   a. Pediatric patients with NTRK gene fusion positive solid tumors and BSA 1.11-1.50m^2 can be approved for a QL of 150/30 for 100mg capsules
6. *Please note:* for applicable lines of businesses (Commercial, Exchange, Child Health Plus), a split-fill program will apply to new starts receiving Rozlytrek capsules. An override to bypass the split-fill program will be provided for existing users that have been maintained on Rozlytrek capsule

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
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 a diagnosis of acute myeloid leukemia (AML) that is FLT3 mutation positive
    a. For treatment induction or re-induction in patients in combination with standard dose cytarabine and daunorubicin **OR**
    b. For post-remission therapy
        i. in combination with high dose cytarabine for patients <60 **OR** intermediate dose cytarabine for patients age ≥60 with complete response to previous intensive therapy **OR**
4. Must have a diagnosis of aggressive systemic mastocytosis, systemic mastocytosis with associated hematological neoplasm, or mast cell leukemia
    a. Used as a single agent **OR**
5. Must have a diagnosis of chronic myelomonocytic leukemia (CMML)
    a. In patients with CMML-associated systemic mastocytosis and KIT816V mutation **AND**
    b. Used as single agent
6. Rydapt will not be approved as single agent therapy for AML.
7. Rydapt will be approved open-ended for a diagnosis of systemic mastocyctosis 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 Rydapt in combination with standard induction or consolidation therapy
8. QL 240 capsules/30 days

Soltamox (tamoxifen citrate) - Rx

1. Must be prescribed by an oncologist **AND**
2. Must be ≥ 18 years of age **AND**
3. Must be used for one of the following indications:
    a. As adjuvant treatment for axillary node-negative and axillary node-positive breast cancer **OR**
    b. For metastatic breast cancer **OR**
    c. For ductal carcinoma in situ (DCIS) following breast surgery and radiation therapy to reduce the risk of invasive breast cancer **OR**
    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) **OR**
    e. See NCCN compendium for additional appropriate indications
4. Must have documentation of an inability to swallow tablets.

5. QL 300ml/ 30 days.

Sprycel (dasatinib) - Rx

1. Must be written by an Oncologist **AND**
2. Must have a diagnosis of Philadelphia chromosome positive (PH+) ALL
    a. In adults: with resistance or intolerance to prior therapy **OR**
    b. As induction therapy in combination with: HyperCVAD (hyper-fractionated cyclophosphamide, vincristine, doxorubicin, and dexamethasone, alternating with high-dose methotrexate) + TKI (dasatinib), OR corticosteroids + (TKI) dasatinib, OR vincristine + dexamethasone + TKI (dasatinib) **OR**
    c. As maintenance therapy
        i. in combination with vincristine and prednisone with or without methotrexate and mercaptopurine **OR**
        ii. after hematopoietic stem cell transplant **OR**
    d. In pediatric patients (1 year or older): newly diagnosed, in combination with chemotherapy **OR**
3. Must have a diagnosis of Philadelphia chromosome positive (PH+) or BCR-ABL1 positive, chronic phase chronic myeloid leukemia (CP-CML) – both adults and pediatric patients **OR**
4. Must have a diagnosis of PH+ CML in any phase
    a. With resistance or intolerance to prior therapy including imatinib **OR**
    b. See NCCN compendium for additional appropriate indications and regimens
5. Must have a diagnosis of widespread metastatic or recurrent chondrosarcoma (bone cancer)
    a. Used as single agent **OR**
6. Must have a diagnosis of gastrointestinal stromal tumors (GIST) with PDGFRA D842V mutation
    a. After progression on single agent therapy with imatinib, sunitinib and regorafenib
7. Quantity limit 60/30DS or 68/34 DS
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 Sprycel

Stivarga (regorafenib) - Rx

1. Must be seen by an oncologist **AND**
2. Must be ≥ 18 years of age **AND**
3. Must 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 RAS wild type, an anti-EGFR (ie Erbitux, Vectibix) must also have been tried. **OR**
4. Must have a diagnosis of locally advanced, unresectable or metastatic gastrointestinal stromal tumor (GIST)
    a. For disease progression after previous treatment with Gleevec (imatinib) or Sutent (sunitinib) **OR**
    b. In combination with Afinitor (everolimus) for disease progression after single agent therapy with Gleevec (imatinib), and Sutent (sunitinib), and Stivarga (regorafenib) **OR**
    c. As palliative therapy for rhabdomyoscarcoma, retroperitoneal/intra-abdominal sarcoma, or metastatic extremity/superficial trunk, head/neck sarcoma
5. Must have a diagnosis of hepatocellular carcinoma (HCC) with previous treatment with Nexavar (sorafenib)
    a. Used as a single agent **OR**

6. Must have a diagnosis of osteosarcoma
    a. Used as second line therapy for relapsed/refractory or metastatic disease as a single agent
7. 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.
8. Hepatic function should be monitored prior to and during treatment. If hepatotoxicity occurs, interrupt and then reduce or discontinue Stivarga
9. Initial Stivarga approval will be for 6 months. Further approval will require evidence of continued benefit without progression of disease
10. QL 84 tablets per 28 days

Sutent (sunitinib malate) - Rx

1. Must be written by oncologist **AND**
2. Must be ≥ 18 years of age **AND**
3. Must have a diagnosis of GIST (gastrointestinal stromal tumor)
    a. With failure or intolerance to Gleevec and used as single agent **OR**
    b. Used in combination with Afinitor (everolimus) for disease progression after single agent therapy with Gleevec (imatinib), and Sutent (sunitinib), and Stivarga (regorafenib) **OR**
4. Must have a diagnosis of advanced (stage IV) or relapsed Renal Cell Carcinoma (RCC)
    a. Used as single agent therapy for clear cell histology (as first line or subsequent therapy) and for non-clear cell histology (as preferred systemic therapy) **OR**
5. Must have a diagnosis of progressive neuroendocrine tumors of pancreatic origin (PNET) that is unresectable, locally advanced or metastatic
    a. Used as a single agent **OR**
6. Must have a diagnosis of thyroid carcinoma – Follicular, Hurthle cell, and Papillary cell carcinoma:
    a. Treatment of clinically progressive or symptomatic metastatic disease in patients with iodine refractory tumors at sites other than central nervous system **OR**
7. Must have a 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 **OR**
8. Must have a diagnosis of thymic carcinoma
    a. Used for second-line therapy as a single agent **OR**
9. Must have a diagnosis of angiosarcoma or solitary fibrous tumor/hemangiopericytoma
    a. Used as single agent therapy **OR**
10. Must have a diagnosis of chordoma (bone cancer)
    a. Used as single agent for recurrent disease
11. 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 **AND**
2. Must have a diagnosis of melanoma with microscopic or gross nodal involvement within 84 days of definitive surgical including complete lymphadenectomy **OR**
3. Must have a diagnosis of aggressive systemic mastocytosis, or systemic mastocytosis with associated hematologic neoplasm (SM-AHN)
    a. Used as single agent or with prednisone **OR**

4. Must have a diagnosis of polycythemia vera, myelofibrosis, or essential thrombocythemia
5. Those with autoimmune hepatitis or hepatic decompensation (Child-Pugh > 6; Class B or C) will be excluded from coverage

Tafinlar (dabrafenib) - Rx

1. Must be followed by an oncologist **AND**
2. Must be ≥ 18 years of age **AND**
3. Must have a diagnosis of unresectable or metastatic melanoma with BRAF V600 mutation
    a. Used as a single agent **OR**
    b. Used in combination with Mekinist (trametinib) **OR**
4. Must have a diagnosis of 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 Mekinist (trametinib) or as a single agent if the combination is not tolerated **OR**
5. Must have a diagnosis of locally advanced or metastatic anaplastic thyroid cancer (ATC) with BRAF V600E mutation **OR**
6. Must have a diagnosis of thyroid cancer – Hurthle cell, papillary, follicular
    a. For treatment of progressive and/or symptomatic iodine-refractory BRAF-positive disease
        i. If clinical trials or other systemic therapies not available or appropriate **AND**
        ii. For unresectable locoregional recurrent or persistent disease, or for distant metastatic disease **OR**
7. Used in combination with Mekinist (trametinib) 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 **OR**
8. Must have a diagnosis of advanced or metastatic colorectal cancer (BRAF V600E mutation positive)
    a. Must be used as subsequent therapy in combination with Mekinist (trametinib) **AND** either Erbitux (cetuximab) or Vectibix (panitumumab) for disease not previously treated with Erbitux or Vectibix **AND** for disease that was previously treated with
        i. oxaliplatin-based therapy without irinotecan **OR**
        ii. irinotecan-based therapy without oxaliplatin **OR**
        iii. FOLFOXIRI (fluorouracil, leucovorin, oxaliplatin, and irinotecan) regimen **OR**
        iv. a fluoropyrimidine without irinotecan or oxaliplatin followed by FOLFOX (fluorouracil, leucovorin, and oxaliplatin) or CapeOX (capecitabine and oxaliplatin) with or without bevacizumab
9. Besides Mekinist, Tafinlar will not be approved in combination with any other anti-neoplastic agents (such as Yervoy or Zelboraf)
10. Dermatologic evaluations should be performed prior to initiation of therapy and every two months
11. Patients with wild-type BRAF melanoma will be excluded
12. 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 **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 (erlotinib), Gilotrif

(afatinib), Iressa(gefitinib), Vizimpro (dacomitinib)) **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
6. QL 30 tablets/30 days

Talzenna (talazoparib) –Rx

1. Must be prescribed by an oncologist **AND**
2. Must be ≥ 18 years of age **AND**
3. Must be used for the treatment of BRCA-mutated (gBRCAm) HER2-negative recurrent or metastatic breast cancer
    a. With HR- disease
    b. With HR+ disease who are endocrine therapy refractory or have visceral crisis
4. QL of 30/30 for 1 mg capsules. QL of 90/30 for 0.25 mg capsules
5. *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 Talzenna

Tarceva (erlotinib) – Rx

1. Prescribed by an oncologist **AND**
2. Must be ≥ 18 years of age **AND**
3. Must have a diagnosis of pancreatic adenocarcinoma
    a. Used in combination with gemcitabine as first line therapy for metastatic disease in patients with good performance status (ECOG PS 0-1) **OR**
    b. Used in combination with gemcitabine as second line therapy for locally advanced or metastatic disease with EOCG PS 0-1 and disease progression previously treated with fluoropyrimidine-based chemotherapy **OR**
4. Must have a diagnosis of recurrent chordoma (bone cancer)
    a. As a single agent **OR**
5. Must have a diagnosis of relapsed or metastatic renal cell carcinoma
    a. Used as single agent for non-clear cell histology **OR**
    b. Used in combination with Avastin (bevacizumab) for non-clear cell histology in selected patients with advanced papillary renal cell carcinoma **OR**
6. Must have a diagnosis of recurrent or metastatic non-small cell lung cancer with a known sensitizing EGFR mutation [Exon 19 deletion or Exon 21 (L858R) substitution] as detected by an FDA approved test
    a. Used as a single agent for first line therapy, maintenance, or second or greater line therapy after progression on at least one prior chemotherapy regimen
6. Tarceva used in combination with other targeted therapies is considered experimental/ investigational and will not be covered.
7. Quantity limit of 30/30 or 34/34 DS
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 Tarceva

Targretin Capsules (bexarotene) - Rx

1. Must be prescribed by an oncologist or dermatologist **AND**
2. Must be ≥ 18 years of age **AND**
3. Must have a diagnosis of primary cutaneous T-cell lymphoma **OR**
4. Must have a diagnosis of Mycosis Fungoides (MF) or Sezary Syndrome (SS) **OR**
5. Must have a diagnosis of primary cutaneous anaplastic large cell lymphoma (ALCL) **OR**
6. Must have a diagnosis of symptomatic lymphomatoid papulosis (LyP)
7. QL of 300 capsules/30 days
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 Targretin

Targretin gel(bexarotene) - Rx

1. Must be prescribed by an oncologist **AND**
2. Must be ≥ 18 years of age **AND**
3. Must have a diagnosis of 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**
4. Must have a diagnosis of chronic or smoldering T-Cell Leukemia/Lymphoma
    a. Used as first-line skin-directed therapy **OR**
5. Must have a diagnosis of Mycosis Fungoides (MF)/Sezary Syndrome (SS)
    a. Used as a single agent or in combination with other limited/localized skin-directed therapies **OR**
    b. Refer to NCCN compendia for a list of approvable uses **OR**
6. Must have a diagnosis of primary cutaneous marginal zone or follicle center cutaneous B-Cell lymphoma
7. Targretin gel will not be approved for a diagnosis of psoriasis or AIDs-related Kaposi's sarcoma

Tasigna (nilotinib) - Rx

1. Must be prescribed by an oncologist **AND**
2. Must have a diagnosis of chronic or accelerated phase Philadelphia chromosome positive chronic myelogenous leukemia (CML) **AND**
    a. As initial therapy for adult and pediatric patients ≥ 1 years of **OR**
    b. After resistance or intolerance to prior therapy that included imatinib for adults ≥18 year of age **OR**
    c. After resistance or intolerance to prior tyrosine-kinase inhibitor (TKI) therapy in pediatric patients ≥ 1 years **OR**
3. Must have a diagnosis of Philadelphia chromosome-positive acute lymphoblastic leukemia (PH+ ALL) **AND**
    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 **OR**
4. Diagnosis of GIST **AND**
    a. Used after disease progression on single agent therapy with imatinib (Gleevec), sunitinib (Sutent), or regorafenib (Stivarga)
5. Quantity limit 120/30 DS or 136/34 DS

Tazverik (tazemetostat) - Rx
1. Must be prescribed by an oncologist **AND** 2. Must be ≥ 16 years of age **AND** 3. Must have a diagnosis of metastatic or locally advanced epithelioid sarcoma not eligible for complete resection 4. QL 240 tablets/30 days
Tibsovo (ivosidenib) - Rx
1. Must be prescribed by an Oncologist or Hematologist **AND** 2. Must be ≥ 18 years of age **AND** 3. Must have a diagnosis of relapsed or refractory Acute Myeloid Leukemia (AML) with an Isocitrate Dehydrogenase-1 (IDH1) mutation **OR** 4. Must have a diagnosis of Acute Myeloid Leukemia (AML) with an Isocitrate Dehydrogenase-1 (IDH1) mutation and be ≥60 years old or who have comorbidities that preclude use of intensive induction chemotherapy 5. Initial approval will be for 6 months. Further approval will require documentation of stable or improved disease 6. QL 60 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 Tibsovo
Turalio (pexidartinib) - Rx
1. Must be prescribed by an Oncologist or Hematologist **AND** 2. Must be ≥ 18 years of age **AND** 3. Must have a diagnosis of pigmented villonodular synovitis/tenosynovial giant cell tumor (PVNS/TGCT) **AND** a. Used as single agent 4. Dosage must not exceed 400mg twice daily 5. Quantity limit 120 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 Turalio
Tykerb (lapatinib) - Rx
1. Prescribed by an oncologist **AND** 2. Must be ≥ 18 years of age **AND** 3. Must have a diagnosis of recurrent, EGFR-positive chordoma (bone cancer) a. Used as single agent therapy **OR** 4. Must have a diagnosis of advanced or metastatic HER2+ breast cancer in post-menopausal women or in premenopausal women treated with ovarian ablation/suppression with LHRH agonist a. For HR+ disease, i. Used in combination with aromatase inhibition, with or without trastuzumab (Herceptin) **OR** ii. Used in combination with trastuzumab (Herceptin) or capecitabine (Xeloda), with or without endocrine therapy **OR** b. For HR- disease, i. Used in combination with trastuzumab (Herceptin) or capecitabine **OR** 5. Diagnosis of central nervous system cancer

a. In combination with capecitabine if active against primary tumor (breast) as treatment for brain metastases in patients with recurrent disease **OR**

6. Must have a diagnosis of advanced or metastatic colorectal cancer
    a. Tumor must be HER2+ and RAS WT and not previously treated with a HER2 inhibitor in patients previously treated with:
        a. oxaliplatin-based therapy without irinotecan **OR**
        b. irinotecan-based therapy without oxaliplatin **OR**
        c. FOLFOXIRI (fluorouracil, leucovorin, oxaliplatin, and irinotecan) regimen **OR**
        d. a fluoropyrimidine without irinotecan or oxaliplatin
7. Quantity limit of 180/30 or 204/34 DS

Valchlor (mechlorethamine) - Rx

1. Must be prescribed by an oncologist or dermatologist **AND**
2. Must be ≥ 18 years of age **AND**
3. Must have a diagnosis of Mycosis Fungoides (MF)/Sezary Syndrome (SS)
    a. Must have had prior treatment with skin-directed therapy (topical corticosteroids, carmustine, local radiation, topical retinoids, phototherapy, topical imiquimod) **OR**
4. Must have a diagnosis of lymphomatoid papulosis (LyP) **OR**
5. Must have a diagnosis of primary cutaneous marginal zone or follicle center lymphoma **OR**
6. Must have a diagnosis of chronic/smoldering T-Cell Leukemia/Lymphoma, being used as first line therapy
7. Quantity limit 60 grams

Venclexta (venetoclax) - Rx

1. Must be prescribed by an oncologist **AND**
2. Must be ≥ 18 years of age **AND**
3. Must have a diagnosis of Chronic Lymphocytic Leukemia (CLL) or small lymphocytic lymphoma (SLL)
        a. As a single agent or in combination with rituximab (Rituxan) for relapsed/refractory disease **OR**
        b. In combination with obinutuzumab (Gazyva) for first-line therapy **OR**
4. Must have a diagnosis of Mantle Cell Lymphoma
    a. As second-line single agent therapy **OR**
5. Must have a diagnosis of acute myeloid leukemia (AML)
        a. Used in combination with decitabine, azacytidine, or low-dose cytarabine
6. 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
7. Quantity Limits:
    a. Starting pack: 42 tab/28 days
    b. 50mg tab: 224/28 days
    c. 100mg tab: 112 tab/28 days

Verzenio (abemaciclib) - Rx

1. Must be prescribed by an oncologist **AND**
2. Must be ≥ 18 years of age **AND**
3. Must have a diagnosis of advanced (stage 3 or 4) or metastatic hormone receptor positive (HR+), human epidermal growth factor receptor 2 negative (HER2-) breast cancer
   a. For post-menopausal women or pre-menopausal women treated with ovarian ablation/suppression **AND**
      i. Used as first line therapy in combination with an aromatase inhibitor **OR**
      ii. Used as first line therapy in combination with fulvestrant **OR**
      iii. Used as second line therapy or beyond in combination with fulvestrant if CDK4/6 inhibitor not previously used **OR**
      iv. Used as monotherapy if progression on prior 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

Vitrakvi (larotrectinib) – Rx

1. Must be prescribed by an oncologist/hematologist **AND**
2. Must have unresectable or metastatic solid tumors with a neurotrophic receptor tyrosine kinase (NTRK) gene fusion without a known acquired resistance mutation
   a. Must have progressed following treatment or have no satisfactory alternative treatments
3. Recommend dosage is 100mg orally twice daily for adult and pediatric patients with BSA of at least 1 m^2 and 100mg/m^2 orally twice daily for pediatric patients with a BSA of less than 1 m^2
4. QL of 60/30 for 100mg capsules, 90/30 for 25 mg capsules, and 300ml/30 days for the 20mg/ml solution
5. *Please note:* for applicable lines of businesses (Commercial, Exchange, Child Health Plus), a split-fill program will apply to new starts receiving Viktrakvi capsules. An override to bypass the split-fill program will be provided for existing users that have been maintained on Vitrakvi capsules

Vizimpro (decomitinib) - Rx

1. Must be prescribed by an oncologist **AND**
2. Must be ≥ 18 years of age **AND**
3. Must have a diagnosis of recurrent, advanced, or 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. Used as first-line therapy
4. Recommended dose is 45 mg orally once daily with or without food
5. QL 30/30 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 Vizimpro

Votrient (pazopanib) - Rx

1. Must be written by oncologist **AND**
2. Must be ≥ 18 years of age **AND**
3. Must have a diagnosis of relapsed or advanced Renal Cell Carcinoma (RCC)
    a. Used as single agent therapy for clear cell histology and for non-clear cell histology **OR**
4. Must have a diagnosis of advanced soft tissue sarcoma
    a. Refer to NCCN compendium for acceptable indications and regimens **OR**
5. Must have a diagnosis of gastrointestinal stromal tumors (GIST)
    a. Used after disease progression with Sutent (sunitinib) or Stivarga (regorafenib) or Gleevec (imatinib) **OR**
6. Must have a diagnosis of thyroid cancer – Hurthle cell, papillary, or follicular lymphoma
    a. For treatment of progressive and/or symptomatic iodine-refractory BRAF-positive disease
        1. If clinical trials or other systemic therapies not available or appropriate **AND**
        2. For unresectable locoregional recurrent or persistent disease, or for distant metastatic disease **OR**
7. Must have a diagnosis of medullary thyroid carcinoma with recurrent or distant metastases
    a. If clinical trials, Caprelsa (vandetanib), or Cometriq (cabozantinib) are not available or appropriate **OR**
    b. If there is progression on Caprelsa (vandetanib) or Cometriq (cabozantinib) **OR**
8. Must have a diagnosis of recurrent/metastatic uterine sarcoma
    a. Use as single agent therapy after progression on cytotoxic chemotherapy
9. Quantity limit of 120/30 days
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 Votrient

Xalkori (crizotinib) - Rx

1. Must be followed by an oncologist **AND**
2. Must be ≥ 18 years of age **AND**
3. Must have a diagnosis of advanced or metastatic non-small cell lung cancer (NSCLC)
    a. Used as single agent therapy **AND**
        i. Tumor must be anaplastic lymphoma kinase (ALK) positive or ROS1 positive as detected by an FDA-approved test **OR**
        ii. Tumor must have high level MET amplification or MET exon 14 skipping mutation **OR**
4. Must have a diagnosis of soft tissue sarcoma – inflammatory myofibroblastic tumor (IMT) with ALK translocation
    a. Used as a single agent **OR**
5. Must have a diagnosis of relapsed/refractory ALK+ anaplastic large cell lymphoma
    a. Used as a single agent
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 **AND**
3. Must have a diagnosis of metastatic neuroendocrine tumor and carcinoid syndrome associated diarrhea **AND**
    a. Must have continued diarrhea symptoms despite at least a 3-month trial of somatostatin analogue therapy (octreotide or lanreotide) **AND**
    b. Xermelo must be prescribed in combination with a somatostatin analogue therapy
4. QL 90 tablets/30 day

Xospata (gileritinib) - Rx

1. Must be prescribed by an oncologist **AND**
2. Must be ≥ 18 years of age **AND**
3. Must have a diagnosis of relapsed or refractory acute myeloid leukemia (AML) with FMS-like tyrosine kinase 3 (FLT3) mutation (mutations included FLT3-ITD, FLT3-TKD/D835, and FLT3-TKD/1836), as detected by an FDA approved test
    a. Used as a single agent
4. Recommended dosage is 120mg orally once daily
5. Initial approval will be 6 months. Approval for additional 6-month periods will required documentation of stable or improved disease
6. QL of 90 tablets/30 days

Xpovio (selinexor)- Rx

1. Must be prescribed by an oncologist **AND**
2. Must be ≥ 18 years of age **AND**
3. Must have a diagnosis of relapsed/refractory Multiple Myeloma **AND**
4. Must have disease that is refractory to:
    a. At least two proteasome inhibitors (bortezomib [Velcade], carfilzomib [Kyprolis], ixazomib [Ninlaro] **AND**
    b. At least two immunomodulatory agents [lenalidomide [Revlimid], pomalidomide [Pomalyst]) **AND**
    c. An anti-CD38 monoclonal antibody (daratumumab [Darzalex])
5. Recommended starting dosage is 80mg (four 20mg tablets) in combination with dexamethasone taken on days 1 and 3 of each week
6. Initial approval will be for 6 months. Further approval for 6-month periods will require documentation of stable/improved disease
7. QL:
    a. 160 mg weekly dose carton: 32 tab/28 days
    b. 100 mg weekly dose carton: 20 tablets/28 days
    c. 80 mg weekly dose carton: 16 tablets/28 days
    d. 60mg weekly dose carton: 12 tablets/28 days
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 Xpoviopi

Xtandi (enzalutamide) - Rx

1. Must be prescribed by a urologist or oncologist **AND**
2. Must be ≥ 18 years of age **AND**
3. Must have a diagnosis of metastatic castration-resistant prostate cancer
    a. Must have had serious side effects or drug failure with abiraterone acetate 250mg –

UNLESS pt has visceral metastases (liver, lung, adrenal, peritoneal, and brain mets; soft tissue/lymph node sites are not considered visceral mets) **AND**
   b. Used in combination with LHRH agonist or antagonist **OR**
4. Must have a diagnosis of non-metastatic castration-resistant prostate cancer
   a. Must have had serious side effects with Nubeqa **AND**
   b. Used in combination with LHRH agonist or antagonist **OR**
5. Must have a diagnosis of metastatic castration-sensitive prostate cancer
   a. Must have had serious side effects or drug failure with abiraterone acetate 250mg **AND**
   b. Used in combination with LHRH agonist or antagonist – unless patient has had orchiectomy, can then be used as single agent
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.
8. Quantity limit of 120/30 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 Xtandi

Yonsa (abiraterone acetate, micronized) - Rx

1. Must be prescribed by a urologist or oncologist **AND**
2. Must have had serious side effects with abiraterone acetate 250mg **AND**
3. Must have a diagnosis of metastatic castration-resistant prostate cancer (mCRPC)
   a. Must be used in combination with methylprednisolone **OR**
4. 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.
5. Recommended dosage is 500mg (four 125mg tablets) administered once daily in combination with methylprednisolone 4mg administered orally twice daily
6. 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
7. 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
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 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 advanced or recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer
   a. Used as a single agent **OR** in combination with Avastin (bevacizumab) for platinum sensitive disease **AND**
   b. Must have been treated with three or more prior chemotherapy regiments, with cancer associated with homologous recombination deficiency (HRD) positive status defined by either
      i. A deleterious or suspected BRCA mutation **OR**

ii. Genomic instability and progression more than 6 months after response to last platinum-based chemotherapy **OR**

4. Must be used for maintenance of epithelial ovarian, fallopian tube, or primary peritoneal cancer
   a. Used as single agent maintenance therapy, in patients with platinum-sensitive recurrent disease who have completed two or more lines of platinum-based therapy and are in complete or partial response **AND**
   b. Bevacizumab must be discontinued before initiating maintenance therapy with Zejula
5. Recommended dosage is 300mg once daily with or without food
6. QL 90 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 Zejula

Zelboraf (vemurafenib) - Rx

1. Must be prescribed by an oncologist **AND**
2. Must be ≥ 18 year of age **AND**
3. Must have a diagnosis of 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)
   a. Used in combination with cobimetinib (Cotellic), or as single agent if BRAF/MEK inhibitor combination therapy is contraindicated **AND**
   b. Can be used as first line therapy, or as second-line/subsequent therapy if targeted therapy not previously used
4. Must have a diagnosis of brain metastases if active against the primary tumor (BRAF V600E melanoma) for recurrent disease
   a. Used in combination with cobimetinib (Cotellic) **OR**
5. Must have a diagnosis of unresectable advanced or metastatic colorectal cancer (BRAF V600E mutation positive)
   a. Previously treated with FOLFOX or CapeOX within the past 12 months **AND**
      i. Used as primary treatment in combination with irinotecan and cetuximab (Erbitux) or panitumumab (Vectibix) **OR**
   b. Used as subsequent therapy in combination with irinotecan and cetuximab (Erbitux) or panitumumab (Vectibix) in patients not previously treated with cetuximab or panitumumab, in patients previously treated with:
      i. Oxaliplatin-based therapy without irinotecan **OR**
      ii. Irinotecan-based therapy without oxaliplatin **OR**
      iii. FOLFOXIRI (fluorouracil, leucovorin, oxaliplatin, and irinotecan) regimen **OR**
      iv. a fluoropyrimidine without irinotecan or oxaliplatin followed by FOLFOX or CapeOX with or without bevacizumab **OR**
6. Must have a diagnosis of Hairy Cell Leukemia
   a. Used as single agent for less than complete response following initial treatment with cladribine or pentostatin **OR**
   b. Used as single agent for relapse within two years of complete response **OR**
   c. Used with or without rixutimab (Rituxan) for relapsed/refractory disease
7. Must have a diagnosis of recurrent, advanced, or metastatic non-small cell lung cancer (NSCLC) with BRAF V600E mutations if combination of dabrafenib (Tafinlar) and trametinib (Mekinist) is not tolerated
   a. Used as first line therapy **OR**

b. As subsequent following progression on first line therapy
8. Must have a diagnosis of thyroid cancer – Hurthle cell, papillary, follicular
   a. For treatment of progressive and/or symptomatic iodine-refractory BRAF-positive disease
      i. If clinical trials or other systemic therapies not available or appropriate **AND**
      ii. For unresectable locoregional recurrent or persistent disease, or for distant metastatic disease **OR**
9. Must have a diagnosis of Erdheim-Chester disease with BRAF V600 mutation
10. The recommended dosing of Zelboraf is 960mg given twice daily.
11. Dermatologic evaluations should be performed prior to initiation of therapy and every two months.
12. LFTs and bilirubin should be monitored prior to initiation of treatment and monthly.
13. 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.
14. Individuals who are approved for coverage of Zelboraf will be excluded from coverage of Yervoy.
15. Quantity limit of 240/30 days.

Zolinza (vorinostat) - Rx

1. Must be prescribed by a dermatologist with advanced knowledge of CTCL or an oncologist **AND**
2. Must be ≥ 18 year of age **AND**
3. Diagnosis of cutaneous T-cell Lymphoma (Mycosis Fungoides/Sezary Syndrome):
   a. Patient must have failed at least 2 other therapies **OR**
4. Quantity limit 120/30 DS or 136/34 DS

Zydelig (idelalisib) - Rx

1. Must be prescribed by an oncologist/hematologist **AND**
2. Must be ≥ 18 year of age **AND**
3. Must have a diagnosis of relapsed/refractory B-cell lymphoma (follicular, splenic or nodal marginal zone, gastric or non-gastric MALT)
   a. Used as subsequent therapy after 2 prior therapies **OR**
4. Must have a diagnosis of relapsed/refractory chronic lymphocytic leukemia (CLL) or small lymphocytic leukemia (SLL) with or without del(17p)/TP53 mutation
   a. Used as single agent or in combination with rituximab (Rituxan)
5. Recommended starting dose is 150mg twice daily.
6. Patients with a history of serious allergic reactions, including anaphylaxis and toxic epidermal necrolysis will be excluded.
7. QL 60 tablets/30 days

Zykadia (ceritinib) – Rx

1. Must be prescribed by an oncologist
2. Must be ≥ 18 years of age **AND**
3. Must have a diagnosis of ALK positive, advanced or metastatic non-small cell lung cancer (NSCLC)
   a. Used as first line therapy **OR**
   b. Subsequent therapy following disease progression on first-line therapy with crizotinib (Xalkori), or for patients who are intolerant to crizotinib (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 ROS1 arrangement-positive recurrent or metastatic NSCLC
    a. Used as single agent for first-line therapy **OR**
4. Must have a diagnosis of inflammatory myofibroblastic tumor (IMT) with ALK translocation
    a. Used 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

1. Must be prescribed by a urologist or oncologist **AND**
2. Must be ≥ 18 years of age **AND**
3. Requests for brand Zytiga must have had serious side effects with abiraterone acetate 250mg **AND**
4. Must have a diagnosis of metastatic castration-resistant prostate cancer (mCRPC) **OR** a diagnosis of metastatic high-risk castration-sensitive prostate cancer (mCSPC)
    a. Must be used in combination with prednisone or methylprednisolone and an LHRH agonist or antagonist
5. 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.
6. Patients with moderate base line hepatic impairment (Child-Pugh Class B) should be started at a reduced dose of 250mg once daily
7. Quantity limit of 120/30days for 250mg tablet, 60/30 days for 500mg tablet
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 Zytiga

UPDATES:

Date:	Revision:
4/20	Revised
2/20	Revised
1/20	Revised
12/19	Revised
11/19	Revised
10/19	Revised
09/19	Revised
08/19	Revised
05/19	Revised
04/19	Revised
03/19	Revised
01/19	Revised
11/18	Revised
10/18	Revised
09/18	Revised
08/18	Revised
07/18	Revised
03/18	Revised

02/18	Revised
01/18	Revised
12/17	Revised
11/17	Revised
10/17	Revised
8/17	Revised
6/17	Revised
5/17	Revised
4/17	Revised
3/17	Revised
1/17	Revised
11/16	Revised
10/16	Revised
9/16	Revised
8/16	Revised
7/16	Revised
6/16	Revised
5/16	Revised
4/16	Revised
3/16	Revised
2/16	Revised
1/16	Revised
12/15	Revised
11/15	Revised
10/15	Revised
8/15	Revised
7/15	Revised
6/15	Revised
5/15	Revised
3/15	Revised
2/15	Revised
1/15	Revised
11/14	Revised
10/14	Revised
9/14	Revised
8/14	Revised
7/14	Revised
6/14	Revised
5/14	Revised
10/13	Initial Policy Effective Date

REFERENCES:

In addition to the full prescribing information for each individual drug and NCCN Drugs and Biologic Compendium, the following references have been utilized in creating drug specific criteria:

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1. Llovet J, et al. "Sorafenib improves survival in advanced Hepatocellular Carcinoma (HCC): Results of a Phase III randomized placebo-controlled trial (SHARP trial)". Proceedings from the 2007 annual meeting of the American Society of Clinical Oncology. Late-breaking Abstract (LBA) #1.
Tarceva-
1. Pham D., et al. Use of cigarette-smoking history to estimate the likelihood of mutations in epidermal growth factor receptor gene exons 19 and 21 in lung adenocarcinomas. Journal of Clinical Oncology. April 10, 2006; 24(11):1700-1704.
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Xalkori-
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