Pharmacy Medical Necessity Guidelines: Oral Cancer Medications

Effective: August 17, 2020

Prior Authorization Required	√	Type of Review – Care Management	
Not Covered		Type of Review – Clinical Review	√
Pharmacy (RX) or Medical (MED) Benefit	RX	Department to Review	RXUM

These pharmacy medical necessity guidelines apply to the following:

Commercial Products

☒ Tufts Health Plan Commercial products – large group plans
☒ Tufts Health Plan Commercial products – small group and individual plans
☒ Tufts Health Freedom Plan products – large group plans
☒ Tufts Health Freedom Plan products – small group plans
- CareLink℠ – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization

Tufts Health Public Plans Products

☒ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product)
☒ Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans
☒ Tufts Health RITogether – A Rhode Island Medicaid Plan

Fax Numbers:

RXUM: 617.673.0988

Note: This guideline does not apply to Medicare Members (includes dual eligible Members).

OVERVIEW

The following oral cancer medications require prior authorization:

- abiraterone 250 mg
- Afinitor (everolimus)
- Afinitor Disperz (everolimus)
- Alecensa (alectinib)
- Alunbrig (brigatinib)
- Ayvakit (avapritinib)
- Balversa (erdafitinib)
- Bosulif (bosutinib)
- Braftovi (encorafenib)
- Brukinsa (zanubrutinib)
- Cabometyx (cabozantinib)
- Calquence (acalabrutinib)
- Caprelsa (vandetanib)
- Cometriq (cabozantinib)
- Copiktra (duvelisib)
- Cotellic (cobimetinib)
- Daurismo (glasdegib)
- Erivedge (vismodegib)
- Farydak (panobinostat)
- Gilotrif (afatinib)
- Hycamtin (topotecan)
- Ibrance (palbociclib)
- Iclusig (ponatinib)
- Idhifa (enasidenib)
- Imbruvica (ibrutinib)
- Inlyta (axitinib)
- Inrebic (fedratinib)
- Iressa (gefitinib)
- Jakafi (ruxolitinib)
- Kisqali (ribociclib)
- Koselugo (selumetinib)
- Lenvima (lenvatinib)
- Lonsurf (trifluridine/tipiracil)
- Lorbrena (lorlatinib)
- Lynparza (olaparib)
- Mekinist (trametinib)
- Mektovi (binimetinib)
- Nexavar (sorafenib)
- Nerlynx (neratinib)
- Ninlaro (ixazomib)
- Odomzo (sonidegib)
- Pemazyre (pemigatinib)
- Piqray (alpelisib)
- Pomalyst (pomalidomide)
- Qinlock (ripretinib)
- Revlimid (lenalidomide)
- Retevmo (selpercatinib)
- Rozlytrek (entrectinib)
- Rubraca (rucaparib)
- Rydapt (midostaurin)
- Sprycel (dasatinib)
- Stivarga (regorafenib)
- Sutent (sunitinib)
- Tabrecta (capmatinib)
- Tafinlar (dabrafenib)
- Tagrisso (osimertinib)
- Talzenna (talazoparib)
- Tasigna (nilotinib)
- Tazverik (tazemetostat)
- Tibsovo (ivosidenib)
- Tukysa (tucatinib)
- Turalio (pexidartinib)
- Tykerb (lapatinib)
- Venclexta (venetoclax)
- Verzenio (abemaciclib)
- Vitrakvi (larotrectinib)
- Vizimpro (dacomitinib)
- Votrient (pazopanib)
- Xalkori (crizotinib)
- Xpovio (selinexor)
- Xtandi (enzalutamide)
- Xospata (gilteritinib)

- Zejula (niraparib)
- Zelboraf (vemurafenib)
- Zolinza (vorinostat)
- Zydelig (idelalisib)
- Zykadia (ceritinib)

COVERAGE GUIDELINES

Abiraterone 250 mg

The plan may authorize coverage of abiraterone 250 mg for Members, when all of the following criteria are met:

1. Documented diagnosis of one of the following:
    a) Metastatic castration-resistant prostate-cancer
    b) Metastatic high-risk castration-sensitive prostate cancer

AND

2. The prescribing physician is an oncologist or urologist

AND

3. Documentation that treatment is in combination with prednisone

Note: Brand Zytiga 250 and 500 mg are non-covered. See Limitations.

Afinitor (everolimus)

The plan may authorize coverage of **Afinitor (everolimus) tablets** for Members, when **all** of the following criteria are met:

Advanced Renal Cell Carcinoma

1. Documented diagnosis of advanced renal cell carcinoma

AND

2. The prescribing physician is an oncologist

AND

3. The Member has a demonstrated disease progression or intolerance following an appropriate trial with sunitinib (Sutent®) or sorafenib (Nexavar®)

Subependymal Giant Cell Astrocytoma (SEGA)

1. Documented diagnosis of subependymal giant cell astrocytoma associated with tuberous sclerosis complex

AND

2. The prescribing physician is an oncologist

AND

3. Documentation the Member is not a candidate for surgical resection

Progressive Neuroendocrine Tumors

1. Documentation of at least one of the following:
    a) Diagnosis of progressive neuroendocrine tumor located in the pancreas
    b) Diagnosis of progressive, well-differentiated, non-functional neuroendocrine tumor located in the gastrointestinal tract or lung

AND

2. The prescribing physician is an oncologist

AND

3. The tumor cannot be removed by surgery or has spread to other parts of the body

Renal Angiomyolipoma with Tuberous Sclerosis Complex

1. Documented presence of tuberous sclerosis and renal angiomyolipoma(s) greater than or equal to 3 cm in longest diameter

AND

2. The prescribing physician is an oncologist

Advanced Hormone Receptor-Positive, HER2-Negative Breast Cancer (Advanced HR+ BC)

1. Documented diagnosis of advanced hormone receptor-positive, HER2-negative breast cancer

AND

2. The Member is postmenopausal

AND

3. The prescribing physician is an oncologist

AND

4. Documented failure of letrozole (Femara®) or anastrozole (Arimidex®)

AND

5. Documentation that Afinitor (everolimus) tablets will be administered in combination with exemestane (Aromasin®)

Tuberous Sclerosis Complex-Associated Partial-Onset Seizures

1. Documented diagnosis of partial-onset seizures associated with tuberous sclerosis complex

AND

2. Documentation of use as adjunctive therapy in combination with other therapies (e.g., anticonvulsants)

AND

3. The Member is at least 2 years of age

AND

4. The prescribing physician is an oncologist or a neurologist

Afinitor Disperz (everolimus)

The plan may authorize coverage of **Afinitor Disperz (everolimus) tablets for oral suspension** for Members when **all** of the following criteria are met:

Subependymal Giant Cell Astrocytoma (SEGA)

1. Documented diagnosis of subependymal giant cell astrocytoma associated with tuberous sclerosis complex

AND

2. The prescribing physician is an oncologist

AND

3. Member is not a candidate for surgical resection

Tuberous Sclerosis Complex-Associated Partial-Onset Seizures

1. Documented diagnosis of partial-onset seizures associated with tuberous sclerosis complex

AND

2. Documentation of use as adjunctive therapy in combination with other therapies (e.g., anticonvulsants)

AND

3. The Member is at least 2 years of age

AND

4. The prescribing physician is an oncologist or a neurologist

Alecensa (alectinib)

The plan may authorize coverage of Alecensa (alectinib) for Members, when **all** of the following criteria are met:

1. Documented diagnosis of anaplastic lymphoma kinase-positive, metastatic non-small cell lung cancer as detected by an FDA-approved test

AND

2. The prescribing physician is an oncologist

Alunbrig (brigatinib)

The plan may authorize coverage of Alunbrig (brigatinib) for Members, when all of the following criteria are met:

1. Documented diagnosis of anaplastic lymphoma kinase-positive metastatic non-small cell lung cancer

AND

2. The prescribing physician is an oncologist

Ayvakit (avaprtinib)

The plan may authorize coverage of Ayvakit (avapritinib) for Members, when all of the following criteria are met:

1. Documented diagnosis of unresectable or metastatic gastrointestinal stromal tumor

AND

2. Documentation of platelet-derived growth factor receptor alpha (PDGFRA) exon 18 mutation

AND

3. The prescribing physician is an oncologist

Balversa (erdafitinib)

The plan may authorize coverage of Balversa (erdafitinib) for Members, when all of the following criteria are met:

1. Documented diagnosis of metastatic urothelial carcinoma

AND

2. Documentation of susceptible FGFR3 or FGFR2 genetic alternations

AND

3. Documentation of disease progression following ≥1 line of prior platinum-containing chemotherapy

AND

4. The prescribing physician is an oncologist

Bosulif (bosutinib)

The plan may authorize coverage of Bosulif (bosutinib) for Members when all of the following criteria are met:

1. The prescribing physician is an oncologist or hematologist

AND

2. Documentation of one of the following:
    a) Documented diagnosis of chronic phase Philadelphia chromosome-positive chronic myelogenous leukemia
    b) Diagnosis of accelerated phase or blast phase Philadelphia chromosome-positive chronic myelogenous leukemia AND documented resistance or intolerance to prior therapy (e.g., imatinib)

Braftovi (encorafenib)

The plan may authorize coverage of Braftovi (encorafenib) for Members when all of the following criteria are met:

Colorectal Cancer

1. Documented diagnosis of metastatic colorectal cancer

AND

2. Documentation of BRAF V600E mutation as detected by an FDA approved test

AND

3. The prescribing physician is an oncologist

AND

4. Documentation of use in combination with Erbitux (cetuximab)

AND

5. Documentation the Member has received prior therapy for the treatment of colorectal cancer

Melanoma

1. Documented diagnosis of unresectable or metastatic melanoma

AND

2. Documentation of BRAF V600E or V600K mutation as detected by an FDA approved test

AND

3. The prescribing physician is an oncologist

AND

4. Documentation of use in combination with Mektovi (binimetinib)

Brukinsa (zanubrutinib)

The plan may authorize coverage of Brukinsa (zanubrutinib) for Members when all of the following criteria are met:

1. Documented diagnosis of mantle cell lymphoma

AND

2. Documentation the Member ha received at least one prior therapy

AND

3. The prescribing physician is an oncologist or hematologist

Cabometyx (cabozantinib)

The plan may authorize coverage of Cabometyx (cabozantinib) for Members when all of the following criteria are met:

1. Documentation of one of the following:
    a) Diagnosis of advanced renal cell carcinoma
    b) Diagnosis of hepatocellular carcinoma AND previous treatment with Nexavar

AND

2. The prescribing physician is an oncologist

Calquence (acalabrutinib)

The plan may authorize coverage of Calquence (acalabrutinib) for Members, when all of the following criteria are met:

1. The prescribing physician is an oncologist or hematologist

AND

2. Documentation of one of the following:
    a. Diagnosis of mantle cell lymphoma AND the Member has received at least one prior therapy
    b. Diagnosis of chronic lymphocytic leukemia
    c. Diagnosis of small lymphocytic lymphoma

Caprelsa (vandetanib)

The plan may authorize coverage of Caprelsa (vandetanib) for Members, when all of the following criteria are met:

1. Documented diagnosis of symptomatic or progressive medullary thyroid cancer with unresectable locally advanced or metastatic disease

AND

2. The prescribing physician is an oncologist

Cometriq (cabozantinib)

The plan may authorize coverage of Cometriq (cabozantinib) for Members, when all of the following criteria are met:

1. Documented diagnosis of progressive, metastatic medullary thyroid cancer

AND

2. The prescribing physician is an oncologist

Copiktra (duvelisib)

The plan may authorize coverage of Copiktra (duvelisib) for Members, when all of the following criteria are met

1. Documented diagnosis of one of the following:
    a) Relapsed or refractory chronic lymphocytic leukemia
    b) Relapsed or refractory small lymphocytic lymphoma
    c) Relapsed or refractory follicular lymphoma

AND

2. Documentation the Member has received at least two prior systemic therapies

AND

3. The prescribing physician is an oncologist or hematologist

Cotellic (cobimetinib)

The plan may authorize coverage of Cotellic (cobimetinib) for Members, when all the following criteria are met:

1. Documented diagnosis of unresectable or metastatic melanoma

AND

2. The prescribing physician is an oncologist

AND

3. The Member has BRAF V600E or V600K mutation-positive melanoma as detected by an FDA-approved test

AND

4. Documentation that Cotellic (cobimetinib) will be administered in combination with Zelboraf (vemurafenib)

Daurismo (glasdegib)

The plan may authorize coverage of Daurismo (glasdegib) for Members, when all of the following criteria are met:

1. Documented diagnosis of acute myeloid leukemia

AND

2. Documentation Daurismo will be administered in combination with low-dose cytarabine

AND

3. The prescribing physician is an oncologist or hematologist

AND

4. Documentation of one of the following:
    a) Member is at least 75 years old
    b) Member has a comorbidity that precludes the use of intensive induction chemotherapy

Erivedge (vismodegib)

The plan may authorize coverage of Erivedge (vismodegib) for Members, when all of the following criteria are met:

1. Documentation of one of the following:
    a) Diagnosis of metastatic basal cell carcinoma
    b) Diagnosis of locally advanced basal cell carcinoma AND that disease has recurred following surgery or the Member is not a candidate for surgery or radiation therapy

AND

2. The prescribing physician is an oncologist

Farydak (panobinostat)

The plan may authorize coverage of Farydak (panobinostat) for Members, when all of the following criteria are met:

1. Documented diagnosis of multiple myeloma

AND

2. The prescribing physician is an oncologist

AND

3. Documentation the Member has received at least two prior therapies, including bortezomib and an immunomodulatory agent

AND

4. Documentation the Member will be receiving both bortezomib and dexamethasone in conjunction with panobinostat

Gilotrif (afatinib)

The plan may authorize coverage of Gilotrif (afatinib) for Members when all of the following criteria are met:

1. The prescribing physician is an oncologist

AND

2. Documentation of one of the following:
    a) Documented diagnosis of metastatic non-small cell lung cancer with tumors that have non-resistant epidermal growth factor receptor mutations as detected by an FDA-approved test
    b) Documented diagnosis of metastatic, squamous non-small cell lung cancer progressing after platinum-based chemotherapy

Hycamtin (topotecan)

The plan may authorize coverage of Hycamtin (topotecan) capsules for Members, when all of the following criteria are met:

1. Documented diagnosis of relapsed small cell lung cancer in patients with a prior complete or partial response and who are at least 45 days from the end of first-line chemotherapy

AND

2. The prescribing physician is an oncologist

Ibrance (palbociclib)

The plan may authorize coverage of Ibrance (palbociclib) for Members, when all of the following criteria are met:

1. Documented diagnosis of hormone receptor positive, human epidermal growth factor receptor-2 negative advanced metastatic breast cancer

AND

2. The prescribing physician is an oncologist

AND

3. Documentation of use in combination with one of the following:
    a) An aromatase inhibitor as initial endocrine based therapy in postmenopausal women or men
    b) Fulvestrant in patients with disease progression following endocrine therapy

Iclusig (ponatinib)

The plan may authorize coverage of Iclusig (ponatinib) for Members, when all the following criteria are met:

1. The prescribing physician is an oncologist or hematologist

AND

2. Documentation of one of the following:
    a) Documented diagnosis of T315I-positive chronic myeloid leukemia (chronic phase, accelerated phase, or blast phase) or T315I-positive Philadelphia chromosome positive acute lymphoblastic leukemia
    b) Documented diagnosis of chronic phase, accelerated phase, or blast phase chronic myeloid leukemia or Philadelphia chromosome positive acute lymphoblastic leukemia AND documentation that no other tyrosine kinase inhibitor therapy is indicated

Idhifa (enasidenib)

The plan may authorize coverage of Idhifa (enasidenib) for Members, when **all** of the following criteria are met:

1. Documented diagnosis of isocitrate dehydrogenase-2 mutated acute myeloid leukemia (as detected by an FDA-approved test)

AND

2. Documentation of at least one prior anticancer regimen for the treatment of acute myeloid leukemia

AND

3. Prescribing physician is an oncologist or hematologist

Imbruvica (ibrutinib)

The plan may authorize coverage of Imbruvica (ibrutinib) for Members, when all of the following criteria are met:

Mantle cell lymphoma

1. Documented diagnosis of mantle cell lymphoma

AND

2. The prescribing physician is an oncologist or hematologist

AND

3. The Member has been treated with at least one prior therapy

Chronic lymphocytic leukemia and small lymphocytic lymphoma with or without 17p deletion

1. The Member has a diagnosis of chronic lymphocytic leukemia or small lymphocytic lymphoma with or without 17p deletion

AND

2. The prescribing physician is an oncologist or hematologist

Waldenstrom's macroglobulinemia

1. Documented diagnosis of Waldenstrom's macroglobulinemia

AND

2. The prescribing physician is an oncologist or hematologist

Marginal Zone Lymphoma

1. Documented diagnosis of marginal zone lymphoma with required systemic therapy

AND

2. The Member has been treated with at least one prior anti-CD20-based therapy

AND

3. The prescribing physician is an oncologist or hematologist

Chronic Graft versus Host Disease

1. Documented diagnosis of chronic graft versus host disease

AND

2. The Member has been treated with at least one systemic therapy

Inlyta (axitinib)

The plan may authorize coverage of Inlyta (axitinib) for Members, when the following criteria are met:

1. Documented diagnosis of advanced renal cell carcinoma

AND

2. The prescribing physician is an oncologist

AND

3. Documentation of one of the following:
    a. Use in combination with avelumab or pembrolizumab
    b. Failure of at least one prior first-line systemic therapy (e.g. Sutent, Nexavar, Afinitor, Votrient, Avastin, Torisel)

Inrebic (fedratinib)

The plany may authorize coverage of Inrebic (fedratinib) for Members, when the following criteria are met:

1. Documented diagnosis of intermediate-2 or high-risk, primary or secondary myelofibrosis

AND

2. The prescribing physician is an oncologist or hematologist

Iressa (gefitinib)

The plan may authorize coverage for Iressa (gefitinib) when all of the following criteria are met:

1. Documented diagnosis of metastatic non-small cell lung cancer whose tumors have epidermal growth factor exon 19 deletions or exon 21 (L858R) substitution mutations as detected by an FDA-approved test

AND

2. The prescribing physician is an oncologist

Jakafi (ruxolitinib)

The plan may authorize coverage of Jakafi (ruxolitinib) for Members, when all the following criteria are met:

1. Documentation of one of the following:
    a) Documented diagnosis of intermediate or high-risk myelofibrosis
    b) Documented diagnosis of polycythemia vera AND documented inadequate response or intolerance to hydroxyurea
    c) Documented diagnosis of steroid-refractory acute graft-versus-host disease in patients 12 years and older

Kisqali (ribociclib)

The plan may authorize coverage of Kisqali (ribociclib) for Members, when all of the following criteria are met:

1. Documented diagnosis of breast cancer

AND

2. Documentation the disease meets all of the following:
    a) Hormone receptor positive
    b) Human epidermal growth factor receptor 2 (HER 2) negative
    c) Advanced or metastatic

AND

3. The prescribing physician is an oncologist

AND

4. Documentation of one of the following:
    a) Use in combination with an aromatase inhibitor as initial endocrine-based therapy
    b) Use in combination with fulvestrant as initial endocrine-based therapy or following disease progression on endocrine therapy in a postmenopausal woman

Koselugo (selumetinib)

The plan may authorize coverage of Koselugo (selumetinib) for Members, when all of the following criteria are met:

1. Documented diagnosis of neurofibromatosis type 1

AND

2. Documentation of symptomatic, inoperable plexiform neurofibromas

AND

3. The Member is at least 2 years of age

AND

4. The prescribing physician in an oncologist, geneticist, or neurologist

Lenvima (lenvatinib)

The plan may authorize coverage of Lenvima (lenvatinib) for Members, when all of the following criteria are met:

1. Documented diagnosis of one of the following:
    a) Locally recurrent or metastatic, progressive, radioactive iodine-refractory differentiated thyroid cancer
    b) Use in combination with everolimus for advanced renal cell carcinoma following one prior anti-angiogenic therapy
    c) Unresectable hepatocellular carcinoma
    d) Use in combination with pembrolizumab for advanced endometrial carcinoma that is not microsatellite instability-high or mismatch repair deficient AND disease progression following systemic therapy AND documentation the Member is not a candidate for curative surgery or radiation

AND

2. The prescribing physician is an oncologist

Lonsurf (trifluridine/tipiracil)

The plan may authorize coverage for Lonsurf (trifluridine/tipiracil) when all of the following criteria are met:

1. The prescribing physician is an oncologist

AND

2. Documentation of one of the following
    a) Documented diagnosis of metastatic colorectal cancer (mCRC) AND Documentation the Member has been previously treated with fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy; an anti-vascular endothelial growth factor (VEGF) biological therapy; and if rat sarcoma viral oncogene (RAS) wild-type, an anti-epidermal growth factor receptor (EGFR) therapy
    b) Documented diagnosis of metastatic gastric or gastroesophageal junction adenocarcinoma AND Documentation the Member has been previously treated with at least two prior lines of chemotherapy that included fluoropyrimidine, a platinum, either a taxane or irinotecan, and if appropriate, HER2/neu-targeted therapy

Lorbrena (lorlatinib)

The plan may authorize coverage for Lorbrena (lorlatinib) when all of the following criteria are met:

1. Documented diagnosis of anaplastic lymphoma kinase (ALK)-positive metastatic non-small cell lung cancer

AND

2. The prescribing physician is an oncologist

AND

3. Documentation the disease has progressed on Alecensa, Xalkori, or Zykadia

Lynparza (olaparib)

The plan may authorize coverage of Lynparza (olaparib) for Members, when all of the following criteria are met:

Breast Cancer

1. The prescribing physician is an oncologist

AND

2. Documented diagnosis of deleterious or suspected deleterious germline BRCA-mutated, HER2-negative metastatic breast cancer based on an FDA approved test

AND

3. Documentation the Member has received chemotherapy in the neoadjuvant, adjuvant, or metastatic setting

AND

4. In patients with hormone receptor positive breast cancer, documentation of one of the following:
    a) The Member has previous treatment with an endocrine therapy
    b) The Member is considered inappropriate for endocrine therapy

Ovarian Cancer

1. The prescribing physician is an oncologist

AND

2. Documentation of one of the following:
    a) Diagnosis of recurrent epithelial ovarian, fallopian tube or primary peritoneal cancer AND Member is in complete or partial response to platinum-based chemotherapy
    b) Diagnosis of deleterious or suspected deleterious germline or somatic BRCA mutated advanced epithelial ovarian, fallopian tube, or primary peritoneal cancer as detected by an FDA approved test (germline BRCA mutated only) AND Member is in complete or partial response to first-line platinum based chemotherapy
    c) Diagnosis of deleterious or suspected deleterious germline BRCA mutated advanced ovarian cancer as detected by an FDA approved test AND Member has tried and failed at least three prior lines of chemotherapy
    d) Diagnosis of advanced epithelial ovarian, fallopian tube or primary peritoneal cancer who are in complete or partial response to first-line platinum-based chemotherapy and whose cancer is associated with homologous recombination deficiency-positive status AND documentation of use in combination with bevacizumab

Pancreatic Cancer

1. The prescribing physician is an oncologist

AND

2. Documented diagnosis of deleterious or suspected deleterious germline BRCA-mutated metastatic pancreatic adenocarcinoma as detected by an FDA approved test

AND

3. Documentation of no disease progression after at least 16 weeks of first-line platinum-based chemotherapy

Prostate Cancer

1. Documented diagnosis of metastatic castration-resistant prostate cancer

AND

2. Documentation of deleterious or suspected deleterious germline or somatic homologous recombination repair gene-mutated cancer

AND

3. Documentation the Member has progressed following prior treatment with enzalutamide or abiraterone

AND

4. The prescribing physician is an oncologist

Mekinist (trametinib)

The plan may authorize coverage of Mekinist (trametenib) for Members when all of the following criteria are met:

1. The prescribing physician is an oncologist

AND

2. Documentation of one of the following:
    a) Diagnosis of metastatic non-small cell lung cancer with BRAF V600E mutation as detected by an FDA-approved test
    b) Diagnosis of unresectable or metastatic melanoma with BRAF V600E or V600K mutation as detected by an FDA-approved test
    c) Use in combination with Tafinlar for a diagnosis of locally advanced or metastatic anaplastic thyroid cancer with BRAF V600E mutation AND locoregional treatment options are not appropriate
    d) Use as adjuvant treatment in combination with Tafinlar following complete resection for a diagnosis of melanoma with BRAF V600E or V600K mutations as detected by an FDA-approved test AND lymph node involvement

Mektovi (binimetinib)

The plan may authorize coverage of Mektovi (binimetinib) for Members when all of the following criteria are met:

1. Documented diagnosis of unresectable or metastatic melanoma

AND

2. Documentation of BRAF V600E or V600K mutation as detected by an FDA approved test

AND

3. The prescribing physician is an oncologist

AND

4. Documentation of use in combination with Braftovi (encorafenib)

Nerlynx (neratinib)

The plan may authorize coverage of Nerlynx (neratinib) for Members, when all of the following criteria are met:

1. Documented diagnosis of human epidermal growth factor receptor 2-positive breast cancer

AND

2. Documentation of one of the following:
    a. Early-stage disease AND use following trastuzumab therapy
    b. Advanced or metastatic disease AND use in combination with capecitabine following at least two prior anti-human epidermal growth factor receptor 2 based regimens

AND

3. Prescribing physician is an oncologist

Nexavar (sorafenib)

The plan may authorize coverage of Nexavar (sorafenib) when **all** of the following criteria are met:

Advanced Renal Cell Carcinoma (RCC)

1. The Member is at least 18 years of age

AND

2. Documented diagnosis of advanced renal cell carcinoma

AND

3. The prescribing physician is an oncologist

Unresectable Hepatocellular Carcinoma (HCC)

1. The Member is at least 18 years of age

AND

2. Documented diagnosis of biopsy-proven, unresectable hepatocellular carcinoma

AND

3. The prescribing physician is an oncologist

Differentiated Thyroid Carcinoma

1. The Member is at least 18 years of age

AND

2. Documented diagnosis of locally recurrent or metastatic, progressive, differentiated thyroid carcinoma refractory to radioactive iodine treatment

AND

3. The prescribing physician is an oncologist or Thyroid Specialist

Ninlaro (ixazomib)

The plan may authorize coverage of Ninlaro (ixazomib) for Members, when all of the following criteria are met:

1. Documented diagnosis of multiple myeloma

AND

2. The prescribing physician is an oncologist

AND

3. Documentation the Member has received at least one prior therapy

AND

4. Documentation that Ninlaro (ixazomib) will be administered in combination with lenalidomide and dexamethasone

Odomzo (sonidegib)

The plan may authorize coverage of Odomzo (sonidegib) for Members, when the following criteria are met:

1. Documented diagnosis of locally advanced basal cell carcinoma

AND

2. The prescribing physician is an oncologist

AND

3. Documentation of one of the following:
    a) Documentation of disease recurrence following surgery or radiation therapy
    b) Documentation the Member is not a candidate for surgery or radiation therapy

Pemazyre (pemigatinib)

The plan may authorize coverage of Pemazyre (pemigatinib) for Members, when the following criteria are met:

1. Documented diagnosis of unresectable locally advanced or metastatic cholangiocarcinoma

AND

2. Documentation of fibroblast growth factor receptor 2 (FGFR2) fusion or other rearrangement as detected by an FDA-approved test

AND

3. Documentation the Member has received a previous treatment for the requested condition

AND

4. The prescribing physician is an oncologist

Piqray (alpelisib)

The plan may authorize coverage of Piqray (aleplisib) for Members, when the following criteria are met:

1. Documented diagnosis of hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative, advanced or metastatic breast cancer

AND

2. Documentation of PIK3CA-mutated disease as detected by an FDA-approved test

AND

3. Documentation of disease progression on or after an endocrine-based regimen

AND

4. The prescribing physician is an oncologist

AND

5. Documentation Piqray will be used in combination with fulvestrant

Pomalyst (pomalidomide)

The plan may authorize coverage of Pomalyst (pomalidomide) for Members, when all of the following criteria are met:

Kaposi Sarcoma

1. Documentation of one of the following:
    a. Diagnosis of Kaposi sarcoma and HIV-negative status
    b. Diagnosis of AIDS-related Kaposi sarcoma after failure of highly active antiretroviral therapy

AND

2. The prescribing physician is an oncologist

Multiple Myeloma

1. Documented diagnosis of multiple myeloma

AND

2. The prescribing physician is an oncologist

AND

3. Documentation the Member has failed two prior therapies, including bortezomib and lenalidomide

Qinlock (ripretinib)

The plan may authorize coverage of Qinlock (ripretinib) for Members, when all of the following criteria are met:

1. Documented diagnosis of advanced gastrointestinal stromal tumor

AND

2. The prescribing physician is an oncologist

AND

3. Documentation the Member has previously received treatment with imatinib and at least two other kinase inhibitors

Revlimid (lenalidomide)

The plan may authorize coverage of Revlimid (lenalidomide) for Members when all of the following criteria are met:

Transfusion-dependent Anemia

1. Documented diagnosis of transfusion dependent anemia due to myelodysplastic syndrome associated with the 5q-deletion cytogenetic abnormality

AND

2. The prescribing physician is an oncologist or hematologist

Multiple Myeloma

1. Documentation of one of the following:
    a) Diagnosis of multiple myeloma AND use in combination with dexamethasone
    b) Use as maintenance therapy in a Member following autologous hematopoietic stem cell transplantation

AND

2. The prescribing physician is an oncologist or hematologist

Mantle Cell Lymphoma

1. Documented diagnosis of mantle cell lymphoma

AND

2. Documentation the Member's disease has relapsed or progressed after two prior therapies, one of which included Velcade (bortezomib)

AND

3. The prescribing physician is an oncologist or hematologist

Follicular Lymphoma

1. Documented diagnosis of follicular lymphoma

AND

2. Documentation the Member has been previously treated

AND

3. The prescribing physician is an oncologist or hematologist

AND

4. Revlimid will be used in combination with a rituximab product

Marginal Zone Lymphoma

1. Documented diagnosis of marginal zone lymphoma

AND

2. Documentation the Member has been previously treated

AND

3. The prescribing physician is an oncologist or hematologist

AND

4. Revlimid will be used in combination with a rituximab product

Retevmo (selpercatinib)

The plan may authorize coverage of Retevmo (selpercatinib) for Members when all of the following criteria are met:

Non-small Cell Lung Cancer

1. Documented diagnosis of metastatic non-small cell lung cancer

AND

2. Documentation of RET fusion-positive cancer

AND

3. The Member is at least 18 years of age

AND

4. The prescribing physician is an oncologist

Medullary Thyroid Cancer

1. Documented diagnosis of advanced or metastatic medullary thyroid cancer

AND

2. Documentation of RET-mutant cancer

AND

3. Documentation the Member requires systemic therapy

AND

4. The Member is at least 12 years of age

AND

5. The prescribing physician is an oncologist

Thyroid Cancer

1. Documented diagnosis of advanced or metastatic thyroid cancer

AND

2. Documentation of RET fusion-positive cancer

AND

3. Documentation the Member requires systemic therapy

AND

4. Documentation of one of the following:
    a. The Member is radioactive iodine-refractory
    b. Radioactive iodine is not clinically appropriate

AND

5. The Member is at least 12 years of age

AND

6. The prescribing physician is an oncologist

Rozlytrek (entrectinib)

The plan may authorize coverage of Rozlytrek (entrectinib) for Members, when all the following criteria are met:

1. The prescribing physician is an oncologist

AND

2. Documentation of one of the following:
    a. ROS1-positive, metastatic NSCLC
    b. Solid tumor that have a NTRK gene fusion without a known resistance mutation AND the disease is metastatic or surgical resection is likely to result in severe morbidity AND the Member has progressed following treatment or has no satisfactory alternative therapy

Rubraca (rucaparib)

The plan may authorize coverage of Rubraca (rucaparib) for Members, when all the following criteria are met:

Ovarian Cancer

1. Documentation of one of the following:
    a) Diagnosis of deleterious BRCA mutated (germline and/or somatic) (as detected by an FDA-approved test) epithelial ovarian, fallopian tube, or peritoneal cancer AND the Member has tried and failed at least two prior chemotherapies
    b) Diagnosis of recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer AND the Member is in a complete or partial response to platinum-based chemotherapy

AND

2. The prescribing physician is an oncologist or gynecologist with oncologist training

Prostate Cancer

1. Documented diagnosis metastatic castration-resistant prostate cancer

AND

2. Documentation of deleterious BRCA mutation associated cancer

AND

3. Documentation the Member has been previously treated with androgen receptor-directed therapy and a taxane-based chemotherapy

AND

4. Documentation the prescribing physician is an oncologist

Rydapt (midostaurin)

The plan may authorize coverage of Rydapt (midostaurin) for Members, when all of the following criteria are met:

Acute Myeloid Leukemia

1. Documented diagnosis of FLT3 mutation-positive acute myeloid leukemia as detected by an FDA-approved test

AND

2. Documentation requested use is in combination with cytarabine and daunorubicin induction and cytarabine consolidation

AND

3. The prescribing physician is an oncologist or hematologist

Other Hematologic Conditions

1. Documented diagnosis of one of the following:
    a) Aggressive systemic mastocytosis
    b) Systemic mastocytosis with associated hematological neoplasm
    c) Mast cell leukemia

AND

2. The prescribing physician is an oncologist or hematologist

Sprycel (dasatinib)

The plan may authorize coverage of Sprycel (dasatinib) for Members, when all of the following criteria are met:

Chronic Myeloid Leukemia (CML)

1. Documentation of at least one of the following:
    a) Newly diagnosed Philadelphia chromosome-positive CML in chronic phase
    b) Chronic, accelerated, or myeloid or lymphoid blast phase Philadelphia chromosome CML with documented resistance or intolerance to prior therapy, including imatinib
    c) Pediatric patient with Philadelphia chromosome positive CML in chronic phase

AND

2. The prescribing physician is an oncologist or hematologist

Acute Lymphoblastic Leukemia (ALL)

1. Documented diagnosis of Philadelphia chromosome-positive ALL

AND

2. The prescribing physician is an oncologist or hematologist

Stivarga (regorafenib)

The plan may authorize coverage of Stivarga (regorafenib) for Members, when all of the following criteria are met:

Metastatic Colorectal Cancer

1. The Member has a diagnosis of metastatic colorectal cancer

AND

2. The prescribing physician is an oncologist

AND

3. Documented prior failure, contraindication, or intolerance to prior therapy with **ALL** of the following:
    a) fluoropyrimidine-based chemotherapy
    b) oxaliplatin-based chemotherapy
    c) irinotecan-based chemotherapy
    d) anti-vascular endothelial growth factor (VEGF) therapy (e.g., bevacizumab)
    e) anti-EGFR therapy (e.g., panitumumab or cetuximab) if the Member has RAS wild-type mCRC

Gastrointestinal Stromal Tumor (GIST)

1. The Member has a diagnosis of gastrointestinal stromal tumor

AND

2. The prescribing physician is an oncologist

AND

3. Documented prior failure, contraindication, or intolerance to prior therapy with **ALL** of the following:
    a) imatinib mesylate
    b) sunitinib malate

Hepatocellular Carcinoma

1. The Member has a diagnosis of hepatocellular carcinoma

AND

2. The prescribing physician is an oncologist

AND

3. Documented prior failure, contraindication, or intolerance to prior therapy with sorafenib

Sutent (sunitinib)

The plan may authorize coverage of Sutent (sunitinib) for Members when all of the following criteria are met:

Renal Cell Carcinoma

1. Documented diagnosis of at least one of the following:
    a) Advanced renal cell carcinoma
    b) High risk of recurrent renal cell carcinoma following nephrectomy

AND

2. The prescribing physician is an oncologist

Gastrointestinal Stromal Tumor

1. Documented diagnosis of gastrointestinal stromal tumor

AND

2. The prescribing physician is an oncologist

AND

3. The Member has a demonstrated disease progression or intolerance following an appropriate trial with imatinib mesylate

Progressive Neuroendocrine Tumors

1. Documented diagnosis of progressive neuroendocrine tumor located in the pancreas

AND

2. The prescribing physician is an oncologist

AND

3. The tumor cannot be removed by surgery or has spread to other parts of the body

Tabrecta (capmatinib)

The plan may authorize coverage of Tabrecta (capmatinib) for Members when all of the following criteria are met:

1. Documented diagnosis of metastatic non-small cell lung cancer

AND

2. Documentation the tumors have a mutation that leads to MET exon 14 skipping as detected by an FDA approved test

AND

3. The prescribing physician is an oncologist

Tafinlar (dabrafenib)

The plan may authorize coverage of Tafinlar (dabrafenib) for Members when **all** of the following criteria are met:

Monotherapy

1. Documented diagnosis of unresectable or metastatic melanoma

AND

2. The prescribing physician is an oncologist

AND

3. The Member has BRAF V600E mutation-positive melanoma as detected by an FDA-approved test.

Combination with trametinib

1. The prescribing physician is an oncologist

AND

2. Documentation of use with trametinib for one the following:
    a) Diagnosis of unresectable or metastatic melanoma AND BRAF V600E or V600K mutation-positive disease as detected by and FDA-approved test
    b) Use as adjuvant treatment following complete resection for a diagnosis of melanoma with BRAF V600E or V600K mutations as detected by an FDA-approved test AND lymph node involvement
    c) Diagnosis of metastatic non-small cell lung cancer AND BRAF V600E mutation-positive disease as detected by and FDA-approved test
    d) Diagnosis of locally advanced or metastatic anaplastic thyroid cancer with BRAF V600E mutation AND locoregional treatment options are not appropriate

Tagrisso (osimertinib)

The plan may authorize coverage of Tagrisso (osimertinib) for Members, when the following criteria are met:

1. Documented diagnosis of metastatic non-small cell lung cancer

AND

2. The prescribing physician is an oncologist

AND

3. Documentation of one of the following:
    a) EGFR T790M mutation positive disease as detected by an FDA-approved test AND failure, contraindication, or intolerance to prior tyrosine kinase therapy (e.g., afatinib, erlotinib, gefitinib)
    b) EGFR exon 19 deletions or exon 21 L858R mutation positive disease as detected by an FDA-approved test

Talzenna (talazoparib)

The plan may authorize coverage of Talzenna (talazoparib) for Members, when the following criteria are met:

1. Documented diagnosis of deleterious or suspected deleterious germline BRCA-mutated, HER2-negative locally advanced or metastatic breast cancer based on an FDA approved test

AND

2. The prescribing physician is an oncologist

Tasigna (nilotinib)

The plan may authorize coverage of Tasigna (nilotinib) for Members, when the following criteria are met:

Newly Diagnosed Philadelphia Chromosome Positive Chronic Myeloid Leukemia in Chronic Phase

1. Documented diagnosis of Philadelphia chromosome positive chronic myeloid leukemia in chronic phase

AND

2. The prescribing physician is an oncologist

Resistant or Intolerant Philadelphia Chromosome Positive Chronic Myeloid Leukemia in Chronic Phase and Accelerated Phase

1. Documented diagnosis of Philadelphia chromosome positive chronic myelogenous leukemia in chronic phase or in accelerated phase

AND

2. Documented resistance or intolerance to prior therapy, including imatinib

AND

3. The prescribing physician is an oncologist

Tazverik (tazemetostat)

The plan may authorization coverage of Tazverik (tazemetostat) for Members, when the following criteria are met:

Epithelioid Sarcoma

1. Documented diagnosis of metastatic or locally advanced epithelioid sarcoma not eligible for complete resection

AND

2. The Member is 16 years of age or older

AND

3. The prescribing physician is an oncologist

Relapsed or Refractory Follicular Lymphoma

1. Documented diagnosis of relapsed or refractory follicular lymphoma

AND

2. The prescribing physician is an oncologist or hematologist

AND

3. Documentation of one of the following:
    a. No satisfactory alternative treatment options
    b. Tumors are positive for an EZH2 mutation as detected by an FDA approved test and the Member has received at least two prior systemic therapies

Tibsovo (ivosidenib)

The plan may authorize coverage of Tibsovo (ivosidenib) for Members when all of the following criteria are met:

1. Documented diagnosis of acute myeloid leukemia with a susceptible IDH1 mutation as detected by an FDA-approved test

AND

2. The prescribing physician is an oncologist or hematologist

AND

3. The Member is an adult with one of the following:
    a. Relapsed of refractory acute myeloid leukemia
    b. Newly-diagnosed acute myeloid leukemia, who have comorbidities that preclude the use of intensive induction chemotherapy

Tukysa (tucatinib)

The plan may authorize coverage of Tukysa (tucatinib) for Members when all of the following criteria are met:

1. Documented diagnosis of advanced unresectable or metastatic HER2-positive breast cancer

AND

2. Documentation of use in combination with trastuzumab and capecitabine

AND

3. Documentation the Member has received one or more prior anti-HER2-based regimens in the metastatic setting

AND

4. The prescribing physician is an oncologist

Turalio (pexidartinib)

The plan may authorize coverage of Turalio (pexidartinib) for Members when all of the following criteria are met:

1. Documented diagnosis of tenosynovial giant cell tumor

AND

2. The prescribing physician is an oncologist

AND

3. Documentation the Member is symptomatic with severe morbidity or functional limitations

AND

4. Documentation the condition is not amenable to improvement with surgery

Tykerb (lapatinib)

The plan may authorize coverage of Tykerb (lapatinib) for Members when all of the following criteria are met:

HER2 overexpressing advanced or metastatic breast cancer

1. Documented diagnosis of HER2 overexpressing advanced or metastatic breast cancer

AND

2. Documentation the Member has failed prior therapy with an appropriate trial of an anthracycline and a taxane chemotherapeutic agent.

AND

3. Documentation the Member has failed prior therapy with an appropriate trial of Herceptin (trastuzumab).
   Note: Prior therapy with Herceptin (trastuzumab) implies that the Member's diagnosis of HER2 overexpressing breast cancer has been confirmed via immunohistochemistry (IHC) or fluorescent in situ hybridization (FISH) assay.

AND

4. Documentation Tykerb (lapatinib) will be administered concurrently with capecitabine (Xeloda®)

AND

5. The prescribing physician is an oncologist

Hormone-receptor positive metastatic breast cancer in post-menopausal women

1. Documented diagnosis of hormone receptor positive metastatic breast cancer that overexpresses the HER2 receptor

AND

2. Documentation Tykerb (lapatinib) will be administered concurrently with an aromatase inhibitor

AND

3. The prescribing physician is an oncologist

Venclexta (venetoclax)

The plan may authorize coverage of Venclexta (venetoclax) when all of the following criteria are met:

Acute myeloid leukemia

1. Documented diagnosis of acute myeloid leukemia

AND

2. Documentation of one of the following:
    a) The Member is at least 75 years of age
    b) Comorbidities that preclude use of intensive induction chemotherapy

AND

3. Documentation of use in combination with azacitidine, decitabine, or cytarabine

AND

4. The prescribing physician is an oncologist or a hematologist

Chronic lymphocytic leukemia

1. Documented diagnosis of chronic lymphocytic leukemia, with or without 17p deletion

AND

2. The prescribing physician is an oncologist or a hematologist

AND

3. Documentation the member has received at least one prior therapy

Small lymphocytic leukemia

1. Documented diagnosis of small lymphocytic leukemia, with or without 17p deletion

AND

2. The prescribing physician is an oncologist or a hematologist

AND

3. Documentation the member has received at least one prior therapy

Verzenio (abemaciclib)

The plan may authorize coverage of Verzenio (abemaciclib) for Members, when the following criteria are met:

1. Documented diagnosis of breast cancer

AND

2. Documented the disease meets all of the following:
    a) Hormone receptor positive
    b) Human epidermal growth factor receptor 2 (HER 2) negative
    c) Advanced or metastatic

AND

3. The prescribing physician is an oncologist

AND

4. Documentation of one of the following:
    a) Use in combination with an aromatase inhibitor AND documentation the Member is postmenopausal
    b) Use in combination with fulvestrant AND documentation of disease progression following endocrine therapy
    c) Use as monotherapy AND documentation of disease progression following endocrine therapy and prior chemotherapy in the metastatic setting

Vitrakvi (larotrectinib)

The plan may authorize coverage of Vitrakvi (larotrectinib) for Members, when the following criteria are met:

1. Documented diagnosis of a solid tumor that has a neurotrophic receptor tyrosine kinase (NTRK) gene fusion without a known acquired resistance mutation

AND

2. The prescribing physician is an oncologist

AND

3. Documentation of both of the following:
    a) Member's disease is metastatic or surgical resection is likely to result in severe morbidity
    b) There are no satisfactory alternative treatments or Member's disease has progressed following treatment

Vizimpro (dacomitinib)

The plan may authorized coverage of Vizimpro (dacomitinib) for Members when all of the following criteria are met:

1. Documented diagnosis of metastatic non-small cell lung cancer whose tumors have epidermal growth factor exon 19 deletions or exon 21 (L858R) substitution mutations as detected by an FDA-approved test

AND

2. The prescribing physician is an oncologist

Votrient (pazopanib)

The plan may authorize coverage of Votrient (pazopanib) for Members when all of the following criteria are met:

Advanced Renal Cell Carcinoma

1. Documented diagnosis of advanced renal cell carcinoma

AND

2. The prescribing physician is an oncologist

Advanced Soft Tissue Sarcoma

1. Documented diagnosis of advanced soft tissue sarcoma

AND

2. The prescribing physician is an oncologist

AND

3. The Member has received prior chemotherapy, including anthracycline treatment, or was unsuited for such therapy

Xalkori (crizotinib)

The plan may authorize coverage of Xalkori (crizotinib) for Members when all of the following criteria are met:

1. Documented diagnosis of metastatic non-small cell lung cancer

AND

2. The prescribing physician is an oncologist

AND

3. Documentation of at least one of the following:
    a) The Member has the anaplastic lymphoma receptor tyrosine kinase (ALK) genetic mutation as detected by an Food and Drug Administration-approved test
    b) The Member has ROS1-positive tumors

Xospata (gilteritinib)

The plan may authorize coverage of Xospata (gilteritinib) for Members when all of the following criteria are met:

1. Documented diagnosis of relapsed or refractory acute myeloid leukemia

AND

2. The prescribing physician is an oncologist or hematologist

AND

3. Documentation of a FLT3 mutation as detected by an FDA-approved test

Xpovio (selinexor)

The plan may authorize coverage of Xpovio (selinexor) for Members when all of the following criteria are met:

Diffuse Large B-Cell Lymphoma

1. Documented diagnosis of relapsed or refractory diffuse large B-cell lymphoma

AND

2. The prescribing physician is an oncologist or hematologist

AND

3. Documentation the Member has received at least two prior lines of systemic therapy

Multiple Myeloma

1. Documented diagnosis of relapsed or refractory multiple myeloma

AND

2. The prescribing physician is an oncologist or hematologist

AND

3. Documentation the Member has received at least four prior therapies

AND

4. Documentation disease is refractory to all of the following:
    a. At least two proteasome inhibitors
    b. At least two immunomodulatory agents
    c. An anti-CD38 monoclonal antibody

Xtandi (enzalutamide)

The plan may authorize coverage of Xtandi (enzalutamide) for Members when all of the following criteria are met:

1. The prescribing physician is an oncologist or urologist

AND

2. Documented diagnosis of one of the following:
    a) Castration-resistant prostate cancer
    b) Metastatic castration-sensitive prostate cancer

Zejula (niraparib)

The plan may authorize coverage of Zejula (niraparib) for Members, when all of the following criteria are met:

1. Documented diagnosis of epithelial ovarian, fallopian tube, or primary peritoneal cancer

AND

2. Documentation of recurrent disease in a Member with complete or partial response to platinum-based chemotherapy

AND

3. The prescribing physician is an oncologist

Zelboraf (vemurafenib)

The plan may authorize coverage of Zelboraf (vemurafenib) for Members when all of the following criteria are met:

Melanoma

1. Documented diagnosis of unresectable or metastatic melanoma

AND

2. The prescribing physician is an oncologist

AND

3. The Member has BRAF V600E mutation-positive melanoma as detected by an FDA-approved test

Erdheim-Chester Disease

1. Documented diagnosis of Erdheim-Chester Disease with BRAF V600 mutation

Zolinza (vorinostat)

The plan may authorize coverage of Zolinza (vorinostat) for Members when all of the following criteria are met:

1. Documented diagnosis of advanced cutaneous T-cell lymphoma (Stage IIB and higher)

AND

2. Documentation the Member has progressive, persistent or recurrent disease

AND

3. Documentation of current or prior treatment or treatment failure with at least one systemic chemotherapeutic agent for cutaneous T-cell lymphoma

AND

4. The prescribing physician is an oncologist or hematologist

Zydelig (idelalisib)

The plan may authorize coverage of Zydelig (idelalisib) for Members when all of the following criteria are met:

Chronic Lymphocytic Leukemia (CLL)

1. Documented diagnosis of relapsed chronic lymphocytic leukemia

AND

2. The prescribing physician is an oncologist or hematologist

AND

3. Documentation Zydelig (idelalisib) will be given in combination with rituximab

Follicular B-cell non-Hodgkin Lymphoma (FL)

1. Documented diagnosis of relapsed follicular B-cell non-Hodgkin lymphoma

AND

2. The prescribing physician is an oncologist or hematologist

AND

3. Documentation the Member has tried two prior systemic therapies (i.e., rituximab, alkylating agents, etc.)

Small Lymphocytic Lymphoma (SLL)

1. Documented diagnosis of relapsed small lymphocytic lymphoma

AND

2. The prescribing physician is an oncologist or hematologist

AND

3. Documentation the Member has tried two prior systemic therapies (i.e., rituximab, alkylating agents, etc.)

Zykadia (ceritinib)

The plan may authorize coverage of Zykadia (ceritinib) for Members, when all of the following criteria are met:

1. Documented diagnosis of metastatic non-small cell lung cancer

AND

2. The prescribing physician is an oncologist

AND

3. Documentation the Member has anaplastic lymphoma receptor tyrosine kinase (ALK) genetic mutation

Off-label Use Coverage for Other Cancer Diagnoses

Coverage for other cancer diagnoses may be authorized provided effective treatment with such drug is recognized for treatment of such indication in one of the standard reference compendia, or in the medical literature, or by the Massachusetts commissioner of Insurance (commissioner) under the provisions of the "Sullivan Law": (M.G.L. c.175, s.47K).

The plan may authorize coverage for use for other cancer diagnoses provided effective treatment with such drug is recognized as a "Medically Accepted Indication" according to the National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium as indicated by a Category 1 or 2A for quality of evidence and level of consensus.

Note: The plan requires prescribers to submit clinical documentation supporting the drug's effectiveness in treating the intended malignancy, including the applicable NCCN guideline(s).

In cases where the requested off-label use for the diagnosis is not recognized by the NCCN Drugs and Biologics Compendium, the plan will follow the Centers for Medicare and Medicaid Services (CMS) guidance, unless otherwise directed by the commissioner, and accept clinical documentation referenced in one of the other "Standard Reference Compendia" noted below or supported by clinical research that appears in a regular edition of a "Peer-Reviewed Medical Literature" noted below.

"Standard Reference Compendia"

1. American Hospital Formulary Service – Drug Information (AHFS-DI)
2. Thomson Micromedex DrugDex
3. Clinical Pharmacology (Gold Standard)
4. Wolters Kluwer Lexi-Drugs

"Peer Reviewed Medical Literature"

- American Journal of Medicine
- Annals of Internal Medicine
- Annals of Oncology
- Annals of Surgical Oncology
- Biology of Blood and Marrow Transplantation
- Blood
- Bone Marrow Transplantation
- British Journal of Cancer
- British Journal of Hematology
- British Medical Journal
- Cancer
- Clinical Cancer Research
- Drugs
- European Journal of Cancer (formerly the European Journal of Cancer and Clinical Oncology)
- Gynecologic Oncology
- International Journal of Radiation, Oncology, Biology, and Physics
- The Journal of the American Medical Association
- Journal of Clinical Oncology
- Journal of the National Cancer Institute
- Journal of the National Comprehensive Cancer Network (NCCN)
- Journal of Urology
- Lancet
- Lancet Oncology
- Leukemia
- The New England Journal of Medicine
- Radiation Oncology

When the plan evaluates the evidence in published, peer-reviewed medical literature, consideration will be given to the following:

1. Whether the clinical characteristics of the beneficiary and the cancer are adequately represented in the published evidence.
2. Whether the administered chemotherapy regimen is adequately represented in the published evidence.
3. Whether the reported study outcomes represent clinically meaningful outcomes experienced by patients.
4. Whether the study is appropriate to address the clinical question.
   a. whether the experimental design, in light of the drugs and conditions under investigation, is appropriate to address the investigative question (for example, in some clinical studies it may be unnecessary or not feasible to use randomization, double blind trials, placebos, or crossover);
   b. that non-randomized clinical trials with a significant number of subjects may be a basis for supportive clinical evidence for determining accepted uses of drugs; and,
   c. that case reports are generally considered uncontrolled and anecdotal information and do not provide adequate supportive clinical evidence for determining accepted uses of drugs.

LIMITATIONS

- The plan will not authorize the use of an oral cancer medication for a condition other than those listed above without appropriate documentation.
- The following quantity limitations apply:
  - Afinitor (everolimus) tablets: 30 units/30 days
  - Afinitor Disperz (everolimus) tablets for oral suspension: 60 units/30 days
  - Bosulif (bosutinib) tablets:
    - 100 mg: 120 units/30 days
    - 500 mg: 30 units/30 days
  - Caprelsa (vandetanib) tablets:
    - 100 mg tablet: 60 units/30 days
    - 300 mg tablet: 30 units/30 days
  - Hycamtin (topotecan) capsules:
    - 0.25 mg capsule: 15 units/21 days

        - 1 mg capsule: 25 units/21 days
    - Iclusig (ponatinib) tablets:
        - 15 mg tablet: 60 units/30 days
        - 45 mg tablet: 30 units/30 days
    - Idhifa (enasidenib) tablets: 30 units/30 days
    - Nexavar (sorafenib) tablets: 120 units/30 days
    - Retevmo (selpercatinib) capsules
        - 40 mg: 180 units/30 days
        - 80 mg: 120 units/30 days
    - Rubraca (rucaparib) tablets: 120 units/30 days
    - Sprycel (dasatinib) tablets:
        - 20, 50, 70, 80 mg tablets: 60 units/30 days
        - 100, 140 mg tablets: 30 units/30 days
    - Stivarga (regorafenib) capsules: 84 units/21 days
    - Tagrisso (osimertinib) 40 mg tablets: 30 units/30 days
    - Tykerb (lapatinib) tablets: 180 units/30 days
    - Votrient (pazopanib) 200 mg tablets: 120 units/30 days
    - Xtandi (enzalutamide) capsules: 120 units/30 days
- For the diagnoses of myelofibrosis and polycythemia vera, Tufts Health Plan will initially authorize Jakafi (ruxolitinib) for a period of 6 months. Subsequent authorization requires documentation of spleen size reduction and symptomatic improvement.
- Mekinist (trametinib) will not be authorized for the treatment of melanoma if there is history of prior BRAF-inhibitor therapy.
- Tafinlar (dabrafenib) will not be authorized for patients with wild-type BRAF melanoma or wild-type BRAF non-small cell lung cancer.
- The plan will not authorize coverage of Tykerb (lapatinib) for advanced or metastatic breast cancer tumors that do not overexpress the HER2 protein, unless such use satisfies the provisions noted in Off-label Use Coverage for Other Cancer Diagnoses.
- The efficacy of Votrient (pazopanib) for the treatment of patients with adipocytic soft tissue sarcoma or gastrointestinal stromal tumors has not been demonstrated.
- Zelboraf (vemurafenib) will not be authorized for the treatment of patients with wild-type BRAF melanoma.
- The plan does not cover multi-source branded oral cancer medications. Refer to the Pharmacy Medical Necessity Guidelines for Non-covered Drugs with Suggested Alternatives.
- The plan does not cover the following medications on all Commercial and Medicaid formularies: Erleada, Nubeqa, Yonsa, and Zytiga 500 mg.

CODES

None

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66. Pemazyre (pemigatinib) [prescribing information]. Wilmington, DE: Incyte Corporation; April 2020.

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90. Vitrakvi (larotrectinib) [prescribing information]. Stamford, CT: Loxo Oncology; November 2018.
91. Vizimpro (dacomitinib) [prescribing information]. New York, NY: Pfizer Labs; September 2018.
92. Votrient (pazopanib) [prescribing information] Research Triangle Park, NC: GlaxoSmithKline; August 2016.
93. Xalkori (crizotinib) [prescribing information]. New York, NY: Pfizer Labs; 2016 April.
94. Xospata (gilteritinib) [prescribing information]. Northbrook, IL: Astellas Pharma US, Inc.; 2018 November.
95. Xpovio (selinexor) [prescribing information]. Newton, MA: Karyopharm Therapeutics Inc.; 2020 June.
96. Xtandi (enzalutamide) [prescribing information]. Northbrook, IL: Astellas Pharma US, Inc., December 2019.
97. Yonsa (abiraterone) [prescribing information]. Cranbury, NJ: Sun Pharmaceutical Industries, Inc. May 2018.
98. Zejula (niraparib) [prescribing information]. Waltham (MA): Tesaro, Inc.; March 2017.
99. Zelboraf (vemurafenib) [package insert]. South San Francisco, CA: Genentech, Inc.; November 2017.
100. Zolinza (vorinostat) [prescribing information]. Whitehouse Station, NJ: Merck & Co., Inc.; Dec 2015.
101. Zydelig (idelalisib) [prescribing information]. Foster City, CA: Gilead Sciences, Inc.; 2016 September.
102. Zykadia (ceritinib) [prescribing information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; 2017 June.
103. Zytiga (abiraterone) [prescribing information]. Horsham, PA: Janssen Biotech, Inc., February 2018.

APPROVAL HISTORY

March 13, 2018: Reviewed by Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:

1. March 13, 2018: Consolidated existing individual oral chemo medication Medical Necessity Guidelines (MNG) into a class MNG. The individual MNGs (49) are retired effective March 19, 2018. Added hematologist as an approvable provider specialty to Bosulif, Iclusig, and Revlimid.
2. April 10, 2018: Updated criteria for Verzenio based on supplemental indication for use in combination with an aromatase inhibitor as initial endocrine-based therapy for the treatment of postmenopausal women with hormone receptor-positive, human epidermal growth factor receptor 2-negative advance or metastatic breast cancer. Updated criteria for Zytiga based on supplemental indication for use in combination with prednisone for the treatment of patients with metastatic high-risk castration-sensitive prostate cancer.
3. May 8, 2018: Added coverage criteria for Afinitor/Afinitor Disperz for adjunctive treatment of tuberous sclerosis complex-associated partial-onset seizures, Erleada for the treatment of non-metastatic castration-resistant prostate cancer, Rubraca for maintenance treatment of recurrent ovarian cancer, and Tagrisso for first-line treatment of EGFR mutation-positive metastatic non-small cell lung cancer. Added the following Limitation: "The plan does not cover multi-source branded oral cancer medications. Refer to the Pharmacy Medical Necessity Guidelines for Noncovered Drugs with Suggested Alternatives." Administrative update: Retired existing drug-specific MNGs for Idhifa and Nerlynx and added to Oral Cancer Medications MNG-no changes were made to the individual criteria.
4. June 12, 2018: Added coverage criteria for Tafinlar and Mekinist in combination for the adjuvant treatment of melanoma with BRAF V600E or V600K mutation, as detected by an FDA-approve test.
5. July 10, 2018: Updated the approvable diagnosis for Venclexta to be documentation of chronic lymphocytic leukemia or small lymphocytic lymphoma, with or without 17p deletion, based on updated FDA-approved indications.
6. August 7, 2018: Added Yonsa to the Medical Necessity Guideline. Updated coverage criteria for Xtandi based on new indication in for non-metastatic castration resistant prostate cancer. Updated the prescriber requirements for Rubraca to allow for a gynecologist with oncology training.
7. September 18, 2018: Added Bratovi and Mektovi to the Medical Necessity Guideline. Updated the coverage criteria for Lenvima to allow for coverage of renal cell carcinoma and hepatocellular carcinoma. Updated the coverage criteria for Ibrance to allow for combination therapy with any aromatase inhibitor in postmenopausal women as initial endocrine therapy.
8. October 16, 2018: Effective November 12, 2018, added Tibsovo to the Medical Necessity Guideline.
9. November 13, 2018: Updated Kisqali criteria to be in line with updated indications. Specified required criteria when Kisqali is used in combination with an aromatase inhibitor or fulvestrant.
10. December 11, 2018: Added coverage criteria for new Venclexta supplemental indication for acute myeloid leukemia. Added Copiktra to the Medical Necessity Guideline.
11. January 8, 2019: Added Talzenna and Vizimpro to the Medical Necessity Guideline. Updated coverage criteria for Lynparza based on updated package labeling.
12. February 12, 2019: Added Lorbrena to the Medical Necessity Guideline. Updated the Cabometyx criteria to allow for coverage of new supplemental indication for the treatment of hepatocellular carcinoma.
13. March 12, 2019: Added Daurismo, Vitravki, and Xospata to the Medical Necessity Guideline (MNG). Effective July 1, 2019, updated the coverage criteria for Xtandi to remove the following criterion: For metastatic castration-resistant prostate cancer (mCRPC), documented failure, contraindication or intolerance to prior treatment with abiraterone. Removed brand Erleada, Yonsa, and Zytiga from the Medical Necessity Guideline because they are non-covered for all Commercial and Medicaid formularies.
14. April 9, 2019: Added coverage criteria for new Lonsurf supplemental indication for treatment of metastatic gastric or gastroesophageal junction adenocarcinoma.
15. May 7, 2019: Updated coverage criteria for expanded Ibrance indication for the treatment of men with breast cancer.
16. June 11, 2019: Updated coverage criteria for the supplemental Tibsovo indication for newly-diagnosed ALM for Members who are $\geq$ 75 years old who have comorbidities that preclude use of intensive indication chemotherapy.
17. July 9, 2019: Effective September 16, 2019, added expanded indication and edited criteria for Jakafi for Members 12 years and older with steroid-refractory acute graft-versus-host disease.

Added expanded indication and criteria for Revlimid for Follicular and Marginal zone Lymphoma to be used in combination with a rituximab product.
18. August 13, 2019: Effective September 16, 2019, added Balversa to the Medical Necessity Guideline.
19. September 10, 2019: Added Piqray to the Medical Necessity Guideline.
20. October 15, 2019: Added Turalio and Xpovio to the Medical Necessity Guideline. Added coverage criteria for the supplemental Lenvima indication for endometrial cancer.
21. November 12, 2019: Added Inrebic and Rozlytrek to the Medical Necessity Guideline. Added the following Limitation "The plan does not cover the following medications on all Commercial and Medicaid formularies: Erleada, Nubeqa, Yonsa, andn Zytiga 500 mg."
22. January 14, 2020: Updated coverage criteria for the supplemental Calquence indication for chronic lymphocytic leukemia and small lymphocytic lymphoma. Updated coverage criteria for the updated Xtandi indications for castration-resistance prostate cancer and metastatic castration-sensitive prostate cancer. Effective February 11, 2020, added Brukinsa to the Medical Necessity Guideline.
23. February 11, 2020: Updated coverage criteria for the supplemental Lynparza indication for first-line maintenance treatment of germline BRCA-mutated metastatic pancreatic adenocarcinoma.
24. April 14, 2020: Added Ayvakit and Tazverik to the Medical Necessity Guideline. Updated coverage criteria for the supplemental Nerlynx indication for extended adjuvant treatment of early-stage breast cancer and advanced or metastatic breast cancer.
25. May 12, 2020: Updated coverage criteria for the supplemental Braftovi indication for treatment of metastatic colorectal cancer.
26. June 9, 2020: Updated coverage criteria for the supplemental Lynparza indication for treatment of advanced epithelial ovarian, fallopian tube, or primary peritoneal cancer and prostate cancer. Updated coverage criteria for the supplemental Pomalyst indication for the treatment of Kaposi sarcoma. Updated coverage criteria for the supplemental Rubraca indication for the treatment of metastatic castration-resistant prostate cancer with BRCA mutations.
27. July 14, 2020: Removed "Documentation of progression on or intolerance to crizotinib" from the coverage criteria for Alunbrig based on FDA approved labeling. Added Tukysa, Pemazyre, and Koselugo to the Medical Necessity Guideline. Updated coverage criteria for the supplemental Tazverik indication for the treatment of relapsed or refractory follicular lymphoma. Updated coverage criteria for the supplemental Inlyta indication for first-line treatment in advanced renal cell carcinoma. Updated coverage criteria for the supplemental Xpovio indication for diffuse large B-cell lymphoma.
28. August 11, 2020: Added Qinlock, Retevmo, and Tabrecta to the Medical Necessity Guideline.

BACKGROUND, PRODUCT AND DISCLAIMER INFORMATION

Pharmacy Medical Necessity Guidelines have been developed for determining coverage for plan benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. The plan makes coverage decisions on a case-by-case basis considering the individual member's health care needs. Pharmacy Medical Necessity Guidelines are developed for selected therapeutic classes or drugs found to be safe, but proven to be effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. The plan revises and updates Pharmacy Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Pharmacy Medical Necessity Guideline and a self-insured Member's benefit document, the provisions of the benefit document will govern.

Treating providers are solely responsible for the medical advice and treatment of members. The use of this policy is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to member eligibility and benefits on the date of service, coordination of benefits, referral/authorization and utilization management guidelines when applicable, and adherence to plan policies and procedures and claims editing logic.

Provider Services