Pharmacy Medical Necessity Guidelines: Oral Cancer Medications

Effective: January 18, 2021

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)
- erlotinib
- Erivedge (vismodegib)
- Farydak (panobinostat)
- Gavreto (pralsetinib)
- Gilotrif (afatinib)
- Hycamtin (topotecan)
- Ibrance (palbociclib)
- Iclusig (ponatinib)
- Idhifa (enasidenib)
- Imbruvica (ibrutinib)
- Inlyta (axitinib)
- Inqovi (decitabine/cedazuridine)
- Inrebic (fedratinib)
- Iressa (gefitinib)
- Jakafi (ruxolitinib)
- Kisqali (ribociclib)
- Kisqali-Femara Co-Pack (ribociclib/letrozole)
- Koselugo (selumetinib)
- Lenvima (lenvatinib)
- Lonsurf (trifluridine/tipiracil)
- Lorbrena (lorlatinib)
- Lynparza (olaparib)
- Mekinist (trametinib)
- Mektovi (binimetinib)
- Nexavar (sorafenib)
- Nerlynx (neratinib)
- Ninlaro (ixazomib)
- Odomzo (sonidegib)
- Onureg (azacytidine)
- Pemazyre (pemigatinib)
- Piqray (alpelisib)
- Pomalyst (pomalidomide)
- Qinlock (ripretinib)
- Revlimid (lenalidomide)
- Retevmo (selpercatinib)
- Rozlytrek (entrectinib)
- Rubraca (rucaparib)
- Rydapt (midostaurin)
- Stivarga (regorafenib)
- Sutent (sunitinib)
- Tabrecta (capmatinib)
- Tafinlar (dabrafenib)
- Tagrisso (osimertinib)
- Talzenna (talazoparib)
- Tazverik (tazemetostat)
- Tibsovo (ivosidenib)
- Tukysa (tucatinib)
- Turalio (pexidartinib)
- 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:

Breast Cancer

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

AND

2. The prescribing physician is an oncologist

AND

3. Requested regimen includes exemestane, fulvestrant, or tamoxifen

AND

Documented inadequate response or adverse reaction to **one (1)** or contraindication to **all** of the following: Anastrozole, letrozole, tamoxifen, toremifene, exemestane

Epilepsy associated with tuberous sclerosis complex (TSC)

1. Documented diagnosis of treatment-resistant epilepsy associated with TSC

AND

2. Prescribed by or in consultation with a neurologist

AND

3. Documented inadequate response to combination therapy with at least two anticonvulsants or contraindication to all other anticonvulsants

AND

4. Documentation Afinitor will be used as adjunctive therapy with at least one anticonvulsant agent

Renal angiomyolipoma with tuberous sclerosis complex (TSC), advanced pancreatic neuroendocrine tumors (PNET), advanced neuroendocrine tumors (NET) of gastrointestinal or lung origin, or subependymal giant cell astrocytoma (SEGA) with TSC

1. Documented diagnosis of **one (1)** of the following:
    a. Advanced neuroendocrine tumors (NET) of gastrointestinal or lung origin
    b. Advanced pancreatic neuroendocrine tumors (PNET)
    c. Renal angiomyolipoma with tuberous sclerosis complex (TSC)
    d. Subependymal giant cell astrocytoma (SEGA) with TSC

AND

2. The prescribing physician is an oncologist

Renal Cell Carcinoma

1. Documented diagnosis of advanced renal cell carcinoma

AND

2. The prescribing physician is an oncologist

AND

3. Documentation of **one (1)** of the following:

a. Tumor is non-clear cell histology
b. Tumor is clear cell histology and inadequate response or adverse reaction to **one (1)** or contraindication to **all** first-line therapies (pazopanib, sunitinib, temsirolimus, axitinib monotherapy or in combination with pembrolizumb, ipilimumab + nivolumab, cabozantinib, high-dose IL-2, sorafenib)

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 with tuberous sclerosis complex

AND

2. The prescribing physician is an oncologist

Tuberous Sclerosis Complex-Associated Partial-Onset Seizures

1. Documented diagnosis of treatment-resistant epilepsy associated with tuberous sclerosis complex

AND

2. Prescribed by or in consultation with a neurologist

AND

3. Documented inadequate response to combination therapy with at least two anticonvulsants or contraindication to all other anticonvulsants

AND

4. Documentation Afinitor Disperz will be used as adjunctive therapy with at least one anticonvulsant agent

Alecensa (alectinib)

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

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

AND

2. The prescribing physician is an oncologist

AND

3. Documentation cancer is anaplastic lymphoma kinase (ALK)-positive

Alunbrig (brigatinib)

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

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

AND

2. The prescribing physician is an oncologist

AND

3. Documentation cancer is anaplastic lymphoma kinase (ALK)-positive

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 FGFR3 or FGFR2-mutated locally advanced or metastatic urothelial carcinoma

AND

2. The prescribing physician is an oncologist

AND

3. Documentation the Member has received prior treatment with platinum-containing chemotherapy or is ineligible for platinum-containing chemotherapy

Bosulif (bosutinib)

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

1. Documented diagnosis of chronic myelogenous leukemia

AND

2. The prescribing physician is an oncologist or hematologist

AND

3. Documentation of **one (1)** of the following:
    a. Chronic phase Philadelphia chromosome-positive chronic myelogenous leukemia
    b. 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. The prescribing physician is an oncologist

AND

3. Documentation of positive BRAF V600E mutation

AND

4. Documentation Braftovi will be used in combination with Erbitux or Vectibix

AND

5. Documented inadequate response or adverse reaction to at least **one (1)** of the following regimens or a contraindication to **all** of the following regimens:
    a. CAPEOX (capecitabine/oxaliplatin)
    b. FOLFOX (leucovorin calcium [folinic acid]/fluorouracil/oxaliplatin)
    c. irinotecan-based therapy
    d. oxaliplatin-based therapy

Melanoma

1. Documented diagnosis of unresectable or metastatic melanoma

AND

2. The prescribing physician is an oncologist

AND

3. Documentation of positive BRAV V600E or V600K mutation

AND

4. Documentation Braftovi will be used 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. The Member is 18 years of age or older

AND

3. The prescribing physician is an oncologist or hematologist

AND

4. Documentation the Member has received at least one prior therapy for the treatment of mantle cell lymphoma

Cabometyx (cabozantinib)

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

Hepatocellular Carcinoma

1. Documented diagnosis of unresectable hepatocellular carcinoma

AND

2. The prescribing physician is an oncologist

AND

3. Documented inadequate response, adverse reaction, or contraindication to Nexavar

Renal Cell Carcinoma

1. Documented diagnosis of advanced renal cell carcinoma

AND

2. The prescribing physician is an oncologist

AND

3. Documentation of **one (1)** of the following:
    a. Member has poor/intermediate risk and the request is for first-line treatment of clear cell histology
    b. Member has favorable risk and clear cell histology and inadequate response or adverse reaction to one or contraindication to both of the following:
        i. Sutent
        ii. Votrient
    c. Member has clear cell histology and has received a previous treatment in the metastatic setting
    d. Member has non-clear cell histology and Member has an inadequate response, adverse reaction, or contraindication to Sutent

Calquence (acalabrutinib)

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

Chronic Lymphocytic Leukemia (CLL) and Small Lymphocytic Lymphoma (SLL)

1. Documented diagnosis of chronic lymphocytic leukemia or small lymphocytic lymphoma

AND

2. The Member is 18 years of age or older

AND

3. The prescribing physician is an oncologist or hematologist

AND

4. Documentation of **one (1)** of the following:
    a. Member is treatment naïve and **one (1)** of the following:
        i. Requested agent will be used in combination with Gazyva (obinutuzumab)
        ii. Clinical rationale for use of the requested agent as monotherapy
    b. Member has relapsed or refractory disease or prior therapy for the treatment of chronic lymphocytic leukemia/small lymphocytic lymphoma

Mantle Cell Lymphoma (MCL)

1. Documented diagnosis of mantle cell lymphoma

AND

2. The Member is 18 years of age or older

AND

3. The prescribing physician is an oncologist or hematologist

AND

4. Documentation of prior therapy for the treatment of mantle cell 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

Cometriq (cabozantinib)

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

1. Documented diagnosis of symptomatic or progressive medullary thyroid cancer

Copiktra (duvelisib)

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

Chronic Lymphocytic Leukemia (CLL) and Small Lymphocytic Lymphoma (SLL)

1. Documented diagnosis of chronic lymphocytic leukemia or small lymphocytic lymphoma:

AND

2. The Member is 18 years of age or older

AND

3. The prescribing physician is an oncologist or hematologist

AND

4. Documentation the Member has received at least two prior therapies for chronic lymphocytic leukemia/small lymphocytic lymphoma

Follicular Lymphoma

1. Documented diagnosis of follicular lymphoma

AND

2. The Member is 18 years of age or older

AND

3. The prescribing physician is an oncologist or hematologist

AND

4. Documentation the Member has received at least two prior therapies for follicular lymphoma

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. Documentation of positive BRAF V600E or V600K mutation

AND

4. Documentation Cotellic 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

Erlotinib

The plan may authorize coverage of erlotinib for Members, when the following criteria are met:

Non-small cell lung cancer

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

AND

2. The prescribing physician is an oncologist

AND

3. Documentation the Member has EGFR mutations

Pancreatic cancer

1. Documented diagnosis of advanced or metastatic pancreatic cancer

AND

2. The prescribing physician is an oncologist

AND

3. Documentation the Member will be using the requested agent in combination with gemcitabine

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

Gavreto (pralsetinib)

The plan may authorize coverage of Gavreto (pralsetinib) 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

Thyroid Cancer

1. Documented diagnosis of advanced or metastatic medullary thyroid cancer or thyroid cancer

AND

2. Documentation of RET-mutant or RET fusion-positive cancer

AND

3. The Member is at least 18 years of age

AND

4. The prescribing physician is an oncologist

Gilotrif (afatinib)

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

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

AND

2. The prescribing physician is an oncologist

AND

3. Documentation of **one (1)** of the following:
    a. Member has epidermal growth factor receptor (EGFR) mutations
    b. Inadequate response or adverse reaction to at least one platinum-based chemotherapy regimen or contraindication to the use of 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 HER2-negative ER-positive breast cancer

AND

2. The prescribing physician is an oncologist

AND

3. Documentation of **one (1)** of the following:
    a. Concomitant drug therapy with an aromatase inhibitor
    b. Concomitant drug therapy with fulvestrant

AND

4. If applicable, documentation the Member is postmenopausal or has received ovarian ablation or suppression

Iclusig (ponatinib)

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

Acute Lymphoblastic Leukemia (AML)

1. Documented diagnosis of acute lymphoblastic leukemia

AND

2. The prescribing physician is an oncologist or hematologist

AND

3. Documented inadequate response or adverse reaction to **one (1)** or contraindication to all of the following:
    a. imatinib
    b. Sprycel (dasatinib)
    c. Tasigna (nilotinib)

Chronic Myelogenous Leukemia (CML)

1. Documented diagnosis of chronic myelogenous leukemia

AND

2. The prescribing physician is an oncologist or hematologist

AND

3. Documentation of **one (1)** of the following:
    a. Confirmed T315I mutation
    b. Inadequate response or adverse reaction to **one (1)** or contraindication to all of the following:
        i. Imatinib
        ii. Sprycel (dasatinib)
        iii. Tasigna (nilotinib)

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 and Marginal Zone Lymphoma

1. Documented diagnosis of mantle cell lymphoma or marginal zone lymphoma

AND

2. The Member is 18 years of age or older

AND

3. The prescribing physician is an oncologist or hematologist

AND

4. Documentation the Member has received at least one prior therapy for the treatment of mantle cell lymphoma/marginal zone lymphoma

Chronic lymphocytic leukemia (CLL), small lymphocytic lymphoma (SLL), CLL with 17p deletion, SLL with 17p deletion, and Waldenstrom's macroglobulinemia

1. Documented diagnosis of one (1) of the following:
    a. Chronic lymphocytic leukemia
    b. Chronic lymphocytic leukemia with 17p deletion
    c. Small lymphocytic leukemia
    d. Small lymphocytic leukemia with 17p deletion
    e. Waldenstrom's macroglobulinemia

AND

2. The Member is 18 years of age or older

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 is 18 years of age or older

AND

3. The prescribing physician is an oncologist or hematologist

AND

4. Documentation the Member has received at least one previous therapy for the treatment of chronic grafts versus host disease

Inqovi (decitabine and cedazuridine)

The plan may authorize coverage of Inqovi (decitabine and cedazuridine) for Members, when the following criteria are met:

1. Documented diagnosis of myelodysplastic syndromes

AND

2. The prescribing physician is an oncologist or hematologist

AND

3. Documentation the Member is not administering Inqovi concomitantly with intravenous decitabine

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

Inrebic (fedratinib)

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

1. Documented diagnosis of **one (1)** of the following:
    a. Intermediate or high-risk primary myelofibrosis
    b. Intermediate or high-risk post-polycythemia vera myelofibrosis
    c. Intermediate or high-risk post-essential thrombocythemia myelofibrosis

AND

2. The Member is 18 years of age or older

AND

3. Documented inadequate response, adverse reaction, or contraindication to Jakafi (ruxolitinib)

Iressa (gefitinib)

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

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

AND

2. The prescribing physician is an oncologist

AND

3. Documentation the Member has epidermal growth factor receptor (EGFR) mutations

Jakafi (ruxolitinib)

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

Acute graft-versus-host disease

1. Documented diagnosis of acute graft-versus-host disease

AND

2. The Member is 12 years of age or older

AND

3. Documented inadequate response, adverse reaction, or contraindication to systemic glucocorticoids

Myelofibrosis

1. Documented diagnosis of **one (1)** of the following:
    a. Intermediate or high-risk primary myelofibrosis
    b. Intermediate or high-risk post-polycythemia vera myelofibrosis
    c. Intermediate or high-risk post-essential thrombocythemia myelofibrosis

Polycythemia vera

1. Documented diagnosis of polycythemia vera

AND

2. Documented inadequate response, adverse reaction, or contraindication to hydroxyurea

Kisqali (ribociclib)

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

1. Documented diagnosis of HER2-negative ER-positive breast cancer

AND

2. The prescribing physician is an oncologist

AND

3. Documentation of **one (1)** of the following:
    a. Concomitant drug therapy with an aromatase inhibitor
    b. Concomitant drug therapy with fulvestrant

Kisqali-Femara Co-Pack (ribociclib/letrozole)

The plan may authorize coverage of Kisqali-Femara Co-Pack (ribociclib/letrozole) for Members, when all of the following criteria are met:

1. Documented diagnosis of HER2-negative ER-positive breast cancer

AND

2. The prescribing physician is an oncologist

AND

3. Documentation the Member is postmenopausal or has received ovarian ablation or suppression

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:

Endometrial Carcinoma

1. Documented diagnosis of endometrial cancer

AND

2. The prescribing physician is an oncologist

AND

3. Documented inadequate response or adverse reaction to one prior line of systemic therapy or contraindication to systemic therapy

AND

4. Documentation Lenvima will be used in combination with Keytruda

Renal Cell Carcinoma

1. Documented diagnosis of advanced renal cell carcinoma

AND

2. The prescribing physician is an oncologist

AND

3. Documented the requested treatment regimen includes everolimus

AND

4. Documentation of **one (1)** of the following:
    a. Tumor is clear cell histology and inadequate response or adverse reaction to **one (1)** or contraindication to **all** first-line therapies (pazoparib, sunitinib, temsirolimus, axitinib monotherapy or in combination with pembrolizumab, ipilimumab + nivolumab, cabozantinib, high-dose IL-2, sorafenib)
    b. Tumor is non-clear cell histology and inadequate response or adverse reaction **one (1)** or contraindication to **all** systemic therapies (e.g., sunitinib, axitinib, bevacizumab or biosimilar, cabozanitinib, erlotinib, everolimus, nivolumab, pazopanib, sorafenib, temsirolimus)

Thyroid Cancer

1. Documented diagnosis of differentiated thyroid cancer

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 advanced or metastatic non-small cell lung cancer

AND

2. The prescribing physician is an oncologist

AND

3. Documentation cancer is anaplastic lymphoma kinase (ALK)-positive

AND

4. Documentation of **one (1)** of the following:
    a. Inadequate response or adverse reaction to Xalkori (crizotinib) and at least one other ALK inhibitor
    b. Inadequate response or adverse reaction to Alecensa 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:

Anaplastic Thyroid Cancer

1. Documented diagnosis of locally advanced or metastatic anaplastic thyroid cancer

AND

2. The prescribing physician is an oncologist

AND

3. Documentation of positive BRAF V600E mutation

AND

4. Documentation Mekinist will be used in combination with Tafinlar

AND

5. Documentation the Member has no satisfactory locoregional treatment options

Non-small Cell Lung Cancer

1. Documented diagnosis of non-small cell lung cancer

AND

2. The prescribing physician is an oncologist

AND

3. Documentation of positive BRAF V600E mutation

AND

4. Documentation Mekinist will be used in combination with Tafinlar

Melanoma (adjuvant treatment)

1. Documented diagnosis of melanoma

AND

2. The prescribing physician is an oncologist

AND

3. Documentation of positive BRAF V600E or V600K mutation

AND

4. Documentation Mekinist will be used in combination with Tafinlar

AND

5. Documentation the Member has lymph node involvement and complete resection

Unresectable or Metastatic Melanoma

1. Documented diagnosis of unresectable or metastatic melanoma

AND

2. The prescribing physician is an oncologist

AND

3. Documentation of positive BRAF V600E or V600K mutation

AND

4. Documentation of **one (1)** of the following:
    a. Mekinist will be used in combination with Tafinlar
    b. All of the following:
        i. Mekinist will be used as a single agent
        ii. No history of prior therapy with a BRAF inhibitor noted on PA request or in all pharmacy claims history
        iii. Clinical rationale for bypassing use of a BRAF inhibitor

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. The prescribing physician is an oncologist

AND

3. Documentation of positive BRAF V600E or V600K mutation

AND

4. Documentation Mektovi will be used in combination with Braftovi

Nerlynx (neratinib)

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

Adjuvant Therapy for Early Stage Disease

1. Documented diagnosis of extended adjuvant treatment of early stage HER2-positive breast cancer

AND

2. The prescribing physician is an oncologist

AND

3. Documentation the Member has received trastuzumab therapy within the past two years

Treatment of Metastatic Disease

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

AND

2. The prescribing physician is an oncologist

AND

3. Documented inadequate response or adverse reaction to two anti-HER2-based regimens

AND

4. Documentation Nerlynx will be used in combination with capecitabine

Nexavar (sorafenib)

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

1. Documented diagnosis of **one (1)** of the following:
    a. Advanced renal cell carcinoma
    b. Differentiated thyroid cancer
    c. Unresectable hepatocellular carcinoma

AND

2. The prescribing physician is an oncologist

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

Onureg (azacitidine)

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

1. Documented diagnosis of acute myeloid leukemia

AND

2. Documentation the Member has achieved first complete remission or complete remission with incomplete blood count recovery following intensive induction chemotherapy

AND

3. Documentation the Member is unable to complete intensive curative therapy (e.g., stem cell transplant)

AND

4. The prescribing physician is an oncologist or hematologist

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 HER2-negative, HR-positive, PIK3CA-mutated breast cancer

AND

2. The prescribing physician is an oncologist

AND

3. Documentation the Member has disease that progressed following treatment with endocrine-based therapy

AND

4. 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:

Solid Tumors with NTRK Gene Fusion

1. Documented diagnosis of solid tumors with neurotrophic receptor tyrosine kinase gene fusion without a known acquired resistance mutation

AND

2. The prescribing physician is an oncologist

AND

3. Documentation of **one (1)** of the following:
    a. Tumor is metastatic
    b. Member is not a candidate for surgical resection

AND

4. Documentation of **one (1)** of the following:
    a. Vitrakvi is first-line for the requested indication
    b. Member has no satisfactory alternative treatment options
    c. Disease has progressed following at least one first-line treatment for the requested indication

AND

5. If the request is for the oral solution formulation, medical necessity for the use of an oral solution formulation (e.g., swallowing disorder)

Non-small Cell Lung Cancer

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

AND

2. The prescribing physician is an oncologist

AND

3. Documentation the cancer is ROS1 positive

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-mutated acute myeloid leukemia

AND

2. The Member is 18 years of age or older

AND

3. The prescribing physician is an oncologist or hematologist

AND

4. Documentation of **one (1)** of the following:

a. For induction therapy, medication will be used in combination with cytarabine and daunorubicin
b. For consolidation therapy, medication will be used with cytarabine

Other Hematologic Conditions

1. Documented diagnosis of aggressive systemic mastocytosis, systemic mastocytosis with associated hematological neoplasm, or mast cell leukemia

AND

2. The Member is 18 years of age or older

AND

3. The prescribing physician is an oncologist or hematologist
4. Documentation of **one (1)** of the following:
    a. If member has aggressive systemic mastocytosis without the D816V c-Kit mutation or with c-Kit mutation status unknown, inadequate response, adverse reaction, or contraindication to imatinib
    b. D816V c-Kit mutation positive

Stivarga (regorafenib)

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

Metastatic Colorectal Cancer

1. Documented diagnosis of metastatic colorectal cancer

AND

2. The prescribing physician is an oncologist

AND

3. Documented inadequate response or adverse reaction to **one (1)** of the following regimens or a contraindication to **all** of the following regimens:
    a. CAPEOX (capecitabine/oxaliplatin)
    b. FOLFIRI (leucovorin calcium [folinic acid]/fluorouracil/irinotecan)
    c. FOLFOX (leucovorin calcium [folinic acid]/fluorouracil/oxaliplatin)
    d. FOLFOXIRI (leucovorin calcium [folinic acid]/5-fluorouracil/oxaliplatin/ irinotecan)
    e. irinotecan-based therapy
    f. oxaliplatin-based therapy

AND

4. If KRAS/NRAS/BRAF wild-type cancer is present, documented inadequate response or adverse reaction to **one (1)** of the following or contraindication to **both** of the following:
    a. Erbitux (cetuximab)
    b. Vectibix (panitumumab)

Gastrointestinal Stromal Tumor (GIST)

1. Documented diagnosis of gastrointestinal stromal tumor

AND

2. The prescribing physician is an oncologist

AND

3. Inadequate response, adverse reaction, or contraindication to **both** of the following:
    a. imatinib
    b. sunitinib

Hepatocellular Carcinoma

1. Documented diagnosis of hepatocellular carcinoma

AND

2. The prescribing physician is an oncologist

AND

3. Documentation the Member has Child-Pugh Class A

AND

4. Inadequate response, adverse reaction or a contraindication to sorafenib

Sutent (sunitinib)

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

Renal Cell Carcinoma and Pancreatic Neuroendocrine Tumors

1. Documented diagnosis of advanced renal cell carcinoma or advanced pancreatic neuroendocrine tumors

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. Documented inadequate response, adverse reaction, or contraindication to imatinib

Tabrecta (capmatinib)

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

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

AND

2. The prescribing physician is an oncologist

AND

3. Documentation cancer has mutation that leads to MET exon 14 skipping

Tafinlar (dabrafenib)

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

Anaplastic Thyroid Cancer

1. Documented diagnosis of locally advanced or metastatic anaplastic thyroid cancer

AND

2. The prescribing physician is an oncologist

AND

3. Documentation of positive BRAF V600E mutation

AND

4. Documentation Tafinlar will be used in combination with Mekinist

AND

5. Documentation the Member has no satisfactory locoregional treatment options

Unresectable or Metastatic Melanoma and Non-small Cell Lung Cancer

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

AND

2. The prescribing physician is an oncologist

AND

3. Documentation of **one (1)** of the following:
    a. If the request is for melanoma, positive BRAF V600E or V600K mutation
    b. If the diagnosis is non-small cell lung cancer, positive BRAF V600E mutation

AND

4. For the diagnosis of non-small cell lung cancer, documentation Tafinlar will be used in combination with Mekinist

Melanoma (adjuvant treatment)

1. Documented diagnosis of melanoma

AND

2. The prescribing physician is an oncologist

AND

3. Documentation of positive BRAF V600E or V600K mutation

AND

4. Documentation Tafinlar will be used in combination with Mekinist

AND

5. Documentation the Member has lymph node involvement and complete resection

Tagrisso (osimertinib)

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

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

AND

2. The prescribing physician is an oncologist

AND

3. Documentation of **one (1)** of the following:
    a. Cancer displays the EGFR exon 19 deletions or exon 21 L858R mutation
    b. Cancer displays the EGFR mutation and the T790M resistance mutation
    c. Inadequate response or adverse reaction to **one (1)** of the following or contraindication to **all** of the following:
        i. Erlotinib
        ii. Gilotrif (afatinib)
        iii. Iressa (gefitinib)
        iv. Vizimpro (dacomitinib)

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

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 Member is 18 years of age or older

AND

3. The prescribing physician is an oncologist

AND

4. Documentation the Member is not a candidate for surgery

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. The prescribing physician is an oncologist or hematologist

AND

3. Documentation of **one (1)** of the following:
    a. The Member is at least 60 years of age
    b. Clinical rationale for use of requested agent instead of intensive induction chemotherapy

AND

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

Chronic lymphocytic leukemia (CLL) and Small Lymphocytic Leukemia (SLL)

1. Documented diagnosis of **one (1)** of the following:
    a. Chronic lymphocytic leukemia
    b. Small lymphocytic leukemia

AND

2. The Member is 18 years of age or older

AND

3. The prescribing physician is an oncologist or a hematologist

Verzenio (abemaciclib)

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

1. Documented diagnosis of HR-positive, HER2-negative advanced or metastatic breast cancer

AND

2. The prescribing physician is an oncologist

AND

3. Documentation the Member is postmenopausal or has received ovarian suppression or ablation

AND

4. Documentation of **one (1)** of the following:
    a. Concomitant treatment with an aromatase inhibitor
    b. Concomitant drug therapy with fulvestrant
    c. Verzenio will be used as monotherapy when disease has progressed after both hormonal therapy and chemotherapy

Vitrakvi (larotrectinib)

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

1. Documented diagnosis of solid tumors with neurotrophic receptor tyrosine kinase gene fusion without a known acquired resistance mutation

AND

2. The prescribing physician is an oncologist

AND

3. Documentation of **one (1)** of the following:
    a. Tumor is metastatic
    b. Member is not a candidate for surgical resection

AND

4. Documentation of **one (1)** of the following:
    a. Vitrakvi is first line for the requested indication
    b. Member has no satisfactory alternative treatment options
    c. Disease has progressed following at least one first-line treatment for the requested indication

AND

5. If the request is for the oral solution formulation, medical necessity for the use of an oral solution formulation (e.g., swallowing disorder)

Vizimpro (dacomitinib)

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

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

AND

2. The prescribing physician is an oncologist

AND

3. Documentation the Member has epidermal growth factor receptor (EGFR) mutations

Votrient (pazopanib)

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

Renal Cell Carcinoma

1. Documented diagnosis of advanced renal cell carcinoma

AND

2. The prescribing physician is an oncologist

Soft Tissue Sarcoma

1. Documented diagnosis of advanced soft tissue sarcoma

AND

2. The prescribing physician is an oncologist

AND

3. Documented inadequate response, adverse reaction or contraindication to prior chemotherapy

Xalkori (crizotinib)

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

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

AND

2. The prescribing physician is an oncologist

AND

3. Documentation cancer is anaplastic lymphoma kinase (ALK)-positive or ROS1 positive

Xospata (gilteritinib)

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

1. Documented diagnosis of FLT3-mutated acute myeloid leukemia

AND

2. The Member is 18 years of age or older

AND

3. The prescribing physician is an oncologist or hematologist

AND

4. Documentation of **one (1)** of the following:
    a. Member has received at least one line of treatment
    b. Member has relapsed or refractory disease

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 chronic lymphocytic leukemia

AND

2. The Member is 18 years of age or older

AND

3. The prescribing physician is an oncologist or hematologist

AND

4. Documentation of **one (1)** of the following:
    a. Relapsed or refractory chronic lymphocytic leukemia
    b. Member has received at least one prior systemic therapy for the treatment of chronic lymphocytic leukemia

AND

5. Documentation of inadequate response, adverse reaction, or contraindication to Imbruvica (ibrutinib)

Follicular B-cell non-Hodgkin Lymphoma (FL) and Small Lymphocytic Lymphoma (SLL)

1. Documented diagnosis of follicular lymphoma or small lymphocytic lymphoma

AND

2. The Member is 18 years of age or older

AND

3. The prescribing physician is an oncologist or hematologist

AND

4. Documentation the Member has received at least two prior systemic therapies for the treatment of follicular lymphoma/small lymphocytic lymphoma

Zykadia (ceritinib)

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

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

AND

2. The prescribing physician is an oncologist

AND

3. Documentation cancer is anaplastic lymphoma kinase (ALK)-positive

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
    - Stivarga (regorafenib) capsules: 84 units/21 days
    - Tagrisso (osimertinib) 40 mg tablets: 30 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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APPROVAL HISTORY

November 24, 2020: Reviewed by Pharmacy & Therapeutics Committee for an effective date of January 1, 2020 for implementation of MassHealth ACPP/MCO Partial Unified Formulary. Coverage criteria for

Sprycel. Tasigna, and Tykerb has been removed. Added Tarceva to the Medical Necessity Guideline. Coverage criteria updated for the following drugs: Afinitor, Afinitor Disperz, Alecensa, Alunbrig, Balversa, Bosulif, Braftovi, Brukinsa, Cabometyx, Calquence, Caprelsa, Cometriq, Copiktra, Cotellic, Gilotrif, Ibrance, Iclusig, Imbruvica, Inlyta, Inrebic, Iressa, Jakafi, Kisqali, Kisqali Co-pack, Lenvima, Lobrena, Mekinist, Mektovi, Nerlynx, Nexavar, Piqray, Rozlytrek, Rydapt, Stivarga, Sutent, Tabrecta, Tafinilar, Tagrisso, Turalio, Venclexta, Verezenio, Vitrakvi, Vizimpro, Votirent, Xalkori, Xospata, Zydelig, and Zykadia.

Subsequent endorsement date(s) and changes made:
1. January 12, 2021: Updated coverage criteria for the supplemental Gavreto indications in thyroid cancer.

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.