Pharmacy Medical Necessity Guidelines: Antineoplastics

Effective: April 1, 2024

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: ☒ Tufts Health RITogether – A Rhode Island Medicaid Plan		**Fax Numbers:** RXUM: 617.673.0939	

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

OVERVIEW

The following oral cancer medications require prior authorization:

- abiraterone
- Akeega (niraparib/abiraterone)
- Alecensa (alectinib)
- Alunbrig (brigatinib)
- Augtyro (repotrectinib)
- 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)
- Everolimus tablet
- Everolimus tablets for oral suspension
- Exkivity (mobocertinib)
- Farydak (panobinostat)
- Fotivda (tivozanib)
- Fruzaqla (fruquintinib)
- Gavreto (pralsetinib)
- Gilotrif (afatinib)
- Hycamtin (topotecan)
- Ibrance (palbociclib)
- Iclusig (ponatinib)
- Idhifa (enasidenib)
- Imbruvica (ibrutinib)
- Inlyta (axitinib)
- Inqovi (decitabine/cedazuridine)
- Inrebic (fedratinib)
- Iressa (gefitinib)
- Iwilfin (eflornithine)
- Jakafi (ruxolitinib)
- Jaypirca (pirtobrutinib)
- Kisqali (ribociclib)
- Koselugo (selumetinib)
- Krazati (adagrasib)
- Lenvima (lenvatinib)
- Lonsurf (trifluridine/tipiracil)
- Lorbrena (lorlatinib)
- Lumakras (sotorasib)
- Lynparza (olaparib)
- Lytgobi (futibatinib)
- Mekinist (trametinib)
- Mektovi (binimetinib)
- Nexavar (sorafenib)
- Nerlynx (neratinib)
- Ninlaro (ixazomib)
- Odomzo (sonidegib)
- Ogsiveo (nirogacestat)
- Ojjaara (momeotinib)
- Onureg (azacytidine)
- Orgovyx (relugolix)
- Orserdu (elacestrant)
- Pemazyre (pemigatinib)
- Piqray (alpelisib)
- Pomalyst (pomalidomide)
- Qinlock (ripretinib)
- Revlimid (lenalidomide)
- Retevmo (selpercatinib)
- Rezlidhia (olutasidenib)
- Rozlytrek (entrectinib)
- Rubraca (rucaparib)
- Rydapt (midostaurin)
- Scemblix (asciminib)
- Sprycel (dasatinib)
- Stivarga (regorafenib)
- Sutent (sunitinib)
- Tabrecta (capmatinib)
- Tafinlar (dabrafenib)
- Tagrisso (osimertinib)
- Talzenna (talazoparib)
- Tasigna (nilotinib)
- Tazverik (tazemetostat)
- Tepmetko (tepotinib)
- Tibsovo (ivosidenib)
- Truqap (capivasertib)
- Truseltiq (infigratinib)
- Tukysa (tucatinib)
- Turalio (pexidartinib)
- Tykerb (lapatinib)
- Vanflyta (quizartinib)
- Venclexta (venetoclax)
- Verzenio (abemaciclib)
- Vitrakvi (larotrectinib)
- Vizimpro (dacomitinib)
- Vonjo (pacritinib)
- Votrient (pazopanib)
- Welireg (belzutifan)
- Xalkori (crizotinib)

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- Xpovio (selinexor)
- Xtandi (enzalutamide)
- Xospata (gilteritinib)
- Zejula (niraparib)
- Zelboraf (vemurafenib)
- Zolinza (vorinostat)
- Zydelig (idelalisib)
- Zykadia (ceritinib)

COVERAGE GUIDELINES

Abiraterone

The plan may authorize coverage of abiraterone 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

Akeega (niraparib and abiraterone)

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

1. Documented diagnosis of metastatic castration-resistant prostate cancer

AND

2. Documentation of deleterious or suspected deleterious BRCA-mutated cancer

AND

3. Documentation of use in combination with prednisone

AND

4. The prescribing physician is an oncologist

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 as detected by an Food and Drug Administration-approved test

AND

2. The prescribing physician is an oncologist

Augtyro (repotrectinib)

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

1. Documented diagnosis of local advanced or metastatic ROS1-positive 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:

Advanced Systemic Mastocytosis

1. Documented diagnosis of advanced systemic mastocytosis

AND

2. The prescribing physician is an oncologist, hematologist, immunologist, or allergist

Gastrointestinal Stromal Tumor

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

Indolent Systemic Mastocytosis

1. Documented diagnosis of indolent systemic mastocytosis

AND

2. The prescribing physician is an oncologist, hematologist, immunologist, or allergist

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:

Chronic Lymphocytic Leukemia or Small Lymphocytic Leukemia

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

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 has received at least one prior therapy

AND

3. The prescribing physician is an oncologist or hematologist

Marginal Zone Lymphoma

1. Documented diagnosis of marginal zone lymphoma

AND

2. Documentation the Member has received at least one prior anti-CD20-based regimen

AND

3. 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

Cabometyx (cabozantinib)

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

Differentiated Thyroid Cancer

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

AND

2. Documentation of disease progression following prior VEGFR-targeted therapy

AND

3. Documentation the Member is refractory to or ineligible for radioactive iodine

AND

4. The prescribing physician is an oncologist

Hepatocellular Carcinoma

1. Documented diagnosis of hepatocellular carcinoma

AND

2. Documentation of previous treatment with sorafenib

AND

3. The prescribing physician is an oncologist

Renal Cell Carcinoma

1. Documented diagnosis of renal cell carcinoma

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

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

Everolimus tablet

The plan may authorize coverage of **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 patient has a demonstrated disease progression or intolerance following an appropriate trial with sunitinib or sorafenib

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 or anastrozole

AND

5. Documentation that the requested agent will be administered in combination with exemestane

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

Everolimus tablets for oral suspension

The plan may authorize coverage of **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

Exkivity (mobocertinib)

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

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

AND

2. Documentation of epidermal growth factor receptor exon 20 insertion mutation as detected by an FDA approved test

AND

3. Documentation the Member has previously received platinum-based chemotherapy

AND

4. 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

Fotivda (tivozanib)

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

1. Documented diagnosis of relapsed or refractory advanced renal cell carcinoma

AND

2. The prescribing physician is an oncologist

AND

3. Documentation the member has received at least two prior systemic therapies

Fruzaqla (fruquintinib)

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

1. Documented diagnosis of metastatic colorectal cancer

AND

2. Documentation the patient has received treatment with fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy

AND

3. Documentation the patient has received treatment with anti-VEGF therapy

AND

4. If RAS wild-type, documentation of **one (1)** of the following:
    a. The patient has received treatment with anti-EGFR therapy
    b. Anti-EGFR therapy is not medically appropriate

AND

5. The prescribing physician is an oncologist

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

Medullary Thyroid Cancer

1. Documented diagnosis of advanced or metastatic medullary thyroid cancer

AND

2. Documentation of RET-mutant cancer

AND

3. Documentation the patient requires systemic therapy

AND

4. The patient 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 patient requires systemic therapy

AND

4. Documentation of **one (1)** of the following:
    a. The patient is radioactive iodine-refractory
    b. Radioactive iodine is not clinically appropriate

AND

5. The patient is at least 12 years of age

AND

6. 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. 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) Chronic phase chronic myeloid leukemia with resistance or intolerance to at least two prior kinase inhibitors
    b) Accelerated phase or blast phase chronic myeloid leukemia or Philadelphia chromosome positive acute lymphoblastic leukemia for whom no other kinase inhibitors are indicated
    c) T315I-positive chronic myeloid leukemia or T315I-positive Philadelphia chromosome positive acute lymphoblastic leukemia

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 (e.g., corticosteroids)

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

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

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

Iwilfin (eflornithine)

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

1. Documented diagnosis of high-risk neuroblastoma

AND

2. Documentation the patient has had at least a partial response to prior multiagent, multimodality therapy including anti-GD2 immunotherapy

AND

3. Documentation Iwilfin will be used as a single agent

AND

4. 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:

Graft-Versus-Host Disease

1. Documentation of **one (1)** of the following:
    a. Steroid-refractory acute graft-versus-host disease
    b. Chronic graft-versus-host disease AND failure with at least one prior line of systemic therapy (e.g., corticosteroids)

AND

2. Member is at least 12 years of age

Myelofibrosis

1. Documented diagnosis of intermediate or high-risk myelofibrosis

Polycythemia Vera

1. Documented diagnosis of polycythemia

AND

2. Documented inadequate response or intolerance to hydroxyurea

Jaypirca (pirtobrutinib)

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

1. Documented diagnosis of relapsed or refractory mantle 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 therapies

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

Krazati (adagrasib)

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

AND

2. Documentation cancer is KRAS G12C-mutatation positive as detected by a Food and Drug Administration-approved test

AND

3. The prescribing physician is an oncologist

AND

4. Documentation the patient has received at least one (1) prior systemic therapy

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 as detected by a Food and Drug Administration-approved test

AND

2. The prescribing physician is an oncologist

Lumakras (sotorasib)

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

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

AND

2. Documentation cancer is KRAS G12C-mutatation positive as detected by an FDA-approved test

AND

3. Documentation the prescribing physician is an oncologist

AND

4. Documentation the Member has received at least one prior systemic therapy

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 **one (1)** of the following based on an FDA-approved test:
    a. Deleterious or suspected deleterious germline BRCA-mutated, HER2-negative metastatic breast cancer
    b. Deleterious or suspected deleterious germline BRCA-mutated, HER2-negative high risk early breast cancer

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 or gynecologist with oncologist training

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 **one (1)** of the following:
    a. Both of the following:
        i. Deleterious or suspected deleterious germline or somatic homologous recombination repair gene-mutated cancer
        ii. The Member has progressed following prior treatment with enzalutamide or abiraterone
    b. Both of the following:
        i. Deleterious or suspected deleterious BRCA-mutated cancer
    c. Use in combination with abiraterone and prednisone or prednisolone

AND

3. The prescribing physician is an oncologist

Lytgobi (futibatinib)

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

1. Documented diagnosis of unresectable, locally advanced or metastatic intrahepatic cholangiocarcinoma

AND

2. Documentation the cancer has a fibroblast growth factor receptor 2 fusion or other rearrangements

AND

3. The prescribing physician is an oncologist

AND

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

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) 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 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
    e) Diagnosis of unresectable or metastatic solid tumors with BRAF V600E mutation AND disease progression following prior treatment AND no satisfactory alternative treatment options
    f) Diagnosis of low-grade glioma with BRAF V600E mutation AND the patient requires systemic therapy

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

Ogsiveo (nirogacestat)

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

1. Documented diagnosis of a desmoid tumor

AND

2. Patient is at least 18 years of age

AND

3. The prescribing physician is an oncologist or a sarcoma specialist

AND

4. Documentation of **one (1)** of the following:
    a. Persistent disease progression (e.g., evidence of disease progression at more than one assessment)
    b. Increase of symptoms of burden

Ojjaara (momeotinib)

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

1. Documented diagnosis intermediate or high-risk myelofibrosis

AND

2. Documentation the patient has anemia defined as a measured hemoglobin level of less than or equal to 10 g/dL in previous 30 days

AND

3. The prescribing physician is an oncologist or hematologist

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

Orgovyx (relugolix)

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

1. Documented diagnosis of advanced prostate cancer as defined by **one (1) of the following**:
    a. Evidence of biochemical (i.e., prostate-specific antigen) or clinical relapse following local primary intervention with curative intent (e.g., surgery, radiation therapy, cryotherapy, or high-frequency ultrasound) and not a candidate for salvage treatment by surgery
    b. Newly diagnosed androgen-sensitive metastatic disease
    c. Advanced localized disease (Stage III; cancer has spread outside of the prostate but only to nearby tissues) unlikely to be cured by local primary intervention with either surgery or radiation with curative intent

AND

2. The prescribing physician is an oncologist or urologist

Orserdu (elacestrant)

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

1. Documentation diagnosis of estrogen receptor positive, HER2 negative advanced or metastatic breast cancer

AND

2. Documentation the Member has ESR1-mutated disease

AND

3. If female, documentation the Member is post-menopausal

AND

4. The prescribing physician is an oncologist

AND

5. Documentation the Member has disease progression following at least one line of endocrine therapy, which must include a CDK 4/6 inhibitor (e.g., Ibrance, Kisqali, Verzenio)

Pemazyre (pemigatinib)

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

Cholangiocarcinoma

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

Myeloid/Lymphoid Neoplasms

1. Documented diagnosis of relapsed or refractory myeloid/lymphoid neoplasms

AND

2. Documentation of fibroblast growth factor receptor 1 (FGFR1) rearrangement

AND

3. 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

Rezlidhia (olutasidenib)

1. Documented diagnosis of relapsed or refractory acute myeloid leukemia

AND

2. Documentation cancer has susceptible IDH1 mutation as detected by a Food and Drug Administration-approved test

AND

3. The prescribing physician is an oncologist or hematologist

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

AND

2. Documentation of deleterious BRCA mutation associated cancer

AND

3. Documentation the Member is in a complete or partial response to platinum-based chemotherapy

AND

4. 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 as detected by a Food and Drug Administration-approved test

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

3. The prescribing physician is an oncologist, hematologist, immunologist, or allergist

Scemblix (asciminib)

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

1. Documented diagnosis of Philadelphia chromosome-positive chronic myeloid leukemia (CML)

AND

2. Documentation from the prescribing physician that the member has chronic phase CML

AND

3. Documentation of **one (1)** of the following:
    a) T315I mutation
    b) Previous treatment with at least two other tyrosine kinase inhibitors

AND

4. 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:

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. 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 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
    e. Diagnosis of unresectable or metastatic solid tumors with BRAF V600E mutation AND disease progression following prior treatment AND no satisfactory alternative treatment options
    f. Diagnosis of low-grade glioma with a BRAF V600E mutation AND patient requires systemic therapy

Tagrisso (osimertinib)

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

1. Documented diagnosis of non-small cell lung cancer

AND

2. The prescribing physician is an oncologist

AND

3. Documentation of one of the following:
    a. Use as adjuvant therapy after tumor resection in adult patients with non-small cell lung cancer whose tumors have epidermal growth factor receptor exon 19 deletions or exon 21 L858R, as detected by a Food and Drug Administration-approved test
    b. Use as first-line treatment of adult patients with metastatic disease whose tumors have epideral growth factor receptor exon 19 deletions or exon 21 L858R mutations as detected by a Food and Drug Administration-approved test
    c. Use in metastatic epidermal growth factor receptor T790M mutation-positive disease as detected by a Food and Drug Administration-approved test, in patients whose disease has progressed on or after epidermal growth factor tyrosine kinase inhibitor therapy

Talzenna (talazoparib)

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

1. Documentation of **one (1)** of the following:
    a. Diagnosis of deleterious or suspected deleterious germline BRCA-mutated, HER2-negative locally advanced or metastatic breast cancer based on a Food and Drug Administration-approved test
    b. Both of the following:
        i. Diagnosis of homologous recombination repair (HRR) gene-mutated metastatic castration-resistant prostate cancer
        ii. Use in combination with enzalutamide

AND

2. The prescribing physician is an oncologist or urologist

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 authorize 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

Tepmetko (tepotinib)

The plan may authorize coverage of Tepmetko (tepotinib) for Members, when 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

AND

3. The prescribing physician is an oncologist

Tibsovo (ivosidenib)

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

Acute Myeloid Leukemia

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. Documentation of **one (1)** of the following:
    a. Relapsed of refractory acute myeloid leukemia
    b. Documentation of **ALL** of the following:
        i. Member is at least 75 years of age or comorbidities that preclude use of intensive induction chemotherapy
        ii. Newly-diagnosed acute myeloid leukemia

Cholangiocarcinoma

1. Documented diagnosis of locally advanced or metastatic cholangiocarcinoma with a susceptible IDH1 mutation as detected by an FDA-approved test

AND

2. The prescribing physician is an oncologist

AND

3. Documentation the Members has received prior treatment

Truqap (capivasertib)

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

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

AND

2. Documentation of one or more PIK3CA/AKT1/PTEN-alterations as detected by an FDA-approved test

AND

3. Documentation of **one (1)** of the following:
    a. Disease progression on at least one endocrine-based regimen in the metastatic setting
    b. Recurrence on or within 12 months of completing adjuvant therapy

AND

4. Documentation the requested medication will be used in combination with fulvestrant

AND

5. The prescribing physician is an oncologist

Truseltiq (infigratinib)

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

1. Documented diagnosis of locally advanced or metastatic cholangiocarcinoma

AND

2. Documentation the cancer has a fibroblast growth factor receptor 2 fusion or other rearrangement as detected by an FDA-approved test

AND

3. The prescribing physician is an oncologist

AND

4. Documentation the cancer is unresectable

AND

5. Documentation the Member has received prior treatment

Tukysa (tucatinib)

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

Metastatic Breast Cancer

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

Unresectable or Metastatic Colorectal Cancer

1. Documented diagnosis of unresectable or metastatic RAS wild-type, HER2-positive colorectal cancer

AND

2. Documentation of use in combination with trastuzumab

AND

3. Documentation the patient has received treatment with fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy

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

Vanflyta (quizartinib)

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

1. Documented diagnosis of newly diagnosed acute myeloid leukemia

AND

2. Documentation of FLT3 internal tandem duplication (ITD)-positive disease

AND

3. Documentation the physician is an oncologist or hematologist

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 and Small lymphocytic leukemia

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

AND

2. 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:

Advanced or Metastatic Breast Cancer

1. Documented diagnosis of advanced or metastatic breast cancer

AND

2. Documentation of hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative disease

AND

3. The prescribing physician is an oncologist

Early Breast Cancer

1. Documented diagnosis of early breast cancer

AND

2. Documentation of hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative, node-positive disease

AND

3. The prescribing physician is an oncologist

AND

4. Documentation of use in combination with endocrine therapy (e.g., tamoxifen, aromatase inhibitor)

AND

5. Documentation the patient is at high risk of recurrence

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 authorize 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

Vonjo (pacritinib)

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

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

AND

2. The prescribing physician is an oncologist or hematologist

AND

3. Documented platelet count below 50 x 10^9/L

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

Welireg (belzutifan)

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

1. Documented diagnosis of von Hippel-Lindau disease

AND

2. Documentation treatment is required for associated renal cell carcinoma (RCC), central nervous system (CNS) hemangioblastomas, or pancreatic neuroendocrine tumors

AND

3. The prescribing physician is an oncologist

Xalkori (crizotinib)

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

Anaplastic Large Cell Lymphoma

1. Documented diagnosis of anaplastic lymphoma kinase (ALK)-positive anaplastic large cell lymphoma

AND

2. Member is at least 1 year of age

Myofibroblastic Tumors

1. Documented diagnosis of anaplastic lymphoma kinase (ALK)-positive unresectable, recurrent or refractory inflammatory myofibroblastic tumor

AND

2. The prescribing physician is an oncologist

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 tumors are anaplastic lymphoma kinase (ALK) or ROS1-positive as detected by an FDA-approved test

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 multiple myeloma

AND

2. The prescribing physician is an oncologist or hematologist

AND

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

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 **one (1)** of the following:
    a. Advanced disease in a patient with complete or partial response to first-line platinum-based chemotherapy
    b. Recurrent disease with a deleterious or suspected deleterious germline BRCA-mutation in a patient 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:

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

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 as detected by a Food and Drug Administration-approved test

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

- Approval duration of Ogsiveo will be limited to 12-months.
- Authorizations of Iwilfin will be limited to 2 years.
- The plan will not authorize the use of an oral cancer medication for a condition other than those listed above without appropriate documentation.
- 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: Erleada, Nubeqa, Yonsa, and Zytiga 500 mg.

CODES

None

REFERENCES

1. Drugs@FDA: FDA-Approved Drugs [website on the internet]. Available from: https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm. Accessed February 2024.
2. The Desmoid Tumor Working Group. The management of desmoid tumors: A joint global consensus-based guideline approach for adult and paediatric patients, 2020. European journal of cancer. March 2020;127:96-107.

APPROVAL HISTORY

September 13, 2022: Reviewed by Pharmacy & Therapeutics Committee.

1. January 10, 2023: Added Lytgobi to the Medical Necessity Guideline.
2. March 14, 2023: Added Krazati and Rezlidhia to the Medical Necessity Guideline (effective 5/1/23). Added coverage criteria for the supplemental indication for Tukysa in unresectable or metastatic colorectal cancer (effective 5/1/23). Removed Ukoniq from the Medical Necessity Guideline because the drug has been discontinued (effective 5/1/23). Updated coverage criteria

for the following based on updated package labeling: Rubraca for ovarian cancer, Zejula for ovarian cancer (effective 5/1/23).
3. April 11, 2023: Added Jaypirca and Orserdu to the Medical Necessity Guideline (effective 6/1/23).
4. July 11, 2023: Added coverage criteria for the supplemental indication for Ayvakit in indolent systemic mastocytosis. Added coverage criteria for the supplemental indication for Lynparza in BRCA-mutated metastatic castration-resistant prostate cancer in combination with abiraterone and prednisone or prednisolone. Updated Verzenio's coverage criteria in early breast cancer based on updated package labeling to no longer a Ki-67 score of at least 20% as determined by a Food and Drug Administration-approved test. Added coverage criteria for the supplemental indication for Tafinlar and Mekinist in BRAF V600E mutation-positive low-grade glioma. Added coverage criteria for supplemental indication for Tafinlar in solid tumors (effective 8/1/23).
5. August 8, 2023: Added coverage criteria for the supplemental indication for Talzenna in HRR gene-mutated metastatic castration-resistant prostate cancer (effective 9/1/23).
6. September 12, 2023: Added coverage criteria for the supplemental indication Brukinsa in chronic lymphocytic leukemia or small lymphocytic leukemia (effective 10/1/2023).
7. October 10, 2023: Added Vanflyta to the Medical Necessity Guideline (effective 11/1/2023).
8. December 12, 2023: Added Ojjaara to the Medical Necessity Guideline (effective 1/1/2024).
9. January 9, 2023: Added Akeega to the Medical Necessity Guideline. Expanded provider specialty requirements to "The prescribing physician is an oncologist, hematologist, immunologist, or allergist" for Rydapt and Ayvakit for systemic mastocytosis indications (effective 2/1/2024).
10. February 13, 2024: Added Augtyro Fruzaqla, Ogsiveo, and Truqap to the Medical Necessity Guideline (effective 3/1/2024).
11. March 12, 2024: Added Iwilfin to the Medical Necessity Guideline (effective 4/1/2024).

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