Harvard Pilgrim Health Care | TUFTS Health Plan

Pharmacy Medical Necessity Guidelines:
Antineoplastics

Effective: October 1, 2025

Guideline Type	☒ Prior Authorization ☐ Non-Formulary ☐ Step-Therapy ☐ Administrative

Applies to:

Commercial Products

☒ Harvard Pilgrim Health Care Commercial products; Fax: 617-673-0988

☒ Tufts Health Plan Commercial products; Fax: 617-673-0988

CareLinkSM – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization

Public Plans Products

☒ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product); Fax: 617-673-0988

Note: While you may not be the provider responsible for obtaining prior authorization, as a condition of payment you will need to ensure that prior authorization has been obtained.

Overview

Food and Drug Administration – Approved Indications

The following antineoplastics require prior authorization. Coverage criteria is in line with Food and Drug Administration-approved package labeling:

abiraterone, everolimus, everolimus disperz, 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), Emcyt (estramustine), Ensacove (ensartinib), Erivedge (vismodegib), Erleada (apalutamide), Eulexin (flutamide), Exkivity (mobocertinib), Fotivda (tivozanib), Fruzaqla (fruquintinib), Gavreto (pralsetinib), Gilotrif (afatinib), Gomekli (mirdametinib), Ibrance (palbociclib), Iclusig (ponatinib), Idhifa (enasidenib), Imbruvica (ibrutinib), Inlyta (axitinib), Inqovi (decitabine/cedazuridine), Inrebic (fedratinib), Itovebi (inavolisib), Iwilfin (eflornithine), Jakafi (ruxolitinib), Jaypirca (pirtobrutinib), Kisqali/Kisqali PAK (ribociclib), Koselugo (selumetinib), Krazati (adagrasib), Lazcluze (lazertinib), lenalidomide, Lenvima (lenvatinib), Lonsurf (trifluridine/tipiracil), Lorbrena (lorlatinib), Lumakras (sotorasib), Lynparza (olaparib), Lytgobi (futibatinib), Mekinist (trametinib), Mektovi (binimetinib), Nexavar (sorafenib), Nerlynx (neratinib), Ninlaro (ixazomib), Nubeqa (darolutamide), Odomzo (sonidegib), Ogsiveo (nirogacestat), Ojemda (tovorafenib), Ojjaara (momelotinib), Onureg (azacytidine), Orgovyx (relugolix), Orserdu (elacestrant), Pemazyre (pemigatinib), Piqray (alpelisib), Pomalyst (pomalidomide), Qinlock (ripretinib), Retevmo (selpercatinib), Revuforj (revumenib), Rezlidhia (olutasidenib), Romvimza (vimseltinib), Rozlytrek (entrectinib), Rubraca (rucaparib), Rydapt (midostaurin), Scemblix (asciminib), Stivarga (regorafenib), Tabrecta (capmatinib), Tafinlar (dabrafenib), Tagrisso (osimertinib), Talzenna (talazoparib), Tazverik (tazemetostat), Tepmetko (tepotinib), Tibsovo (ivosidenib), Truqap (capivasertib), Tukysa (tucatinib), Turalio (pexidartinib), Vanflyta (quizartinib), Venclexta (venetoclax), Verzenio (abemaciclib), Vitrakvi (larotrectinib), Vizimpro (dacomitinib), Vonjo (pacritinib), Voranigo (vorasidenib), Welireg (belzutifan), Xalkori (crizotinib), Xospata (gilteritinib), Xpovio (selinexor), Xtandi (enzalutamide), Yonsa (abiraterone acetate), Zejula (niraparib), Zelboraf (vemurafenib), Zydelig (idelalisib), Zykadia (ceritinib)

Clinical Guideline Coverage Criteria

The plan may authorize coverage of a requested Antineoplastic for Members, when **ALL** of the following criteria are met:

Abiraterone

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 the requested medication will be used in combination with prednisone

Alecensa (alectinib)

1. Documented diagnosis of anaplastic lymphoma kinase-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

Alunbrig (brigatinib)

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)

1. Documented diagnosis of local advanced or metastatic ROS1-positive non-small cell lung cancer

AND

2. The prescribing physician is an oncologist

Ayvakit (avapritinib)

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)

1. Documented diagnosis of metastatic urothelial carcinoma

AND

2. Documentation of susceptible FGFR3 or FGFR2 genetic alternations

AND

3. Documentation of disease progression following at least one (1) line of prior platinum-containing chemotherapy

AND

4. The prescribing physician is an oncologist

Bosulif (bosutinib)

1. The prescribing physician is an oncologist or hematologist

AND

2. Documentation of one (1) of the following:
    a) Documented diagnosis of chronic phase Philadelphia chromosome-positive chronic myelogenous leukemia
    b) Documentation of both of the following:
        i. Diagnosis of accelerated phase or blast phase Philadelphia chromosome-positive chronic myelogenous leukemia
        ii. Resistance or intolerance to prior therapy (e.g., imatinib)

Braftovi (encorafenib)

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 cetuximab

AND

5. Documentation the patient 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 a Food and Drug Administration-approved test

AND

3. The prescribing physician is an oncologist

AND

4. Documentation of use in combination with binimetinib

Non-small Cell Lung Cancer

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

AND

2. Documentation of BRAF V600E mutation as detected by a Food and Drug Administration-approved test

AND

3. The prescribing physician is an oncologist

AND

4. Documentation of use in combination with binimetinib

Brukinsa (zanubrutinib)

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 patient 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 patient has received at least one prior anti-CD20-based regimen

AND

3. The prescribing physician is an oncologist or hematologist

Waldenström Macroglobulinemia

1. Documented diagnosis of Waldenstrom’s macroglobulinemia

AND

2. The prescribing physician is an oncologist or hematologist

Cabometyx (cabozantinib)

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 patient 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)

1. The prescribing physician is an oncologist or hematologist

AND

2. Documented diagnosis of **one (1)** of the following:
    a. Mantle cell lymphoma
    b. Chronic lymphocytic leukemia
    c. Small lymphocytic lymphoma

AND

3. If the diagnosis is mantle cell lymphoma, documentation of **one (1)** of the following:
    a. The patient has received at least one (1) prior therapy
    b. Documentation of **both** of the following:
        i. The patient is previously untreated and ineligible for autologous hematopoietic stem cell transplantation
        ii. The requested medication will be used in combination with bendamustine and rituximab

Caprelsa (vandetanib)

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)

1. Documented diagnosis of progressive, metastatic medullary thyroid cancer

AND

2. The prescribing physician is an oncologist

Copiktra (duvelisib)

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 patient has received at least two (2) prior systemic therapies

AND

3. The prescribing physician is an oncologist or hematologist

Cotellic (cobimetinib)

1. Documented diagnosis of unresectable or metastatic melanoma

AND

2. The prescribing physician is an oncologist

AND

3. Documentation the patient has BRAF V600E or V600K mutation-positive melanoma as detected by a Food and Drug Administration-approved test

AND

4. Documentation the requested medication will be administered in combination with vemurafenib

Daurismo (glasdegib)

1. Documented diagnosis of acute myeloid leukemia

AND

2. Documentation the requested medication will be administered in combination with low-dose cytarabine

AND

3. The prescribing physician is an oncologist or hematologist

AND

4. Documentation of one (1) of the following:
    a. The patient is at least 75 years old
    b. The patient has a comorbidity that precludes the use of intensive induction chemotherapy

Emcyt (estramustine)

1. Documented diagnosis metastatic and/or progressive prostate cancer

AND

2. The prescribing physician is an oncologist

Ensacove (ensartinib)

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

AND

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

AND

3. Documentation the member has not previously received an anaplastic lymphoma kinase (ALK)-inhibitor

AND

4. The prescribing physician is an oncologist

Erivedge (vismodegib)

1. Documentation of one (1) of the following:
    a. Diagnosis of metastatic basal cell carcinoma
    b. Documentation of both of the following:
        i. Diagnosis of locally advanced basal cell carcinoma
        ii. The disease has recurred following surgery or the patient is not a candidate for surgery or radiation therapy

AND

2. The prescribing physician is an oncologist

Erleada (apalutamide)

1. Documentation of one (1) of the following:
    a. Metastatic castration-sensitive prostate cancer
    b. Non-metastatic castration-resistant prostate cancer

AND

2. The prescribing physician is an oncologist

Eulexin (flutamide)

1. Documented diagnosis of locally confined Stage B2-C and Stage D2 metastatic prostate cancer

AND

2. The prescribing physician is an oncologist

AND

3. Documentation the requested medication will be used in combination with a luteinizing hormone-releasing hormone agonist

Everolimus tablet

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 patient 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 patient 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 patient is at least 2 years of age or older

AND

4. The prescribing physician is an oncologist or a neurologist

Everolimus tablets for oral suspension

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. The patient 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 patient is at least 2 years of age or older

AND

4. The prescribing physician is an oncologist or a neurologist

Exkivity (mobocertinib)

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 a Food and Drug Administration-approved test

AND

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

AND

4. The prescribing physician is an oncologist

Fotivda (tivozanib)

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

AND

2. The prescribing physician is an oncologist

AND

3. Documentation the patient has received at least two (2) prior systemic therapies

Fruzaqla (fruquintinib)

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)

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 patient is at least 18 years of age or older

AND

4. 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 or older

AND

6. The prescribing physician is an oncologist

Gilotrif (afatinib)

1. The prescribing physician is an oncologist

AND

2. Documentation of one (1) 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 a Food and Drug Administration-approved test
   b. Documented diagnosis of metastatic, squamous non-small cell lung cancer progressing after platinum-based chemotherapy

Gomekli (mirdametinib)

1. Documented diagnosis of neurofibromatosis type 1

AND

2. Documentation of symptomatic, inoperable plexiform neurofibromas

AND

3. The patient is at least 2 years of age or older

AND

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

Ibrance (palbociclib)

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 **one (1)** of the following:
   a) Contraindication, intolerance, or clinical inappropriateness of treatment with Kisqali AND Verzenio
   b) Continuation of prior Ibrance therapy

AND

4. Documentation of use in combination with **one (1)** 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)

Acute Lymphoblastic Leukemia

1. The prescribing physician is an oncologist or hematologist

AND

2. Documented diagnosis of Philadelphia chromosome-positive acute lymphoblastic leukemia

AND

3. Documentation of **one (1)** of the following:
   a. Patient is newly diagnosed and Iclusig will be used in combination with chemotherapy
   b. No other kinase inhibitor is indicated or T315I-positive disease and Iclusig will be used as monotherapy

Chronic Myeloid Leukemia

1. The prescribing physician is an oncologist or hematologist

AND

2. Documented diagnosis of chronic myeloid leukemia

AND

3. Documentation of **one (1)** of the following:
   a. Chronic phase chronic myeloid leukemia with resistance or intolerance to at least two (2) prior kinase inhibitors
   b. Accelerated phase or blast phase chronic myeloid leukemia for whom no other kinase inhibitors are indicated
   c. T315I-positive chronic myeloid leukemia (chronic phase, accelerated phase, or blast phase)

Idhifa (enasidenib)

1. Documented diagnosis of isocitrate dehydrogenase-2 mutated acute myeloid leukemia as detected by a Food and Drug Administration-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)

Mantle cell lymphoma

1. Documented diagnosis of mantle cell lymphoma

AND

2. The prescribing physician is an oncologist or hematologist

AND

3. Documentation the patient has been treated with at least one (1) prior therapy

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

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

AND

2. The prescribing physician is an oncologist or hematologist

Waldenström 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. Documentation the patient has been treated with at least one (1) 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. Documentation the patient has been treated with at least one (1) systemic therapy (e.g., corticosteroids)

Inlyta (axitinib)

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 (1) prior first-line systemic therapy (e.g. Sutent, Nexavar, Afinitor, Votrient, Avastin, Torisel)

Inrebic (fedratinib)

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)

1. Documented diagnosis of myelodysplastic syndromes

AND

2. The prescribing physician is an oncologist or hematologist

AND

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

Itovebi (inavolisib)

1. Documented diagnosis of endocrine-resistant, PIK3CA-mutated, hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative, locally advanced or metastatic breast cancer, as detected by an FDA-approved test

AND

2. The prescribing physician is an oncologist

AND

3. Documentation the requested medication will be used in combination with palbociclib and fulvestrant

AND

4. Documentation of disease recurrence on or after completing adjuvant endocrine therapy

Iwilfin (eflornithine)

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)

Graft-Versus-Host Disease

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

AND

2. The patient is at least 12 years of age or older

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)

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)

Advanced or Metastatic Breast Cancer

1. Documented diagnosis of advanced or metastatic 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

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

Early Breast Cancer

1. Documented diagnosis of early breast cancer at high risk of recurrence

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. Stage II and III

AND

3. The prescribing physician is an oncologist

Koselugo (selumetinib)

5. Documented diagnosis of neurofibromatosis type 1

AND

6. Documentation of symptomatic, inoperable plexiform neurofibromas

AND

7. The patient is at least 2 years of age or older

AND

8. 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

Lazcluze (lazertinib)

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

AND

2. Documentation of an epidermal growth factor receptor exon 19 deletion or exon 21 L858R substitution mutation as detected by a Food and Drug Administration-approved test

AND

3. Documentation of use in combination with Rybrevant

AND

4. The prescribing physician is an oncologist

Lenalidomide

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 (1) of the following:
   a. Diagnosis of multiple myeloma AND use in combination with dexamethasone
   b. Use as maintenance therapy in a patient 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 patient'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 patient has been previously treated

AND

3. The prescribing physician is an oncologist or hematologist

AND

4. Documentation the requested medication will be used in combination with a rituximab product

Marginal Zone Lymphoma

1. Documented diagnosis of marginal zone lymphoma

AND

2. Documentation the patient has been previously treated

AND

3. The prescribing physician is an oncologist or hematologist

AND

4. Documentation the requested medication will be used in combination with a rituximab product

Lenvima (lenvatinib)

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. Documentation of all of the following:
      i. Use in combination with pembrolizumab for advanced endometrial carcinoma that is not microsatellite instability-high or mismatch repair deficient
      ii. Disease progression following systemic therapy
      iii. The patient is not a candidate for curative surgery or radiation

AND

2. The prescribing physician is an oncologist

Lonsurf (trifluridine/tipiracil)

1. The prescribing physician is an oncologist

AND

2. Documentation of one (1) of the following
   a. Documentation of both of the following:
      i. Diagnosis of metastatic colorectal cancer (mCRC)
      ii. The patient 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. Documentation of both of the following:
      i. Diagnosis of metastatic gastric or gastroesophageal junction adenocarcinoma
      ii. The patient 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)

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

Lumakras (sotorasib)

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. Documentation the prescribing physician is an oncologist

AND

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

Lynparza (olaparib)

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 patient 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 patient has previous treatment with an endocrine therapy
    b. The patient 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 (1)** of the following:
    a. Documentation of both of the following:
        a. Diagnosis of recurrent epithelial ovarian, fallopian tube or primary peritoneal cancer
        b. The patient is in complete or partial response to platinum-based chemotherapy
    b. Documentation of both of the following:
        a. Diagnosis of deleterious or suspected deleterious germline or somatic BRCA mutated advanced epithelial ovarian, fallopian tube, or primary peritoneal cancer as detected by a Food and Drug Administration-approved test (germline BRCA mutated only)
        b. The patient is in complete or partial response to first-line platinum-based chemotherapy
    c. Documentation of both of the following:
        a. Diagnosis of deleterious or suspected deleterious germline BRCA mutated advanced ovarian cancer as detected by a Food and Drug Administration-approved test
        b. The patient has tried and failed at least three prior lines of chemotherapy
    d. Documentation of both of the following:
        a. 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
        b. 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 patient has progressed following prior treatment with enzalutamide or abiraterone
    b. Both of the following:
        i. Deleterious or suspected deleterious BRCA-mutated cancer
        ii. Use in combination with abiraterone and prednisone or prednisolone

AND

3. The prescribing physician is an oncologist

Lytgobi (futibatinib)

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 patient has received a previous treatment for the requested condition

Mekinist (trametinib)

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 the patient requires systemic therapy

Mektovi (binimetinib)

Melanoma

1. Documented diagnosis of unresectable or metastatic melanoma

AND

2. Documentation of BRAF V600E or V600K mutation as detected by a Food and Drug Administration-approved test

AND

3. The prescribing physician is an oncologist

AND

4. Documentation of use in combination with encorafenib

Non-Small Cell Lung Cancer

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

AND

2. Documentation of BRAF V600E mutation as detected by a Food and Drug Administration-approved test

AND

3. The prescribing physician is an oncologist

AND

4. Documentation of use in combination with encorafenib

Nerlynx (neratinib)

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)

Advanced Renal Cell Carcinoma (RCC)

1. The patient is at least 18 years of age or older

AND

2. Documented diagnosis of advanced renal cell carcinoma

AND

3. The prescribing physician is an oncologist

Unresectable Hepatocellular Carcinoma (HCC)

1. The patient is at least 18 years of age or older

AND

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

AND

3. The prescribing physician is an oncologist

Differentiated Thyroid Carcinoma

1. The patient is at least 18 years of age or older

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)

1. Documented diagnosis of multiple myeloma

AND

2. The prescribing physician is an oncologist

AND

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

AND

4. Documentation the requested medication will be administered in combination with lenalidomide and dexamethasone

Nubeqa (darolutamide)

1. Documented diagnosis of **one (1)** of the following:
    a. Non-metastatic castration resistant prostate cancer
    b. Metastatic castration-sensitive prostate cancer
    c. Both of the following:
        i. Metastatic castration-sensitive prostate cancer
        ii. Use in combination with docetaxel

AND

2. The prescribing physician is an oncologist

Odomzo (sonidegib)

1. Documented diagnosis of locally advanced basal cell carcinoma

AND

2. The prescribing physician is an oncologist

AND

3. Documentation of **one (1)** of the following:
    a. Disease recurrence following surgery or radiation therapy
    b. The patient is not a candidate for surgery or radiation therapy

Ogsiveo (nirogacestat)

1. Documented diagnosis of a desmoid tumor

AND

2. Patient is at least 18 years of age or older

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

Ojemda (tovorafenib)

1. Documented diagnosis of relapsed or refractory pediatric low-grade glioma

AND

2. Documentation of a BRAF fusion or rearrangement, or BRAF V600 mutation

AND

3. The prescribing physician is an oncologist

Ojjaara (momelotinib)

1. Documented diagnosis of 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)

1. Documented diagnosis of acute myeloid leukemia

AND

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

AND

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

AND

4. The prescribing physician is an oncologist or hematologist

Orgovyx (relugolix)

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)

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)

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 a Food and Drug Administration-approved test

AND

3. Documentation the patient 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)

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 the requested medication will be used in combination with fulvestrant

Pomalyst (pomalidomide)

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 patient has failed two prior therapies, including bortezomib and lenalidomide

Qinlock (ripretinib)

1. Documented diagnosis of advanced gastrointestinal stromal tumor

AND

2. The prescribing physician is an oncologist

AND

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

Retevmo (selpercatinib)

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 patient is at least 18 years of age or older

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 2 years of age or older

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 2 years of age or older

AND

6. The prescribing physician is an oncologist

RET Fusion-Positive Solid Tumors

1. Documented diagnosis of locally advanced or metastatic solid tumors

AND

2. Documentation of RET gene fusion-positive cancer

AND

3. The patient is at least 2 years of age or older

AND

4. The prescribing physician is an oncologist

AND

5. Documentation of **one (1)** of the following:
    a. Progression on or following prior systemic treatment
    b. No satisfactory alternative treatment options

Revuforj (revumenib)

1. Documented diagnosis of relapsed or refractory acute leukemia

AND

2. Documentation of a lysine methyltransferase 2A gene (KMT2A) translocation

AND

3. The prescribing physician is an oncologist or hematologist

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

Romvimza (vimseltinib)

1. Documented diagnosis of symptomatic tenosynovial giant cell tumor

AND

2. The prescribing physician is an oncologist

AND

3. Documentation the patient is symptomatic

AND

4. Documentation surgery resection will potentially cause worsening functional limitation or severe morbidity

Rozlytrek (entrectinib)

1. The prescribing physician is an oncologist

AND

2. Documentation of one (1) of the following:
    a. ROS1-positive, metastatic non-small cell lung cancer
    b. Documentation of all of the following:
        i. Solid tumor that has a NTRK gene fusion without a known resistance mutation
        ii. The disease is metastatic or surgical resection is likely to result in severe morbidity
        iii. The patient has progressed following treatment or has no satisfactory alternative therapy

Rubraca (rucaparib)

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 patient 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 patient 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)

Acute Myeloid Leukemia

1. Documented diagnosis of FLT3 mutation-positive acute myeloid leukemia as detected by a Food and Drug Administration-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 (1) 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)

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

AND

2. The prescribing physician is an oncologist or hematologist

Stivarga (regorafenib)

Metastatic Colorectal Cancer

1. Documented diagnosis of metastatic colorectal cancer

AND

2. The prescribing physician is an oncologist

AND

3. Documentation the patient has a prior failure, contraindication, or intolerance to **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 patient has RAS wild-type mCRC

Gastrointestinal Stromal Tumor (GIST)

1. Documented diagnosis of gastrointestinal stromal tumor

AND

2. The prescribing physician is an oncologist

AND

3. Documentation the patient has a prior failure, contraindication, or intolerance to **ALL** of the following:
   a. imatinib mesylate
   b. sunitinib malate

Hepatocellular Carcinoma

1. Documented diagnosis of hepatocellular carcinoma

AND

2. The prescribing physician is an oncologist

AND

3. Documentation the patient has a prior failure, contraindication, or intolerance to prior therapy with sorafenib

Tabrecta (capmatinib)

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 a Food and Drug Administration-approved test

AND

3. The prescribing physician is an oncologist

Tafinlar (dabrafenib)

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 a Food and Drug Administration-approved test
   b. Diagnosis of unresectable or metastatic melanoma with BRAF V600E or V600K mutation as detected by a Food and Drug Administration-approved test
   c. Documentation of both of the following:
      i. Diagnosis of locally advanced or metastatic anaplastic thyroid cancer with BRAF V600E mutation
      ii. Locoregional treatment options are not appropriate
   d. Documentation of both of the following:
      i. Use as adjuvant treatment following complete resection for a diagnosis of melanoma with BRAF V600E or V600K mutations as detected by a Food and Drug Administration-approved test
      ii. Lymph node involvement
   e. Documentation of all of the following:
      i. Diagnosis of unresectable or metastatic solid tumors with BRAF V600E mutation
      ii. Disease progression following prior treatment
      iii. No satisfactory alternative treatment options
   ii. Documentation of all of the following:
      i. Diagnosis of low-grade glioma with a BRAF V600E mutation
      ii. Patient requires systemic therapy

Tagrisso (osimertinib)

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 epidermal 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)

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

Tazverik (tazemetostat)

Epithelioid Sarcoma

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

AND

2. The patient 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 (1) of the following:
    a. No satisfactory alternative treatment options
    b. Documentation of both of the following:
        i. Tumors are positive for an EZH2 mutation as detected by a Food and Drug Administration-approved test
        ii. The patient has received at least two prior systemic therapies

Tepmetko (tepotinib)

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)

Acute Myeloid Leukemia

1. Documented diagnosis of acute myeloid leukemia with a susceptible IDH1 mutation as detected by a Food and Drug Administration-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. The patient 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 patient has received prior treatment

Truqap (capivasertib)

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

Tukysa (tucatinib)

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 patient 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)

1. Documented diagnosis of tenosynovial giant cell tumor

AND

2. The prescribing physician is an oncologist

AND

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

AND

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

Vanflyta (quizartinib)

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)

Acute myeloid leukemia

1. Documented diagnosis of acute myeloid leukemia

AND

2. Documentation of one (1) of the following:
    a. The patient is at least 75 years of age or older
    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)

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)

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. The patient's disease is metastatic or surgical resection is likely to result in severe morbidity
    b. There are no satisfactory alternative treatments or patient's disease has progressed following treatment

Vizimpro (dacomitinib)

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 a Food and Drug Administration-approved test

AND

2. The prescribing physician is an oncologist

Vonjo (pacritinib)

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

Voranigo (vorasidenib)

1. Documented diagnosis of Grade 2 astrocytoma or oligodendroglioma with a susceptible isocitrate dehydrogenase-1 (IDH1) or isocitrate dehydrogenase-2 (IDH2) mutation

AND

2. The patient has previously undergone surgery including biopsy, sub-total resection, or gross total resection

AND

3. The patient is at least 12 years of age or older

AND

4. Documentation Voranigo will be used as single agent

AND

5. The prescribing physician is an oncologist or hematologist

Welireg (belzutifan)

Advanced Renal Cell Carcinoma

1. Documented diagnosis of advanced renal cell carcinoma

AND

2. Documentation of previous treatment with a programmed death receptor-1 (PD-1) or programmed death-ligand 1 (PD-L1) inhibitor and a vascular endothelial growth factor tyrosine kinase inhibitor (VEGF-TKI)

AND

3. The prescribing physician is an oncologist

von Hippel-Lindau Disease

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)

Anaplastic Large Cell Lymphoma

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

AND

2. The patient is at least 1 year of age or older

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 a Food and Drug Administration-approved test

Xospata (gilteritinib)

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 a Food and Drug Administration-approved test

Xpovio (selinexor)

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 patient 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 patient has received at least one prior therapy

Xtandi (enzalutamide)

1. The prescribing physician is an oncologist or urologist

AND

2. Documented diagnosis of **one (1)** of the following:
    a. Castration-resistant prostate cancer
    b. Metastatic castration-sensitive prostate cancer

Yonsa (abiraterone acetate)

1. Documented diagnosis of metastatic castration-resistant prostate cancer

AND

2. The prescribing physician is an oncologist

AND

3. Documentation the requested medication will be used in combination with methylprednisolone

Zejula (niraparib)

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 or gynecologist with oncologist training

Zelboraf (vemurafenib)

Melanoma

1. Documented diagnosis of unresectable or metastatic melanoma

AND

2. The prescribing physician is an oncologist

AND

3. The patient has BRAF V600E mutation-positive melanoma as detected by a Food and Drug Administration-approved test

Erdheim-Chester Disease

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

Zydelig (idelalisib)

1. Documented diagnosis of relapsed chronic lymphocytic leukemia

AND

2. The prescribing physician is an oncologist or hematologist

AND

3. Documentation the requested medication will be given in combination with rituximab

Zykadia (ceritinib)

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

AND

2. The prescribing physician is an oncologist

AND

3. Documentation the patient 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 provision 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 Acceptable 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 treatment 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. 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

1. Approval duration of Ogsiveo will be provided in 12-month intervals.
2. Authorizations of Iwilfin will be limited to 2 years.
3. For a non-formulary medication request, please refer to the Pharmacy Medical Necessity Guidelines for Formulary Exceptions and submit a formulary exception request to the plan as indicated.

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 June 2025.
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 And Revision History

September 13, 2022: Reviewed by the 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 (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: 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).
12. June 11, 2024: Added coverage criteria for Welireg's supplemental indication for advanced renal cell carcinoma (eff 7/1/24).
13. August 13, 2024: Added coverage criteria for Retevmo's supplemental indication for other RET fusion-positive solid tumors. Updated age requirements for Retevmo to at least 2 year of age for RET-mutant medullary thyroid cancer and RET fusion-positive thyroid cancer. Updated coverage for Iclusig to address expanded indication in newly diagnosed Ph+ ALL in combination with chemotherapy. Added Ojemda to the Medical Necessity Guideline (eff 9/1/24).
14. November 12, 2024: Removed coverage criteria for Gavreto Medullary Thyroid Cancer based on the FDA removing the indication from package labeling. Added coverage criteria for Kisqal''s supplemental indication in early breast cancer. Added Lazcluze and Voranigo to the Medical Necessity Guideline (eff 12/1/24).
15. December 10, 2024: Added Itovebi to the Medical Necessity Guideline (eff 2/1/25).
16. February 11, 2025: Updated coverage criteria for Calquence based on the expanded indication in mantle cell lymphoma. Added Revuforj to the Medical Necessity Guideline (eff 3/1/25).
17. April 8, 2025: Updated coverage criteria for Braftovi and Mektovi based on the supplemental indication in metastatic non-small cell lung cancer (eff 5/1/25).
18. May 13, 2025: Updated coverage criteria for Scemblix based on expanded indication in newly diagnosed Philadelphia chromosome-positive chronic myeloid leukemia in chronic phase. Added Gomekli to the Medical Necessity Guideline (eff 6/1/25).
19. June 10, 2025: Add Romvimza to the Medical Necessity Guideline (eff 7/1/25). Removed brand Revlimid from the Medical Necessity Guideline because brand Revlimid will be moved to non-formulary (eff 9/1/25).

20. July 8, 2025: Removed Farydak (panobinostat) and Truseltiq (infigratinib) from the Medical Necessity Guideline because the products have been discontinued. Added Ensacove (ensartinib) to the Medical Necessity Guideline. Updated coverage criteria for Nubeqa to address the expanded indication in patients with metastatic castration-sensitive prostate cancer. (eff 8/1/25). Updated coverage criteria for Ibrance to include documentation of one of the following: Contraindication, intolerance or clinical inappropriateness of treatment with Kisqali AND Verzenio or continuation of prior Ibrance therapy (eff 10/1/25).

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.