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Guideline Type	<input checked="" type="checkbox"/> Prior Authorization <input type="checkbox"/> Non-Formulary <input type="checkbox"/> Step-Therapy <input type="checkbox"/> Administrative
<p>Applies to:</p> <p>Commercial Products</p> <p><input checked="" type="checkbox"/> Harvard Pilgrim Health Care Commercial products; Fax: 617-673-0988</p> <p><input checked="" type="checkbox"/> Tufts Health Plan Commercial products; Fax: 617-673-0988</p> <p>CareLinkSM – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization</p> <p>Public Plans Products</p> <p><input checked="" type="checkbox"/> Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product); Fax: 617-673-0988</p>	

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 (alecetinib), 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), Erivedge (vismodegib), Erleada (apalutamide), Eulexin (flutamide), Exkivity (mobocertinib), Farydak (panobinostat), Fotivda (tivozanib), Fruzaqla (fruquintinib), Gavreto (pralsetinib), Gilotrif (afatinib), Ibrance (palbociclib), Iclusig (ponatinib), Idhifa (enasidenib), Imbruvica (ibrutinib), Inlyta (axitinib), Inqovi (decitabine/cedazuridine), Inrebic (fedratinib), Iwifin (eflornithine), Jakafi (ruxolitinib), Jaypirca (pirtobrutinib), Kisqali/Kisqali PAK (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), Nubeqa (darolutamide), Odomzo (sonidegib), Ogsiveo (nirogacestat), Ojjaara (momeotinib), Onureg (azacytidine), Orgovyx (relugolix), Orserdu (elacestrant), Pemazyre (pemigatinib), Piqray (alpelisib), Pomalyst (pomalidomide), Qinlock (ripretinib), Retevmo (selpercatinib), Revlimid (lenalidomide), Rezlidhia (olutasidenib), 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), Truseltiq (infigratinib), Tukysa (tucatinib), Turalio (pexidartinib), Vanflyta (quizartinib), Venclexta (venetoclax), Verzenio (abemaciclib), Vitrakvi (larotrectinib), Vizimpro (dacomitinib), Vonjo (pacritinib), 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

- Documented diagnosis of one of the following:
 - Metastatic castration-resistant prostate-cancer
 - 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) Documentatino 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 Erbitux (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 Mektovi (binimetinib)

Brukina (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

Waldenstrom's 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. Documentation of one (1) of the following:
 - a. Documentation of both of the following:
 - i. Diagnosis of mantle cell lymphoma
 - ii. The patient has received at least one (1) prior therapy
 - b. Diagnosis of chronic lymphocytic leukemia
 - c. Diagnosis of small lymphocytic lymphoma

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

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
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
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

Farydak (panobinostat)

1. Documented diagnosis of multiple myeloma
AND
2. The prescribing physician is an oncologist
AND
3. Documentation the patient has received at least two prior therapies, including bortezomib and an immunomodulatory agent
AND
4. Documentation the patient will be receiving both bortezomib and dexamethasone in conjunction with panobinostat

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
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)

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

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 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)

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 (2) 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)

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

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. 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

Iwifin (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 Iwifin 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

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)

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)

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
- 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-mutation 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)

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-mutation 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
3. The prescribing physician is an oncologist
AND

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)

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 Braftovi (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

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

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

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 hormone-sensitive prostate cancer 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

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 (mometinib)

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
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

Revlimid (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

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)

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
- AND**
2. Documentation from the prescribing physician that the patient has chronic phase chronic myeloid leukemia
- 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

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 or 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

Truseltiq (infigratinib)

1. Documented diagnosis of locally advanced or metastatic cholangiocarcinoma

AND

Documentation the cancer has a fibroblast growth factor receptor 2 fusion or other rearrangement as detected by a Food and Drug Administration-approved test

AND

2. The prescribing physician is an oncologist

AND

3. Documentation the cancer is unresectable

AND

4. Documentation the patient has received prior treatment

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
 - 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 $50 \times 10^9/L$

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

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

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.