Pharmacy Medical Necessity Guidelines: Oral Cancer Medications

Effective: February 18, 2019

Prior Authorization Required: √

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Pharmacy (RX) or Medical (MED) Benefit

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These pharmacy medical necessity guidelines apply to the following:

**Commercial Products**

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

**Tufts Health Public Plans Products**

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

**Fax Numbers:**

RXUM: 617.673.0988

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

**OVERVIEW**

The following oral cancer medications require prior authorization:

- Afinitor (everolimus)
- Afinitor Disperz (everolimus)
- Alecensa (alectinib)
- Alunbrig (brigatinib)
- Bosulif (bosutinib)
- Braftovi (encorafenib)
- Cabometyx (cabozantinib)
- Calquence (acalabrutinib)
- Caprelsa (vandetanib)
- Cometriq (cabozantinib)
- Copiktra (duvelisib)
- Cotelpic (cobimetinib)
- Erivedge (vismodegib)
- Erleada (apalutamide)
- Farydak (panobinostat)
- Gilotrif (afatinib)
- Hycamtin (topotecan)
- Ibrance (palbociclib)
- Iclusig (ponatinib)
- Idhifa (enasidenib)
- Imbruvica (ibrutinib)
- Inlyta (axitinib)
- Iressa (gefitinib)
- Jakafi (ruxolitinib)
- Kisqali (ribociclib)
- Lenvima (lenvatinib)
- Lonsurf (trifluridine/tipiracil)
- Lorbrena (lorlatinib)
- Lynparza (olaparib)
- Mekinist (trametinib)
- Mektovi (binimetinib)
- Nexavar (sorafenib)
- Nerlynx (neratinib)
- Nibrax (ixazomib)
- Odomzo (sonidegib)
- Pomalyst (pomalidomide)
- Revlimid (lenalidomide)
- Rubraca (rucaparib)
- Rydapt (midostaurin)
- Sprycel (dasatinib)
- Stivarga (regorafenib)
- Sutent (sunitinib)
- Tafinlar (dabrafenib)
- Tagrisso (osimertinib)
- Talzenna (talazoparib)
- Targ Crest (nilotinib)
- Tivoos (ivosidenib)
- Tykerb (lapatinib)
- Venclexa (venetoclax)
- Verzenio (abemaciclib)
- Vizimpro (dacomitinib)
- Votrient (pazopanib)
- Xalkori (crizotinib)
- Xtandi (enzalutamide)
- Yonsa (abiraterone)
- Zejula (niraparib)
- Zelboraf (vemurafenib)
- Zolinza (vorinostat)
- Zydelig (idelalisib)
- Zykdia (ceritinib)
- Zytiga (abiraterone)
**Coverage Guidelines**

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

**Advanced Renal Cell Carcinoma**  
1. Documented diagnosis of advanced renal cell carcinoma  
   AND  
2. The prescribing physician is an oncologist  
   AND  
3. The Member has a demonstrated disease progression or intolerance following an appropriate trial with sunitinib (Sutent®) or sorafenib (Nexavar®)

**Subependymal Giant Cell Astrocytoma (SEGA)**  
1. Documented diagnosis of subependymal giant cell astrocytoma associated with tuberous sclerosis complex  
   AND  
2. The prescribing physician is an oncologist  
   AND  
3. Documentation the Member is not a candidate for surgical resection

**Progressive Neuroendocrine Tumors**  
1. Documentation of at least one of the following:  
   a. Diagnosis of progressive neuroendocrine tumor located in the pancreas  
   b. Diagnosis of progressive, well-differentiated, non-functional neuroendocrine tumor located in the gastrointestinal tract or lung  
   AND  
2. The prescribing physician is an oncologist  
   AND  
3. The tumor cannot be removed by surgery or has spread to other parts of the body

**Renal Angiomyolipoma with Tuberous Sclerosis Complex**  
1. Documented presence of tuberous sclerosis and renal angiomyolipoma(s) greater than or equal to 3 cm in longest diameter  
   AND  
2. The prescribing physician is an oncologist

**Advanced Hormone Receptor-Positive, HER2-Negative Breast Cancer (Advanced HR+ BC)**  
1. Documented diagnosis of advanced hormone receptor-positive, HER2-negative breast cancer  
   AND  
2. The Member is postmenopausal  
   AND  
3. The prescribing physician is an oncologist  
   AND  
4. Documented failure of letrozole (Femara®) or anastrozole (Arimidex®)  
   AND  
5. Documentation that Afinitor (everolimus) tablets will be administered in combination with exemestane (Aromasin®)

**Tuberous Sclerosis Complex-Associated Partial-Onset Seizures**  
1. Documented diagnosis of partial-onset seizures associated with tuberous sclerosis complex  
   AND  
2. Documentation of use as adjunctive therapy in combination with other therapies (e.g., anticonvulsants)  
   AND  
3. The Member is at least 2 years of age  
   AND  
4. The prescribing physician is an oncologist or a neurologist
**Afinitor Disperz (everolimus)**
The plan may authorize coverage of **Afinitor Disperz (everolimus) tablets for oral suspension** for Members when all of the following criteria are met:

**Subependymal Giant Cell Astrocytoma (SEGA)**
1. Documented diagnosis of subependymal giant cell astrocytoma associated with tuberous sclerosis complex  
   AND
2. The prescribing physician is an oncologist  
   AND
3. Member is not a candidate for surgical resection

**Tuberous Sclerosis Complex-Associated Partial-Onset Seizures**
1. Documented diagnosis of partial-onset seizures associated with tuberous sclerosis complex  
   AND
2. Documentation of use as adjunctive therapy in combination with other therapies (e.g., anticonvulsants)  
   AND
3. The Member is at least 2 years of age  
   AND
4. The prescribing physician is an oncologist or a neurologist

**Alecensa (alectinib)**
The plan may authorize coverage of **Alecensa (alectinib)** for Members, when all of the following criteria are met:
1. Documented diagnosis of anaplastic lymphoma kinase-positive, metastatic non-small cell lung cancer as detected by an FDA-approved test  
   AND
2. The prescribing physician is an oncologist

**Alunbrig (brigatinib)**
The plan may authorize coverage of **Alunbrig (brigatinib)** for Members, when all of the following criteria are met:
1. Documented diagnosis of anaplastic lymphoma kinase-positive metastatic non-small cell lung cancer  
   AND
2. Documentation of progression on or intolerance to crizotinib  
   AND
3. The prescribing physician is an oncologist

**Bosulif (bosutinib)**
The plan may authorize coverage of **Bosulif (bosutinib)** for Members when all of the following criteria are met:
1. The prescribing physician is an oncologist or hematologist  
   AND
2. Documentation of one of the following:
   a. Documented diagnosis of chronic phase Philadelphia chromosome-positive chronic myelogenous leukemia
   b. Diagnosis of accelerated phase or blast phase Philadelphia chromosome-positive chronic myelogenous leukemia AND documented resistance or intolerance to prior therapy (e.g., imatinib)

**Braftovi (encorafenib)**
The plan may authorize coverage of Braftovi (encorafenib) for Members when all of the following criteria are met:
1. Documented diagnosis of unresectable or metastatic melanoma
2. Documentation of BRAF V600E or V600K mutation as detected by an FDA approved test
3. The prescribing physician is an oncologist
4. Documentation of use in combination with Mektovi (binimetinib)

**Cabometyx (cabozantinib)**
The plan may authorize coverage of Cabometyx (cabozantinib) for Members when all of the following criteria are met:
1. Documentation of one of the following:
   a) Diagnosis of advanced renal cell carcinoma
   b) Diagnosis of hepatocellular carcinoma AND previous treatment with Nexavar
2. The prescribing physician is an oncologist

**Calquence (acalabrutinib)**
The plan may authorize coverage of Calquence (acalabrutinib) for Members, when all of the following criteria are met:
1. The prescribing physician is an oncologist or hematologist
2. Documented diagnosis of mantle cell lymphoma
3. Documentation the Member has received at least one prior therapy

**Caprelsa (vandetanib)**
The plan may authorize coverage of Caprelsa (vandetanib) for Members, when all of the following criteria are met:
1. Documented diagnosis of symptomatic or progressive medullary thyroid cancer with unresectable locally advanced or metastatic disease
2. The prescribing physician is an oncologist

**Cometriq (cabozantinib)**
The plan may authorize coverage of Cometriq (cabozantinib) for Members, when all of the following criteria are met:
1. Documented diagnosis of progressive, metastatic medullary thyroid cancer
2. The prescribing physician is an oncologist

**Copiktra (duvelisib)**
The plan may authorize coverage of Copiktra (duvelisib) for Members, when all of the following criteria are met:
1. Documented diagnosis of one of the following:
   a. Relapsed or refractory chronic lymphocytic leukemia
   b. Relapsed or refractory small lymphocytic lymphoma
   c. Relapsed or refractory follicular lymphoma
2. Documentation the Member has received at least two prior systemic therapies
3. The prescribing physician is an oncologist or hematologist

**Cotellic (cobimetinib)**
The plan may authorize coverage of Cotellic (cobimetinib) for Members, when all the following criteria are met:
1. Documented diagnosis of unresectable or metastatic melanoma
2. The prescribing physician is an oncologist
3. The Member has BRAF V600E or V600K mutation-positive melanoma as detected by an FDA-approved test
4. Documentation that Cotellic (cobimetinib) will be administered in combination with Zelboraf (vemurafenib)

**Erleada (apalutamide)**
The plan may authorize coverage of Erleada (apalutamide) for Members, when all of the following criteria are met:
1. Documented diagnosis of non-metastatic castration-resistant prostate cancer
2. The prescribing physician is an oncologist or urologist

**Erivedge (vismodegib)**
The plan may authorize coverage of Erivedge (vismodegib) for Members, when all of the following criteria are met:
1. Documentation of one of the following:
   a. Diagnosis of metastatic basal cell carcinoma
   b. Diagnosis of locally advanced basal cell carcinoma AND that disease has recurred following surgery or the Member is not a candidate for surgery or radiation therapy
2. The prescribing physician is an oncologist

**Farydak (panobinostat)**
The plan may authorize coverage of Farydak (panobinostat) for Members, when all of the following criteria are met:
1. Documented diagnosis of multiple myeloma
2. The prescribing physician is an oncologist
3. Documentation the Member has received at least two prior therapies, including bortezomib and an immunomodulatory agent
4. Documentation the Member will be receiving both bortezomib and dexamethasone in conjunction with panobinostat

**Gilotrif (afatinib)**
The plan may authorize coverage of Gilotrif (afatinib) for Members when all of the following criteria are met:
1. The prescribing physician is an oncologist
2. Documentation of one of the following:
   a. Documented diagnosis of metastatic non-small cell lung cancer with tumors that have non-resistant epidermal growth factor receptor mutations as detected by an FDA-approved test
   b. Documented diagnosis of metastatic, squamous non-small cell lung cancer progressing after platinum-based chemotherapy

**Hycamtin (topotecan)**
The plan may authorize coverage of Hycamtin (topotecan) capsules for Members, when all of the following criteria are met:
1. Documented diagnosis of relapsed small cell lung cancer in patients with a prior complete or partial response and who are at least 45 days from the end of first-line chemotherapy
2. The prescribing physician is an oncologist

**Ibrance (palbociclib)**
The plan may authorize coverage of Ibrance (palbociclib) for Members, when all of the following criteria are met:
1. Documented diagnosis of hormone receptor positive, human epidermal growth factor receptor-2 negative advanced metastatic breast cancer
2. The prescribing physician is an oncologist
3. Documentation of use in combination with one of the following:
   a. An aromatase inhibitor as initial endocrine based therapy in postmenopausal women
   b. Fulvestrant in women with disease progression following endocrine therapy

**Iclusig (ponatinib)**
The plan may authorize coverage of Iclusig (ponatinib) for Members, when all the following criteria are met:
1. The prescribing physician is an oncologist or hematologist
2. Documentation of one of the following:
   a. Documented diagnosis of T315I-positive chronic myeloid leukemia (chronic phase, accelerated phase, or blast phase) or T315I-positive Philadelphia chromosome positive acute lymphoblastic leukemia
   b. Documented diagnosis of chronic phase, accelerated phase, or blast phase chronic myeloid leukemia or Philadelphia chromosome positive acute lymphoblastic leukemia AND documentation that no other tyrosine kinase inhibitor therapy is indicated

**Idhifa (enasidenib)**
The plan may authorize coverage of Idhifa (enasidenib) for Members, when all of the following criteria are met:
1. Documented diagnosis of isocitrate dehydrogenase-2 mutated acute myeloid leukemia (as detected by an FDA-approved test)
2. Documentation of at least one prior anticancer regimen for the treatment of acute myeloid leukemia
3. Prescribing physician is an oncologist or hematologist

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

**Mantle cell lymphoma**
1. Documented diagnosis of mantle cell lymphoma
2. The prescribing physician is an oncologist or hematologist
3. The Member has been treated with at least one prior therapy

**Chronic lymphocytic leukemia and small lymphocytic lymphoma with or without 17p deletion**
1. The Member has a diagnosis of chronic lymphocytic leukemia or small lymphocytic lymphoma with or without 17p deletion
2. The prescribing physician is an oncologist or hematologist

**Waldenstrom’s macroglobulinemia**
1. Documented diagnosis of Waldenstrom’s macroglobulinemia
2. The prescribing physician is an oncologist or hematologist

**Marginal Zone Lymphoma**
1. Documented diagnosis of marginal zone lymphoma with required systemic therapy
2. The Member has been treated with at least one prior anti-CD20-based therapy
3. The prescribing physician is an oncologist or hematologist

**Chronic Graft versus Host Disease**
1. Documented diagnosis of chronic graft versus host disease
2. The Member has been treated with at least one systemic therapy

**Inlyta (axitinib)**
The plan may authorize coverage of Inlyta (axitinib) for Members, when the following criteria are met:
1. Documented diagnosis of advanced renal cell carcinoma
2. The prescribing physician is an oncologist
3. Failure of at least one prior first-line systemic therapy (e.g. Sutent, Nexavar, Afinitor, Votrient, Avastin, Torisel)

**Iressa (gefitinib)**
The plan may authorize coverage for Iressa (gefitinib) when all of the following criteria are met:
1. Documented diagnosis of metastatic non-small cell lung cancer whose tumors have epidermal growth factor exon 19 deletions or exon 21 (L858R) substitution mutations as detected by an FDA-approved test
2. The prescribing physician is an oncologist

**Jakafi (ruxolitinib)**
The plan may authorize coverage of Jakafi (ruxolitinib) for Members, when all the following criteria are met:
1. Documentation of one of the following:
   a. Documented diagnosis of intermediate or high-risk myelofibrosis
   b. Documented diagnosis of polycythemia vera AND documented inadequate response or intolerance to hydroxyurea

**Kisqali (ribociclib)**
The plan may authorize coverage of Kisqali (ribociclib) for Members, when all of the following criteria are met:
1. Documented diagnosis of breast cancer
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
3. The prescribing physician is an oncologist
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

**Lenvima (lenvatinib)**
The plan may authorize coverage of Lenvima (lenvatinib) for Members, when all of the following criteria are met:
1. Documented diagnosis of one of the following:
   a) Locally recurrent or metastatic, progressive, radioactive iodine-refractory differentiated thyroid cancer
   b) Use in combination with everolimus for advanced renal cell carcinoma following one prior anti-angiogenic therapy
   c) Unresectable hepatocellular carcinoma
2. The prescribing physician is an oncologist

**Lonsurf (trifluridine/tipiracil)**
The plan may authorize coverage for Lonsurf (trifluridine/tipiracil) when all of the following criteria are met:
1. Documented diagnosis of metastatic colorectal cancer (mCRC)
2. The prescribing physician is an oncologist
3. Documentation the Member has been previously treated with fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy; an anti-vascular endothelial growth factor (VEGF) biological therapy; and if rat sarcoma viral oncogene (RAS) wild-type, an anti-epidermal growth factor receptor (EGFR) therapy

**Lorbrena (lorlatinib)**
The plan may authorize coverage for Lorbrena (lorlatinib) when all of the following criteria are met:
1. Documented diagnosis of anaplastic lymphoma kinase (ALK)-positive metastatic non-small cell lung cancer
2. The prescribing physician is an oncologist
3. Documentation the disease has progressed on Alecensa, Xalkori, or Zykadia

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

**Breast Cancer**
1. The prescribing physician is an oncologist  
2. Documented diagnosis of deleterious or suspected deleterious germline BRCA-mutated, HER2-negative metastatic breast cancer based on an FDA approved test  
3. Documentation the Member has received chemotherapy in the neoadjuvant, adjuvant, or metastatic setting  
4. In patients with hormone receptor positive breast cancer, documentation of one of the following:  
   a. The Member has previous treatment with an endocrine therapy  
   b. The Member is considered inappropriate for endocrine therapy

**Ovarian Cancer**
1. The prescribing physician is an oncologist  
2. Documentation of one of the following:  
   a. Diagnosis of recurrent epithelial ovarian, fallopian tube or primary peritoneal cancer AND Member is in complete or partial response to platinum-based chemotherapy  
   b. Diagnosis of deleterious or suspected deleterious germline or somatic BRCA mutated advanced epithelial ovarian, fallopian tube, or primary peritoneal cancer as detected by an FDA approved test (germline BRCA mutated only) AND Member is in complete or partial response to first-line platinum based chemotherapy  
   c. Diagnosis of deleterious or suspected deleterious germline BRCA mutated advanced ovarian cancer as detected by an FDA approved test AND Member has tried and failed at least three prior lines of chemotherapy

**Mekinist (trametinib)**
The plan may authorize coverage of Mekinist (trametinib) for Members when all of the following criteria are met:
1. The prescribing physician is an oncologist  
2. Documentation of one of the following:  
   a. Diagnosis of metastatic non-small cell lung cancer with BRAF V600E mutation as detected by an FDA-approved test  
   b. Diagnosis of unresectable or metastatic melanoma with BRAF V600E or V600K mutation as detected by an FDA-approved test  
   c. Use in combination with Tafinlar for a diagnosis of locally advanced or metastatic anaplastic thyroid cancer with BRAF V600E mutation AND locoregional treatment options are not appropriate  
   d. Use as adjuvant treatment in combination with Tafinlar following complete resection for a diagnosis of melanoma with BRAF V600E or V600K mutations as detected by an FDA-approved test AND lymph node involvement

**Mektovi (binimetinib)**
The plan may authorize coverage of Mektovi (binimetinib) for Members when all of the following criteria are met:
1. Documented diagnosis of unresectable or metastatic melanoma  
2. Documentation of BRAF V600E or V600K mutation as detected by an FDA approved test  
3. The prescribing physician is an oncologist  
4. Documentation of use in combination with Braftovi (encorafenib)

**Nerlynx (neratinib)**
The plan may authorize coverage of Nerlynx (neratinib) for Members, when all of the following criteria are met:
1. Documented diagnosis of HER2-overexpressed/amplified breast cancer
2. Documented treatment with trastuzumab based therapy prior to initiation of Nerlynx (neratinib)
3. Prescribing physician is an oncologist

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

**Advanced Renal Cell Carcinoma (RCC)**
1. The Member is at least 18 years of age
2. Documented diagnosis of advanced renal cell carcinoma
3. The prescribing physician is an oncologist

**Unresectable Hepatocellular Carcinoma (HCC)**
1. The Member is at least 18 years of age
2. Documented diagnosis of biopsy-proven, unresectable hepatocellular carcinoma
3. The prescribing physician is an oncologist

**Differentiated Thyroid Carcinoma**
1. The Member is at least 18 years of age
2. Documented diagnosis of locally recurrent or metastatic, progressive, differentiated thyroid carcinoma refractory to radioactive iodine treatment
3. The prescribing physician is an oncologist or Thyroid Specialist

**Ninlaro (ixazomib)**
The plan may authorize coverage of Ninlaro (ixazomib) for Members, when all of the following criteria are met:
1. Documented diagnosis of multiple myeloma
2. The prescribing physician is an oncologist
3. Documentation the Member has received at least one prior therapy
4. Documentation that Ninlaro (ixazomib) will be administered in combination with lenalidomide and dexamethasone

**Odomzo (sonidegib)**
The plan may authorize coverage of Odomzo (sonidegib) for Members, when the following criteria are met:
1. Documented diagnosis of locally advanced basal cell carcinoma
2. The prescribing physician is an oncologist
3. Documentation of one of the following:
   a. Documentation of disease recurrence following surgery or radiation therapy
   b. Documentation the Member is not a candidate for surgery or radiation therapy

**Pomalyst (pomalidomide)**
The plan may authorize coverage of Pomalyst (pomalidomide) for Members, when all of the following criteria are met:
1. Documented diagnosis of multiple myeloma AND
2. The prescribing physician is an oncologist AND
3. Documentation the Member has failed two prior therapies, including bortezomib and lenalidomide

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

**Transfusion-dependent Anemia**
1. Documented diagnosis of transfusion dependent anemia due to myelodysplastic syndrome associated with the 5q-deletion cytogenetic abnormality AND
2. The prescribing physician is an oncologist or hematologist

**Multiple Myeloma**
1. Documentation of one of the following:
   a. Diagnosis of multiple myeloma AND use in combination with dexamethasone
   b. Use as maintenance therapy in a Member following autologous hematopoietic stem cell transplantation AND
2. The prescribing physician is an oncologist or hematologist

**Mantle Cell Lymphoma**
1. Documented diagnosis of mantle cell lymphoma AND
2. Documentation the Member’s disease has relapsed or progressed after two prior therapies, one of which included Velcade (bortezomib) AND
3. The prescribing physician is an oncologist or hematologist

**Rubraca (rucaparib)**
The plan may authorize coverage of Rubraca (rucaparib) for Members, when all the following criteria are met:
1. Documentation of one of the following:
   a. Diagnosis of deleterious BRCA mutated (germline and/or somatic) (as detected by an FDA-approved test) epithelial ovarian, fallopian tube, or peritoneal cancer AND the Member has tried and failed at least two prior chemotherapies
   b. Diagnosis of recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer AND the Member is in a complete or partial response to platinum-based chemotherapy AND
2. The prescribing physician is an oncologist or gynecologist with oncologist training

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

**Acute Myeloid Leukemia**
1. Documented diagnosis of FLT3 mutation-positive acute myeloid leukemia as detected by an FDA-approved test
   \[ \text{AND} \]
2. Documentation requested use is in combination with cytarabine and daunorubicin induction and cytarabine consolidation
   \[ \text{AND} \]
3. The prescribing physician is an oncologist or hematologist

**Other Hematologic Conditions**
1. Documented diagnosis of one of the following:
   a. Aggressive systemic mastocytosis
   b. Systemic mastocytosis with associated hematological neoplasm
   c. Mast cell leukemia
   \[ \text{AND} \]
2. The prescribing physician is an oncologist or hematologist

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

**Chronic Myeloid Leukemia (CML)**
1. Documentation of at least one of the following:
   a. Newly diagnosed Philadelphia chromosome-positive CML in chronic phase
   b. Chronic, accelerated, or myeloid or lymphoid blast phase Philadelphia chromosome CML with documented resistance or intolerance to prior therapy, including imatinib
   c. Pediatric patient with Philadelphia chromosome positive CML in chronic phase
   \[ \text{AND} \]
2. The prescribing physician is an oncologist or hematologist

**Acute Lymphoblastic Leukemia (ALL)**
1. Documented diagnosis of Philadelphia chromosome-positive ALL
   \[ \text{AND} \]
2. The prescribing physician is an oncologist or hematologist

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

**Metastatic Colorectal Cancer**
3. The Member has a diagnosis of metastatic colorectal cancer
4. The prescribing physician is an oncologist
5. Documented prior failure, contraindication, or intolerance to prior therapy with ALL of the following:
   a. fluoropyrimidine-based chemotherapy
   b. oxaliplatin-based chemotherapy
   c. irinotecan-based chemotherapy
   d. anti-vascular endothelial growth factor (VEGF) therapy (e.g., bevacizumab)
   e. anti-EGFR therapy (e.g., panitumumab or cetuximab) if the Member has RAS wild-type mCRC

**Gastrointestinal Stromal Tumor (GIST)**
1. The Member has a diagnosis of gastrointestinal stromal tumor
2. The prescribing physician is an oncologist
3. Documented prior failure, contraindication, or intolerance to prior therapy with ALL of the following:
   a. imatinib mesylate
   b. sunitinib malate

**Hepatocellular Carcinoma**
1. The Member has a diagnosis of hepatocellular carcinoma
2. The prescribing physician is an oncologist
3. Documented prior failure, contraindication, or intolerance to prior therapy with sorafenib

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

**Renal Cell Carcinoma**
1. Documented diagnosis of at least one of the following:
   a. Advanced renal cell carcinoma
   b. High risk of recurrent renal cell carcinoma following nephrectomy
2. The prescribing physician is an oncologist

**Gastrointestinal Stromal Tumor**
1. Documented diagnosis of gastrointestinal stromal tumor
2. The prescribing physician is an oncologist
3. The Member has a demonstrated disease progression or intolerance following an appropriate trial with imatinib mesylate

**Progressive Neuroendocrine Tumors**
1. Documented diagnosis of progressive neuroendocrine tumor located in the pancreas
2. The prescribing physician is an oncologist
3. The tumor cannot be removed by surgery or has spread to other parts of the body

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

**Monotherapy**
1. Documented diagnosis of unresectable or metastatic melanoma
   AND
2. The prescribing physician is an oncologist
   AND
3. The Member has BRAF V600E mutation-positive melanoma as detected by an FDA-approved test.

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

**Tagrisso (osimertinib)**
The plan may authorize coverage of Tagrisso (osimertinib) for Members, when the following criteria are met:
1. Documented diagnosis of metastatic non-small cell lung cancer
   AND
2. The prescribing physician is an oncologist
   AND
3. Documentation of one of the following:
   a. EGFR T790M mutation positive disease as detected by an FDA-approved test AND failure, contraindication, or intolerance to prior tyrosine kinase therapy (e.g., afatinib, erlotinib, gefitinib)
   b. EGFR exon 19 deletions or exon 21 L858R mutation positive disease as detected by an FDA-approved test

**Talzenna (talazoparib)**
The plan may authorize coverage of Talzenna (talazoparib) for Members, when the following criteria are met:
1. Documented diagnosis of deleterious or suspected deleterious germline BRCA-mutated, HER2-negative locally advanced or metastatic breast cancer based on an FDA approved test
   AND
2. The prescribing physician is an oncologist

**Tasigna (nilotinib)**
The plan may authorize coverage of Tasigna (nilotinib) for Members, when the following criteria are met:
Newly Diagnosed Philadelphia Chromosome Positive Chronic Myeloid Leukemia in Chronic Phase
1. Documented diagnosis of Philadelphia chromosome positive chronic myeloid leukemia in chronic phase
   AND
2. The prescribing physician is an oncologist

Resistant or Intolerant Philadelphia Chromosome Positive Chronic Myeloid Leukemia in Chronic Phase and Accelerated Phase
1. Documented diagnosis of Philadelphia chromosome positive chronic myelogenous leukemia in chronic phase or in accelerated phase
   AND
2. Documented resistance or intolerance to prior therapy, including imatinib
   AND
3. The prescribing physician is an oncologist

Tibsovo (ivosidenib)
The plan may authorize coverage of Tibsovo (ivosidenib) for Members when all of the following criteria are met:
1. Documented diagnosis of acute myeloid leukemia with a susceptible IDH1 mutation as detected by an FDA-approved test
   AND
2. Documented relapsed or refractory disease
   AND
3. The prescribing physician is an oncologist

Tykerb (lapatinib)
The plan may authorize coverage of Tykerb (lapatinib) for Members when all of the following criteria are met:
HER2 overexpressing advanced or metastatic breast cancer
1. Documented diagnosis of HER2 overexpressing advanced or metastatic breast cancer
   AND
2. Documentation the Member has failed prior therapy with an appropriate trial of an anthracycline and a taxane chemotherapeutic agent.
   AND
3. Documentation the Member has failed prior therapy with an appropriate trial of Herceptin (trastuzumab).
   Note: Prior therapy with Herceptin (trastuzumab) implies that the Member’s diagnosis of HER2 overexpressing breast cancer has been confirmed via immunohistochemistry (IHC) or fluorescent in situ hybridization (FISH) assay.
   AND
4. Documentation Tykerb (lapatinib) will be administered concurrently with capecitabine (Xeloda®)
   AND
5. The prescribing physician is an oncologist

Hormone-receptor positive metastatic breast cancer in post-menopausal women
1. Documented diagnosis of hormone receptor positive metastatic breast cancer that overexpresses the HER2 receptor
   AND
2. Documentation Tykerb (lapatinib) will be administered concurrently with an aromatase inhibitor
   AND
3. The prescribing physician is an oncologist

Venclexta (venetoclax)
The plan may authorize coverage of Venclexta (venetoclax) when all of the following criteria are met:
Acute myeloid leukemia
1. Documented diagnosis of acute myeloid leukemia

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

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

4. The prescribing physician is an oncologist or a hematologist

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

2. The prescribing physician is an oncologist or a hematologist

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

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

2. The prescribing physician is an oncologist or a hematologist

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

**Verzenio (abemaciclib)**
The plan may authorize coverage of Verzenio (abemaciclib) for Members, when the following criteria are met:
1. Documented diagnosis of breast cancer

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

3. The prescribing physician is an oncologist

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

**Vizimpro (dacomitinib)**
The plan may authorized coverage of Vizimpro (dacomitinib) for Members when all of the following criteria are met:
1. Documented diagnosis of metastatic non-small cell lung cancer whose tumors have epidermal growth factor exon 19 deletions or exon 21 (L858R) substitution mutations as detected by an FDA-approved test  
   AND

2. The prescribing physician is an oncologist

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

**Advanced Renal Cell Carcinoma**
1. Documented diagnosis of advanced renal cell carcinoma  
   AND

2. The prescribing physician is an oncologist

**Advanced Soft Tissue Sarcoma**
1. Documented diagnosis of advanced soft tissue sarcoma  
   AND

2. The prescribing physician is an oncologist  
   AND

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

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

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

2. The prescribing physician is an oncologist  
   AND

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

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

1. The prescribing physician is an oncologist or urologist  
   AND

2. Documented diagnosis of one of the following:
   a. Non-metastatic castration-resistant prostate cancer (nmCRPC)
   b. Metastatic castration-resistant prostate cancer (mCRPC)  
   AND

3. For metastatic castration-resistant prostate cancer (mCRPC), documented failure, contraindication or intolerance to prior treatment with abiraterone

**Yonsa (abiraterone acetate)**
The plan may authorize coverage of Yonsa (abiraterone acetate) for Members when all of the following criteria are met:

1. Documented diagnosis of metastatic castration-resistant prostate cancer (mCRPC)  
   AND

2. The prescribing physician is an oncologist or urologist

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

1. Documented diagnosis of epithelial ovarian, fallopian tube, or primary peritoneal cancer
2. Documentation of recurrent disease in a Member with complete or partial response to platinum-based chemotherapy

3. The prescribing physician is an oncologist

**Zelboraf (vemurafenib)**

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

- **Melanoma**
  2. Documented diagnosis of unresectable or metastatic melanoma
  
  3. The prescribing physician is an oncologist

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

**Erdheim-Chester Disease**

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

**Zolinza (vorinostat)**

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

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

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

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

4. The prescribing physician is an oncologist or hematologist

**Zydelig (idelalisib)**

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

**Chronic Lymphocytic Leukemia (CLL)**
1. Documented diagnosis of relapsed chronic lymphocytic leukemia AND
2. The prescribing physician is an oncologist or hematologist AND
3. Documentation Zydelig (idelalisib) will be given in combination with rituximab

**Follicular B-cell non-Hodgkin Lymphoma (FL)**
1. Documented diagnosis of relapsed follicular B-cell non-Hodgkin lymphoma AND
2. The prescribing physician is an oncologist or hematologist AND
3. Documentation the Member has tried two prior systemic therapies (i.e., rituximab, alkylating agents, etc.)

**Small Lymphocytic Lymphoma (SLL)**
1. Documented diagnosis of relapsed small lymphocytic lymphoma AND
2. The prescribing physician is an oncologist AND
3. Documentation the Member has tried two prior systemic therapies (i.e., rituximab, alkylating agents, etc.)

**Zykadia (ceritinib)**
The plan may authorize coverage of Zykadia (ceritinib) for Members, when all of the following criteria are met:
1. Documented diagnosis of metastatic non-small cell lung cancer AND
2. The prescribing physician is an oncologist AND
3. Documentation the Member has anaplastic lymphoma receptor tyrosine kinase (ALK) genetic mutation

**Zytiga (abiraterone)**
The plan may authorize coverage of Zytiga (abiraterone) for Members, when all of the following criteria are met:
1. Documented diagnosis of one of the following:
   a. Metastatic castration-resistant prostate-cancer
   b. Metastatic high-risk castration-sensitive prostate cancer AND
2. The prescribing physician is an oncologist or urologist AND
3. Documentation that treatment is in combination with prednisone

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

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

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

In cases where the requested off-label use for the diagnosis is not recognized by the NCCN Drugs and Biologics Compendium, the plan will follow the Centers for Medicare and Medicaid Services (CMS) guidance, unless otherwise directed by the commissioner, and accept clinical documentation referenced in one of the other "Standard Reference Compendia" noted below or supported by clinical research that appears in a regular edition of a "Peer-Reviewed Medical Literature" noted below.
"Standard Reference Compendia"
1. American Hospital Formulary Service – Drug Information (AHFS-DI)
2. Thomson Micromedex DrugDex
3. Clinical Pharmacology (Gold Standard)
4. Wolters Kluwer Lexi-Drugs

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

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

LIMITATIONS
- The plan will not authorize the use of an oral cancer medication for a condition other than those listed above without appropriate documentation.
- The following quantity limitations apply:
  o Afinitor (everolimus) tablets: 30 units/30 days
  o Afinitor Disperz (everolimus) tablets for oral suspension: 60 units/30 days
  o Bosulif (bosutinib) tablets:
    ▪ 100 mg: 120 units/30 days
    ▪ 500 mg: 30 units/30 days
  o Caprelsa (vandetanib) tablets:
    ▪ 100 mg tablet: 60 units/30 days
    ▪ 300 mg tablet: 30 units/30 days
  o Hycamtin (topotecan) capsules:
    ▪ 0.25 mg capsule: 15 units/21 days
    ▪ 1 mg capsule: 25 units/21 days
  o Iclusig (ponatinib) tablets:
    ▪ 15 mg tablet: 60 units/30 days
    ▪ 45 mg tablet: 30 units/30 days
  o Idhifa (enasidenib) tablets: 30 units/30 days
  o Nexavar (sorafenib) tablets: 120 units/30 days
o Rubraca (rucaparib) tablets: 120 units/30 days
o Sprycel (dasatinib) tablets:
  • 20, 50, 70, 80 mg tablets: 60 units/30 days
  • 100, 140 mg tablets: 30 units/30 days
o Stivarga (regorafenib) capsules: 84 units/21 days
o Tagrisso (osimertinib) 40 mg tablets: 30 units/30 days
o Tykerb (lapatinib) tablets: 180 units/30 days
o Votrient (pazopanib) 200 mg tablets: 120 units/30 days
o Xtandi (enzalutamide) capsules: 120 units/30 days
o Zytiga (abiraterone) tablets: 120 units/30 days

- Tufts Health Plan will initially authorize Jakafi (ruxolitinib) for a period of 6 months. Subsequent authorization requires documentation of spleen size reduction and symptomatic improvement.
- Mekinist (trametinib) will not be authorized for the treatment of melanoma if there is history of prior BRAF-inhibitor therapy.
- Tafinlar (dabrafenib) will not be authorized for patients with wild-type BRAF melanoma or wild-type BRAF non-small cell lung cancer.
- The plan will not authorize coverage of Tykerb (lapatinib) for advanced or metastatic breast cancer tumors that do not overexpress the HER2 protein, unless such use satisfies the provisions noted in Off-label Use Coverage for Other Cancer Diagnoses.
- The efficacy of Votrient (pazopanib) for the treatment of patients with adipocytic soft tissue sarcoma or gastrointestinal stromal tumors has not been demonstrated.
- Zelboraf (vemurafenib) will not be authorized for the treatment of patients with wild-type BRAF melanoma.
- The plan does not cover multi-source branded oral cancer medications. Refer to the Pharmacy Medical Necessity Guidelines for Non-covered Drugs with Suggested Alternatives.

**CODES**

None

**REFERENCES**

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22. Iressa (gefitinib) [prescribing information]. Wilmington, DE: AstraZeneca Pharmaceuticals; 2015 July.
24. Kisqali (ribociclib) [prescribing information]. East Hanover (NJ): Novartis Pharmaceuticals Corporation; 2018 December.
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Votrient (pazopanib) [prescribing information]. Research Triangle Park, NC: GlaxoSmithKline; August 2016.
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Zolizia (vorinostat) [prescribing information]. Whitehouse Station, NJ: Merck & Co., Inc.; Dec 2015.
Zydelig (idelalisib) [prescribing information]. Foster City, CA: Gilead Sciences, Inc.; 2016 September.
Zykadia (ceritinib) [prescribing information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; 2017 June.

**APPROVAL HISTORY**

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

Subsequent endorsement date(s) and changes made:
1. March 13, 2018: Consolidated existing individual oral chemo medication Medical Necessity Guidelines (MNG) into a class MNG. The individual MNGs (49) are retired effective March 19, 2018. Added hematologist as an approvable provider specialty to Bosulif, Iclusig, and Revlimid.
4. June 12, 2018: Added coverage criteria for Tafinlar and Mekinist in combination for the adjuvant treatment of melanoma with BRAF V600E or V600K mutation, as detected by an FDA-approve test.
5. July 10, 2018: Updated the approvable diagnosis for Venclexta to be documentation of chronic lymphocytic leukemia or small lymphocytic lymphoma, with or without 17p deletion, based on updated FDA-approved indications.
6. August 7, 2018: Added Yonsa to the Medical Necessity Guideline. Updated coverage criteria for Xtandi based on new indication in for non-metastatic castration-resistant prostate cancer. Updated the prescriber requirements for Rubraca to allow for a gynecologist with oncology training.
7. September 18, 2018: Added Bratovi and Mektovi to the Medical Necessity Guideline. Updated the coverage criteria for Lenvima to allow for coverage of renal cell carcinoma and hepatocellular carcinoma. Updated the coverage criteria for Ibrance to allow for combination therapy with any aromatase inhibitor in postmenopausal women as initial endocrine therapy.
8. October 16, 2018: Effective November 1, 2018, added Tibsovo to the Medical Necessity Guideline.
9. November 13, 2018: Updated Kisqali criteria to be in line with updated indications. Specified required criteria when Kisqali is used in combination with an aromatase inhibitor or fulvestrant.
12. February 12, 2019: Added Lorbrena to the Medical Necessity Guideline. Updated the Cabometyx criteria to allow for coverage of new supplemental indication for the treatment of hepatocellular carcinoma.

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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.