MASSACHUSETTS

Blue Cross Blue Shield of Massachusetts is an Independent Licensee of the Blue Cross and Blue Shield Association

Pharmacy Medical Policy
Oncology Drugs (Oral and Subcutaneous)

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Policy Number: 409

BCBSA Reference Number: None

Policy

Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity

Note: All requests for outpatient retail pharmacy for indications listed and not listed on the medical policy guidelines may be submitted to BCBSMA Clinical Pharmacy Operations by completing the Prior Authorization Form on the last page of this document. Physicians may also call BCBSMA Pharmacy Operations department at (800)366-7778 to request a prior authorization/formulary exception verbally. Patients must have pharmacy benefits under their subscriber certificates.

Prior Authorization Information

<table>
<tr><td colspan="2">☒ Prior Authorization
☐ Step Therapy
☐ Quality Care Dosing</td><td>Pharmacy Operations:
Tel: 1-800-366-7778
Fax: 1-800-583-6289
Policy last updated | 4/2024</td></tr>
<tr><td>Pharmacy (Rx) or Medical (MED) benefit coverage</td><td>☒ Rx
☐ MED</td><td rowspan="2">To request for coverage: Providers may call, fax, or mail the attached form (Formulary Exception/Prior Authorization form) to the address below.
Blue Cross Blue Shield of Massachusetts
Pharmacy Operations Department
25 Technology Place
Hingham, MA 02043

Individual Consideration: Policy for requests that do not meet clinical criteria of this policy, see section labeled Individual Consideration</td></tr>
<tr><td colspan="2">Policy applies to Commercial Members:
Managed Care (HMO and POS),
PPO and Indemnity
MEDEX with Rx plan
Managed Major Medical with Custom BCBSMA Formulary
Comprehensive Managed Major Medical with Custom BCBSMA Formulary
Managed Blue for Seniors with Custom BCBSMA Formulary</td></tr>
</table>

Please refer to the chart below for the formulary and step status of the medications affected by this policy.

Standard Formulary	
Drug	**Formulary Status**
Alecensa ® (alectinib)	PA Required
Alunbrig ™ (brigatinib**)**	PA Required
Ayvakit ™ (avapritinib)	PA Required
Balversa ™ (erdafitinib)	PA Required
Braftovi ™ (encorafenib)	PA Required
Copiktra ™ (duvelisib**)**	PA Required
Cotellic ™ (cobimetinib)	PA Required
Erlotinib	PA Required
Exkivity ™ (mobocertinib)	PA Required
Farydak ® (Panobinostat)	PA Required
Fruzaqla ™ (fruquintinib)	PA Required
Gavreto ™ (pralsetinib)	PA Required
Gilotrif ® **(**afatinib**)**	PA Required
Ibrance ™ (palbociclib**)**	PA Required
Idhifa ® **(**enasidenib**)**	PA Required
Iressa ® **(**gefitinib**)**	PA Required
Jaypirca ™ (pirtobrutinib)	PA Required
Kisqali ® (ribociclib)	PA Required
Kisqali ® **Femara Co-Pack** (letrozole / ribociclib)	PA Required
Krazati ™ (adagrasib)	PA Required
Lenvima ™ (Lenvatinib)	PA Required
Lorbrena ® (lorlatinib**)**	PA Required
Lumakras ™(sotorasib)	PA Required
Lytgobi ® (futibatinib**)**	PA Required
Mekinist ™ (trametinib)	PA Required
Mektovi ® (binimetinib)	PA Required
Ojjaara ® (momelotinib)	PA Required
Orserdu ® (elacestrant)	PA Required
Pemazyre ™ (pemigatinib)	PA Required
Piqray ® (alpelisib)	PA Required
Retevmo ™ (selpercatinib)	PA Required
Rezlidhia ™ (olutasidenib**)**	PA Required
Rozlytrek ™ (entrectinib**)**	PA Required
Rydapt ® (midostaurin)	PA Required
Scemblix ® (asciminib)	PA Required
Tabrecta ™ (capmatinib)	PA Required

Tafinlar ® (dabrafenib)	PA Required
Tagrisso ® **(**osimertinib**)**	PA Required
Tarceva ® **(**erlotinib**)**	PA Required
Tepmetko ®(tepotinib)	PA Required
Tibsovo ® **(**ivosidenib**)**	PA Required
Truqap ™(capivasertib)	PA Required
Truseltiq ™ (infigratinib)	PA Required
Vanflyta ® (quizartinib)	PA Required
Verzenio ™ (abemaciclib)	PA Required
Vitrakvi ® (larotrectinib**)**	PA Required
Vizimpro ® (dacomitinib**)**	PA Required
Vonjo ™ (pacritinib)	PA Required
Xalkori ® (crizotinib)	PA Required
Xospata ® **(**gilteritinib**)**	PA Required
Zelboraf ™ (vemurafenib)	PA Required
Zydelig ® (idelalisib**)**	PA Required
Zykadia ™ (ceritinib)	PA Required

- Solution.

We may cover Alecensa ® (alectinib) for the treatment of patients with metastatic non-small cell lung cancer (NSCLC) when **ALL** of the following criteria are met:

- ALK-Positive mutation as determined by an FDA approved test

We may cover Ayvakit ™ (avapritinib) for the treatment of adults when **ALL** of the following criteria are met:

- PDGFRA Exon 18 Mutation-Positive Unresectable or Metastatic Gastrointestinal Stromal Tumor (GIST), including PDGFRA D842V mutations, **OR**
- For the treatment of adult patients with indolent systemic mastocytosis (ISM), **OR**
- Advanced Systemic Mastocytosis (AdvSM)
    1. AdvSM includes patients with aggressive systemic mastocytosis (ASM), systemic mastocytosis with an associated hematological neoplasm (SM-AHN), and mast cell leukemia (MCL)

We may cover Alunbrig ™ (brigatinib**)** the treatment of adult patients with anaplastic lymphoma kinase (ALK)-positive metastatic non-small cell lung cancer (NSCLC) when **ALL** of the following criteria are met:

- Susceptible ALK genetic mutation confirmed by an FDA test

We may cover Balversa ® (erdafitinib**)** the treatment of adult (18 years of age or older) patients with locally advanced or metastatic urothelial carcinoma when **ALL** of the following criteria are met:

- Susceptible fibroblast growth factor receptors genetic alterations type 2 or type 3 (FGFR3 or FGFR2) confirmed by an FDA test, **AND**
- Progressed during or following at least one line of prior platinum-containing chemotherapy, including within 12 months of neoadjuvant or adjuvant platinum-containing chemotherapy.

We may cover Braftovi ™ (encorafenib) for the treatment of patients when **ALL** of the following criteria are met:

- Diagnosis of unresectable or metastatic melanoma, **AND**
- BRAF V600E or V600K mutation as determined by an FDA approved test, **AND**
- Used in combination with binimetinib **(**Mektovi®**)**

OR

- Diagnosis of metastatic colorectal cancer (CRC), **AND**
- Used in combination with cetuximab (Erbitux®), **AND**
- BRAF V600E mutation, as detected by an FDA-approved test, **AND**
- after prior therapy

We may cover Copiktra ™ (**duvelisib**) for the treatment of adult patients with relapsed or refractory Chronic Lymphocytic Leukemia (CLL), or Small Lymphocytic Lymphoma (SLL) when **ALL** of the following criteria are met:

- Age 18 years of age or older, **AND**
- Documented use of at least two prior therapies

We may cover Cotellic ™ (cobimetinib) for the treatment of patients only with unresectable or metastatic melanoma when **ALL** of the following criteria are met:

- BRAF V600E or V600K mutation as determined by an FDA approved test, **AND**
- Used in combination with vemurafenib.

We may cover erlotinib for the first-line treatment of patients with metastatic non-small cell lung cancer (NSCLC) with epidermal growth factor receptor (EGFR) exon 19 deletion or exon 21 L858R substitution mutations as detected by an FDA-approved test when **ALL** of the following criteria are met:

- The patient has a documented diagnosis of NSCLC **AND**
- The patient has either Exon 19 Deletion or Exon 21 L858R Substitution confirmed by an FDA test

OR

We may cover erlotinib for the first-line treatment of patients with locally advanced, unresectable or metastatic pancreatic cancer.

Tarceva (erlotinib) may be covered if the member has tried and failed generic erlotinib.

We may cover Exkivity ® (mobocertinib) for locally advanced or metastatic non-small cell lung cancer (NSCLC) when **ALL** of the following criteria are met:

- Progressed on or after platinum-based chemotherapy, **AND**
- epidermal growth factor receptor (EGFR) exon 20 insertion mutation detected by an FDA-approved test.

We may cover Farydak ® (Panobinostat) a histone deacetylase inhibitor when **ALL** of the following criteria are met:

- is indicated for the treatment of patients with multiple myeloma who have received at least 2 prior regimens, **AND**
- including, bortezomib and an immunomodulatory agent, **AND**
- Used in combination with bortezomib and dexamethasone.

We may cover Fruzaqla ™ (fruquintinib) for treatment of patients with metastatic colorectal cancer (mCRC) when **ALL** of the following criteria are met:

- Patient must have a diagnosis of mCRC, **AND**
- Patient must show disease progression following treatment with fluoropyrimidine, oxaliplatin, and irinotecan-based chemotherapy, **AND**
- Patient must show disease progression following anti-VEGF therapy (i.e., bevacizumab, Zaltrap, Cyramza), **AND**
- If Patient has RAS wild-type mCRC, they must show disease progression following treatment with anti-EGFR therapy (i.e., cetuximab, panitumumab), **AND**
- Patient must have an Eastern Cooperative Oncology Group (ECOG) performance status ≤1, **AND**
- Clinical rationale or documentation for why Lonsurf plus bevacizumab is not appropriate for use in the member.

We may cover Gavreto ™ (pralsetinib**)** for the treatment when **ALL** of the following criteria are met:

- Age 18 years of age or older, **AND**
- Confirmed diagnosis of metastatic RET fusion-positive non-small cell lung cancer (NSCLC)

OR

- Age 12 years of age or older, **AND**
- Confirmed diagnosis of advanced or metastatic RET-mutant medullary thyroid cancer (MTC) who require systemic therapy

OR

- Age 12 years of age or older, **AND**
- Confirmed diagnosis of advanced or metastatic RET fusion-positive thyroid cancer, **AND**
- requires systemic therapy and who are radioactive iodine-refractory

We may cover Gilotrif ® **(**afatinib**)** for the first-line treatment of patients with metastatic non-small cell lung cancer (NSCLC) whose tumors have non-resistant epidermal growth factor receptor (EGFR) mutations as detected by an FDA-approved test when **ALL** of the following criteria are met:

- The patient has a documented diagnosis of NSCLC, **AND**
- The patient has epidermal growth factor receptor (EGFR) mutations confirmed by an FDA test.

We may cover Ibrance ™ (palbociclib**)** for the treatment of HR-positive, HER2-negative advanced or metastatic breast cancer as indicated in its FDA approved label when used in combination with cancer when **ALL** of the following criteria are met:

- an aromatase inhibitor as initial endocrine-based therapy in postmenopausal women or in men,

OR

- fulvestrant in patients with disease progression following endocrine therapy.

We may cover Idhifa ® **(**enasidenib**)** for the treatment of adult patients with relapsed or refractory acute myeloid leukemia (AML) when **ALL** of the following criteria are met:

- Age 18 years of age or older, **AND**
- An isocitrate dehydrogenase-2 (IDH2) mutation as determined by an FDA approved test

We may cover Iressa ® **(**gefitinib**)** for the first-line treatment of patients with metastatic non-small cell lung cancer (NSCLC) with epidermal growth factor receptor (EGFR) exon 19 deletion or exon 21 L858R substitution mutations as detected by an FDA-approved test when **ALL** of the following criteria are met:

- The patient has a documented diagnosis of NSCLC, **AND**
- The patient has either Exon 19 Deletion or Exon 21 L858R Substitution confirmed by an FDA test.

We may cover Jaypirca ™ (pirtobrutinib**)** for the treatment of patients with relapsed or refractory mantle cell lymphoma (MCL) when **ALL** of the following criteria is met:

- Age 18 years of age or older, **AND**
- Documentation of histologically confirmed mantle cell lymphoma (MCL), **AND**
- The Patient has received at least two prior systemic therapies, one of which was a BTK inhibitor.

OR

- Age 18 years of age or older, **AND**
- Documentation of histologically confirmed chronic lymphocytic leukemia or small lymphocytic lymphoma (CLL/SLL), **AND**
- Patient has received at least two prior lines of therapy, including a BTK inhibitor and a BCL-2 inhibitor.

We may cover Kisqali ® (ribociclib**)** for the treatment of HR-positive, HER2-negative advanced or metastatic breast cancer when **ALL** of the following criteria are met:

- Used in Combination with an aromatase inhibitor for the treatment of pre/perimenopausal or postmenopausal women with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic breast cancer, as initial endocrine-based therapy

OR

- Used in Combination with fulvestrant for the treatment of postmenopausal women with HR-positive, HER2-negative advanced or metastatic breast cancer, as initial endocrine-based therapy or following disease progression on endocrine therapy.

We may cover Kisqali ® Femara Co-Pack (letrozole and ribociclib**)** for the treatment of initial endocrine-based therapy for HR-positive, HER2-negative advanced or metastatic breast cancer when **ALL** of the following criteria are met:

- Patient is a pre/perimenopausal or Postmenopausal woman.

We may cover Lenvima ™ (Lenvatinib**)** for the treatment of:

- Locally recurrent or metastatic, progressive, radioactive iodine-refractory differentiated thyroid cancer, **OR**
- Advanced renal cell carcinoma (RCC) in combination with Everolimus following one prior anti-angiogenic therapy, **OR**
- Advanced renal cell carcinoma (RCC) in combination with pembrolizumab, is indicated for the first-line treatment of adult patients, **OR**
- Unresectable hepatocellular carcinoma (HCC), **OR**
- In combination with pembrolizumab (Keytruda®), is indicated for the treatment of patients with advanced endometrial carcinoma that is not microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR), who have disease progression following prior systemic therapy and are not candidates for curative surgery or radiation. Documentation required for mismatch repair deficient (MMR) as detected by an FDA approved test.

We may cover Krazati ™ (adagrasib**)** for the treatment of patients with *KRAS G12C*-mutated locally advanced or metastatic non-small cell lung cancer (NSCLC) when **ALL** of the following criteria is met:

- Age 18 years of age or older, **AND**
- Documentation of KRAS G12C mutation as detected by an FDA approved test, **AND**
- The Patient has received at least one prior systemic therapy

We may cover Lorbrena ® (lorlatinib**)** for the treatment of patients with anaplastic lymphoma kinase (ALK)-positive metastatic non-small cell lung cancer (NSCLC) or as first-line anaplastic lymphoma kinase (ALK)-positive non-small cell lung cancer (NSCLC) when **ALL** of the following criteria is met:

- Documentation of ALK-positive NSCLC as detected by an FDA approved test

We may cover Lumakras ™ (sotorasib**)** for the treatment of patients with *KRAS G12C*-mutated locally advanced or metastatic non-small cell lung cancer (NSCLC) when **ALL** of the following criteria is met:

- Documentation of KRAS G12C mutation as detected by an FDA approved test, **AND**
- The Patient has received at least one prior systemic therapy.

We may cover Lytgobi ® (futibatinib) for the treatment of patients with previously treated, unresectable, locally advanced, or metastatic intrahepatic cholangiocarcinoma when **ALL** of the following criteria are met:

- Age 18 years of age or older, **AND**
- fibroblast growth factor receptor 2 (FGFR2) gene fusion as determined by an FDA approved test.

We may cover Mekinist ™ (trametinib) for treatment when **ALL** of the following criteria are met[5]:

- Safety and effectiveness have not been established in pediatric patients, **AND**
- as a single agent in BRAF-inhibitor treatment-naïve patients or in combination with dabrafenib (Tafinlar®), for the treatment of patients with unresectable or metastatic melanoma with BRAF V600E or V600K mutations, as detected by an FDA-approved test.

OR

- In combination with dabrafenib (Tafinlar®), for the adjuvant treatment of patients with melanoma with BRAF V600E or V600K mutations, as detected by an FDA-approved test, and involvement of lymph node(s), following complete resection, **OR**
- In combination with dabrafenib (Tafinlar®), for the treatment of patients with metastatic non-small cell lung cancer (NSCLC) with BRAF V600E mutation as detected by an FDA-approved test, **OR**
- In combination with dabrafenib (Tafinlar®), for the treatment of patients with locally advanced or metastatic anaplastic thyroid cancer (ATC) with BRAF V600E mutation and with no satisfactory locoregional treatment options, **OR**
- MEKINIST is indicated, in combination with dabrafenib (Tafinlar ®), for the treatment of adult and pediatric patients 6 years of age and older with unresectable or metastatic solid tumors with BRAF V600E mutation who have progressed following prior treatment and have no satisfactory alternative treatment options, **OR**
- In combination dabrafenib (Tafinlar ®), for previously treated inoperable or metastatic solid tumors that have BRAF V600E mutations in patients ≥ 6 years old who no longer have other remaining therapy choices.

We may cover Mektovi ® (binimetinib**)** for the treatment of patients only with unresectable or metastatic melanoma when **ALL** of the following criteria are met:

- BRAF V600E or V600K mutation as determined by an FDA approved test, **AND**
- Used in combination with encorafenib (Braftovi™).

We may cover Ojjaara ® (momelotinib) for the treatment of intermediate or high-risk myelofibrosis (MF) when **ALL** of the following criteria are met:

- Age 18 years of age or older, **AND**
- Classified as having high-risk MF, including primary MF or secondary MF [post-polycythemia vera (PV) and post-essential thrombocythemia (ET)], **AND**
- Diagnosed with transfusion-dependent anemia associated with MF (not for patients with symptomatic splenomegaly only).

We may cover Orserdu ® (elacestrant**)** for the treatment of adults with estrogen receptor (ER)-positive, human epidermal growth factor receptor 2 (HER2)-negative, ESR1-mutated advanced or metastatic breast cancer with when **ALL** of the following criteria are met:

- Confirmed diagnosis estrogen receptor (ER)-positive, human epidermal growth factor receptor 2 (HER2)-negative, ESR1-mutated advanced or metastatic breast cancer, **AND**
- Age 18 years of age or older**, AND**
- Patient must have disease progression following at least one line of endocrine therapy

We may cover Pemazyre ™ (pemigatinib**)** for the treatment of adults with previously treated, unresectable locally advanced or metastatic cholangiocarcinoma with when **ALL** of the following criteria are met:

- Confirmed diagnosis of unresectable locally advanced or metastatic cholangiocarcinoma, **AND**
- a fibroblast growth factor receptor 2 (FGFR2) fusion or other rearrangement as detected by an FDA-approved test, **AND**
- Document previous treatment

OR

- Confirmed diagnosis of relapsed or refractory myeloid/lymphoid neoplasms (MLNs), **AND**
  a fibroblast growth factor receptor 2 (FGFR2) fusion or other rearrangement as detected by an FDA-approved test.

We may cover Piqray ® (alpelisib) for the treatment of postmenopausal women, and men, with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative, PIK3CA-mutated, advanced or metastatic breast cancer when **ALL** of the following criteria are met:

- Following progression on or after an endocrine-based regimen, **AND**
- Catalytic alpha-subunit of phosphatidylinositol-3-kinase (PIK3CA) mutation is present as detected from an FDA approved test, **AND**

- Used in combination with fulvestrant (Faslodex ®)

We may cover Retevmo™ (selpercatinib**)** for the treatment when **ALL** of the following criteria are met:
- Age 18 years of age or older, **AND**
- Confirmed diagnosis of metastatic RET fusion-positive non-small cell lung cancer (NSCLC)

OR
- Age 12 years of age or older, **AND**
- Confirmed diagnosis of advanced or metastatic RET-mutant medullary thyroid cancer (MTC) who require systemic therapy

OR
- Age 12 years of age or older, **AND**
- Confirmed diagnosis of advanced or metastatic RET fusion-positive thyroid cancer, **AND**
- requires systemic therapy and who are radioactive iodine-refractory.

OR
- Age 18 years of age or older, **AND**
- Confirmed diagnosis of locally advanced or metastatic solid tumors with a RET gene fusion, **AND**
- Has progressed on or following prior systemic treatment or who have no satisfactory alternative treatment options.

We may cover Rezlidhia ™ (olutasidenib**)** for the treatment of adult patients with relapsed or refractory acute myeloid leukemia (AML) with a susceptible isocitrate dehydrogenase-1 (IDH1) mutation when **ALL** of the following criteria is met:
- Age 18 years of age or older, **AND**
- Documentation of isocitrate dehydrogenase-1 (IDH1) mutation as detected by an FDA approved test

We may cover Rozlytrek™ (entrectinib**)** for the treatment when **ALL** the following criteria are met:

- The patient is 12 years of age and older with solid tumors and has a neurotrophic receptor tyrosine kinase (NTRK) gene fusion without a known acquired resistance mutation as determined by an FDA approved test, **AND**
- The patient is metastatic or where surgical resection is likely to result in severe morbidity, **AND**
- The patient has no satisfactory alternative treatments or that have progressed following treatment.

OR
- The patient is an adult with metastatic non-small cell lung cancer (NSCLC) whose tumors are ROS1-positive as determined by an FDA approved test

We may cover Rydapt® (midostaurin) when **ALL** of the following criteria are met:
- A diagnosis of acute myeloid leukemia (AML) that is FLT3 mutation-positive, **AND**
- Documentation of the above diagnosis from an FDA approved test, **AND**
- Used in combination with standard cytarabine and daunorubicin induction and cytarabine consolidation.

We may cover Scemblix ™ (asciminib) when **ALL** of the following criteria are met:
- Age 18 years of age or older, **AND**
- Philadelphia chromosome-positive chronic myeloid leukemia (Ph+ CML) in chronic phase (CP), previously treated with two or more tyrosine kinase inhibitors (TKIs)

OR
- Ph+ CML in CP with the T315I mutation.

We may cover Tabrecta ™ (capmatinib) when **ALL** of the following criteria are met:
- Age 18 years of age or older, **AND**
- Confirmed Diagnosis of metastatic non-small cell lung cancer (NSCLC), **AND**
- Documentation of a mutation that leads to mesenchymal-epithelial transition (MET) exon 14 skipping from an FDA approved test.

We may cover Tafinlar ® (dabrafenib) for the treatment of unresectable or metastatic melanoma when **ALL** of the following criteria are met[6]:
- Unresectable or metastatic melanoma with BRAF V600E mutation as detected by an FDA-approved test, **AND**
- Not indicated for treatment of patients with wild-type BRAF melanoma, **AND**

- Safety and effectiveness have not been established in pediatric patients.

OR

- in combination with trametinib (Mekinist ®), for the treatment of patients with unresectable or metastatic melanoma with BRAF V600E or V600K mutations, as detected by an FDA-approved test, **OR**
- In combination with trametinib (Mekinist ®), for the adjuvant treatment of patients with melanoma with BRAF V600E or V600K mutations, as detected by an FDA-approved test, **OR**
- in combination with trametinib (Mekinist ®), for the treatment of patients with metastatic non-small cell lung cancer (NSCLC) with BRAF V600E mutation as detected by an FDA-approved test, **OR**
- In combination with trametinib (Mekinist ®), for the treatment of patients with locally advanced or metastatic anaplastic thyroid cancer (ATC) with BRAF V600E mutation and with no satisfactory locoregional treatment options, **OR**
- in combination with trametinib (Mekinist ®), for the treatment of adult and pediatric patients 6 years of age and older with unresectable or metastatic solid tumors with BRAF V600E mutation who have progressed following prior treatment and have no satisfactory alternative treatment options.

We may cover Tagrisso (osimertinib**)** for the first-line treatment of patients with metastatic non-small cell lung cancer (NSCLC) with epidermal growth factor receptor (EGFR) exon 19 deletion or exon 21 L858R substitution mutations as detected by an FDA-approved test when **ALL** of the following criteria are met:

- The patient has a documented diagnosis of NSCLC, **AND**
- The patient has either Exon 19 Deletion or Exon 21 L858R Substitution confirmed by an FDA test.

OR

- The patient has a documented diagnosis of NSCLC, **AND**
- The patient has EGFR T790M mutation-positive, as confirmed by an FDA test, **AND**
- The patient has progressed on or after EGFR tyrosine kinase inhibitor (TKI) therapy

We may cover Tepmetko ® (tepotinib**)** for the treatment of adult patients with metastatic non-small cell lung cancer (NSCLC) harboring mesenchymal-epithelial transition (MET) exon 14 skipping alterations when **ALL** of the following criteria are met:

- Age 18 years of age or older, **AND**
- Confirmed Diagnosis of metastatic non-small cell lung cancer (NSCLC), **AND**
- Documentation of a mutation that leads to mesenchymal-epithelial transition (MET) exon 14 skipping from an FDA approved test.

We may cover Tibsovo ® (ivosidenib**)** for the treatment of patients when **ALL** of the following criteria are met:

- in combination with azacitidine (Vidaza) or as monotherapy, **AND**
- Diagnosis of newly diagnosed acute myeloid leukemia (AML), **AND**
- Susceptible isocitrate dehydrogenase-1 (IDH1) mutation as detected by an FDA-approved test, **AND**
- patient is ≥ 75 years old or who have comorbidities which preclude use of intensive induction chemotherapy.

OR

- Diagnosis of relapsed or refractory acute myeloid leukemia (AML), **AND**
- Susceptible isocitrate dehydrogenase-1 (IDH1) mutation as detected by an FDA-approved test, **AND**
- relapsed or refractory to previous treatments, **AND**
- Patient is ≥ 18 years of Age.

OR

- Diagnosis of locally advanced or metastatic cholangiocarcinoma**, AND**
- Susceptible isocitrate dehydrogenase-1 (IDH1) mutation as detected by an FDA-approved test, **AND**
- Patient is ≥ 18 years of Age.

We may cover Truqap ™(capivasertib) for the treatment of adult patients with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative, locally advanced or metastatic breast cancer with one or more PIK3CA/AKT1/PTEN-alteration as detected by an FDA-approved test when **ALL** of the following criteria are met:

- Age 18 years of age or older, **AND**
- Patient must have advanced or metastatic breast cancer with one or more PIK3CA/AKT1/PTEN alterations, **AND**
- Patient must have disease progression following at least one line of endocrine therapy in the metastatic setting or recurrence on or within 12 months of completing adjuvant therapy, **AND**
- Truqap will be given in combination with fulvestrant as subsequent therapy, **AND**
- Patient must have an Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1.

We may cover Truseltiq ® (infigratinib**)** for the treatment of adults with previously treated, unresectable locally advanced or metastatic cholangiocarcinoma with a fibroblast growth factor receptor 2 (FGFR2) fusion or other rearrangement when **ALL** of the following criteria are met:

- Documentation of fibroblast growth factor receptor 2 (FGFR2) mutation as detected by an FDA approved test

We may cover Vanflyta ® (quizartinib**)** for the treatment of acute myeloid leukemia (AML) when ALL of the following criteria are met:

- Newly Diagnosed acute myeloid leukemia (AML)
- Patient is > 18 years of Age.
- combination with standard cytarabine and anthracycline induction **OR** cytarabine consolidation
- Confirmed FLT3 internal tandem duplication (ITD)-positive Mutation.

We may cover Verzenio ™ (abemaciclib) when **ALL** of the following criteria are met:

- Used with endocrine therapy (tamoxifen or an aromatase inhibitor) for the adjuvant treatment of adult patients with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative, node-positive, early breast cancer at high risk of recurrence, **OR**
- Used as initial endocrine-based therapy for postmenopausal women with hormone receptor-positive (HR+), HER-2 negative, advanced metastatic breast cancer, when used in combination with an aromatase inhibitor, **OR**
- Used in combination with fulvestrant for the treatment of women with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic breast cancer with disease progression following endocrine therapy, **OR**
- Used as monotherapy for the treatment of adult patients with HR-positive, HER2-negative advanced or metastatic breast cancer with disease progression following endocrine therapy and prior chemotherapy in the metastatic setting.

We may cover Vitrakvi ® (larotrectinib**)** for the treatment of adult and pediatric patients with solid tumors when **ALL** of the following criteria are met:

- The patient has a neurotrophic receptor tyrosine kinase (NTRK) gene fusion without a known acquired resistance mutation as determined by an FDA approved test, **AND**
- The patient is metastatic or where surgical resection is likely to result in severe morbidity, **AND**
- The patient has no satisfactory alternative treatments or that have progressed following treatment.

We may cover Vizimpro ® (dacomitinib**)** for the first-line treatment of patients with metastatic non-small cell lung cancer (NSCLC) with epidermal growth factor receptor (EGFR) exon 19 deletion or exon 21 L858R substitution mutations as detected by an FDA-approved test when **ALL** of the following criteria are met:

- The patient has a documented diagnosis of NSCLC, **AND**
- The patient has either Exon 19 Deletion or Exon 21 L858R Substitution confirmed by an FDA test

We may cover Vonjo ™ (pacritinib**)** for intermediate or high-risk primary or secondary (post-polycythemia vera or post-essential thrombocythemia) myelofibrosis (MF) with a platelet count below 50 × 10^9/L when **ALL** of the following criteria are met:

- The patient has a documented diagnosis of myelofibrosis (MF), **AND**
- The patient has a platelet count below 50 × 10^9/L

We may cover Xalkori ® (crizotinib**)** or when **ALL** of the following criteria are met[2]:

- Age 18 years of age for older for the treatment of locally advanced or metastatic nonsmall cell lung cancer (NSCLC) **AND** Documentation of ROS1-positive metastatic NSCLC as detected by an FDA approved test,

OR

- Age 1 years of age for older for the treatment of relapsed or refractory, systemic anaplastic large cell lymphoma (ALCL) that is anaplastic lymphoma kinase positive (ALK+) **AND** Documentation of ALK-positive as detected by an FDA approved test,

OR

- Age 1 years of age for older for the treatment of unresectable, recurrent, or refractory inflammatory myofibroblastic tumor (IMT) that is ALK-positive (ALK+) **AND** Documentation of ALK-positive as detected by an FDA approved test.

We may cover Xospata ® (gilteritinib**)** for the treatment of patients when **ALL** of the following criteria are met[1]:

- Diagnosis of relapsed or refractory acute myeloid leukemia (AML), **AND**
- Documentation of FMS-like tyrosine kinase 3 (FLT3) mutation detected by an FDA-approved test, **AND**
- Age 18 years of age or older

We may cover Zelboraf ™ (vemurafenib**)** for the treatment of patients when **ALL** of the following criteria are met[1]:

- Diagnosis of unresectable melanoma, metastatic melanoma **OR** Erdheim-Chester Disease (ECD), **AND**
- Documentation of BRAF V600E mutation detected by an FDA-approved test, **AND**
- Safety and efficacy in pediatric patients below the age of 18 have not been established.

We may cover Zykadia ™ (ceritinib**)** ZYKADIA is indicated for the treatment of patients with metastatic non-small cell lung cancer (NSCLC) whose tumors are anaplastic lymphoma kinase (ALK)-positive as detected by an FDA-approved test when **ALL** of the following criteria are met:

- Age 18 years of age or older, **AND**
- The tumors are anaplastic lymphoma kinase (ALK)-positive.

We may cover ZYDELIG ® (idelalisib**) as indicated in its FDA approved label:**

- Relapsed Chronic Lymphocytic Leukemia -- Zydelig is indicated, in combination with rituximab, for the treatment of patients with relapsed chronic lymphocytic leukemia (CLL) for whom rituximab alone would be considered appropriate therapy due to other co-morbidities, **OR**
- Relapsed Small Lymphocytic Lymphoma -- Zydelig is indicated for the treatment of patients with relapsed small lymphocytic lymphoma (SLL) who have received at least two prior systemic therapies.

We do not cover the above drugs for other conditions not listed above.

Other Information

Blue Cross Blue Shield of Massachusetts (BCBSMA*) members (other than Medex®; Blue MedicareRx, Medicare Advantage plans that include prescription drug coverage) will be required to fill their prescriptions for the above medications at one of the providers in our retail specialty pharmacy network, see link below:

Link to Specialty Pharmacy List

Individual Consideration

Our medical policies are written for most people with a given condition. Each policy is based on peer reviewed clinical evidence. We also take into consideration the needs of atypical patient populations and diagnoses.

If the coverage criteria outlined is unlikely to be clinically effective for the prescribed purpose, the health care provider may request an exception to cover the requested medication based on an individual's unique clinical circumstances. This is also referred to as "individual consideration" or an "exception request."

Some reasons why you may need us to make an exception include: therapeutic contraindications; history of adverse effects; expected to be ineffective or likely to cause harm (physical, mental, or adverse reaction).

To facilitate a thorough and prompt review of an exception request, we encourage the provider to include additional supporting clinical documentation with their request. This may include:

- Clinical notes or supporting clinical statements.
- The name and strength of formulary alternatives tried and failed (if alternatives were tried) and specifics regarding the treatment failure, if applicable.
- Clinical literature from reputable peer reviewed journals.
- References from nationally recognized and approved drug compendia such as American Hospital Formulary Service® Drug Information (AHFS-DI), Lexi-Drug, Clinical Pharmacology, Micromedex or Drugdex®; and
- References from consensus documents and/or nationally sanctioned guidelines.

Providers may call, fax or mail relevant clinical information, including clinical references for individual patient consideration, to:

Blue Cross Blue Shield of Massachusetts
Pharmacy Operations Department
25 Technology Place
Hingham, MA 02043
Phone: 1-800-366-7778
Fax: 1-800-583-6289

We may also use prescription claims records to establish prior use of formulary alternatives or to show if step therapy criteria has been met. We will require the provider to share additional information when prescription claims data is either not available or the medication fill history fails to establish use of preferred formulary medications or that step therapy criteria has been met.

Policy History

Date	Action
4/2024	Updated to add new indication for Jaypirca ™(pirtobrutinib).
2/2024	Updated to add Fruzaqla ™ (fruquintinib), Ojjaara ® (momelotinib), and Truqap ™ (capivasertib) to the policy.
10/2023	Updated to add Vanflyta ® (quizartinib) to the policy.
9/2023	Updated to add new indications for Ayvakit ™, Tibsovo ®, and removed PA from Talzenna ™ and Lynparza and updated IC to align with 118E MGL § 51A.
7/2023	Updated to include Jaypirca ™ and Orserdu ® to the policy.

4/2023	Updated to add Krazati ™ and Rezlidhia ™ to the policy and to remove KI 67 score from Verzenio ® criteria.
2/2023	Updated to add Lytgobi ™ to the policy.
11/2022	Updated to include new indication for Mekinist ®, Pemazyre ™, Retevmo ™, and Xalkori ®. Also, updated FDA test for MMR for Lenvima ®.
8/2022	Update to include Tafinlar ® and Mekinist ® new combination indication and to add new indication for Tibsovo ®.
7/2022	Updated to remove an indication from Zydelig ® add new indication for Lynparza ® and to add Vonjo ™.
4/2022	Updated to remove FL indication for Copiktra ™.
2/2022	Updated to add Scemblix to the policy and remove PA for Koselugo.
1/2022	Updated to add Alunbrig ™ and Exkivity ™ to the policy and a new indication for Verzenio. Clarified the incorrect note for Tarceva from 1/1/2021.
10/2021	Updated to include new Indication for Ayvakit ™.
8/2021	Updated to include Lumakras ™ and Truseltiq ™ to the policy.
7/2021	Updated to include new indication for Lorbrena and to move Opdivo to medical policy 099.
4/2021	Updated to add new indication for Xalkori, a new indication for Opdivo, and to add Tepmetko to the policy.
1/1/2021	Updated Tarceva®, to add Gavreto™, add a new indication for Opdivo® and to remove one Opdivo® Indication because it failed its confirmatory trial.
10/2020	Updated to add new Opdivo® indication.
9/2020	Updated to include new Braftovi® Indication, Lynparza® indication and Opdivo® indication. Added Pemazyre™, Retevmo™, and Tabrecta™ to the policy.
6/2020	Updated to include new HCC indication with Yervoy® for Opdivo® and to add Koselugo™ to the policy.
4/2020	Updated to include the new indication for Lynparza® and to add Ayvakit™ to the policy.
2/2020	Updated to add erlotinib and place the generic in front of the brand.
1/2020	Updated to include Rozlytrek™ to the policy and to add indications to Lenvima™ & Mekinist™ & Step to Inrebic.
8/2019	Updated to add new Tibsovo® indication and to add Piqray & Balversa to the policy.
7/2019	Updated to add Iressa®, Gilotrif®, Tarceva®, & Tagrisso® to the policy.
2/2019	Updated to include Copiktra™, Lorbrena®., Talzenna™, Vitrakvi®, Vizimpro®, Xospata® and a new indication for Lynparza™.
11/2018	Updated to include Braftovi™, Mektovi®, & Tibsovo® to the policy.
9/2018	Clarified Ibrance™ indications and added new indications for Kisqali®, Lenvima, Mekinist, Opdivo, and Tafinlar. Also, remove Prior Auth requirements for Venclexta.
5/2018	Updated to include new indication for Verzenio™.
2/2018	Updated to include Verzenio™ and new indications for Lynparza™.
1/2018	Updated for new indications of Alecensa® and Zelboraf™.
11/2017	Updated to clarify Venclexta™ criteria and include Idhifa® plus change Walgreen's Specialty name.
10/2017	Updated for new indications, added Rydapt®, to remove Step requirement for Xtandi®,
9/2017	Moved Erbitux® & Vectibix® to Medical policy 033.

7/2017	Updated address for Pharmacy Operations and added Kisqali® & Kisqali® Femara.
5/2017	Updated to add new Opdivo® indication (mUC).
11/2016	Moved 114 (Erbitux® & Vectibix®) into this policy and new indication for Opdivo®.
10/2016	Updated to include Venclexta™ & update Opdivo® Indications.
6/2016	Updated to include Alecensa® & update Opdivo® Indications.
4/2016	Updated to include Cotellic™ and additional indication for Ibrance™, Opdivo® & Xalkori®.
7/2015	Updated to include All Cancer Policies and added Farydak® and Lenvima™.
2/2014	Updated Onco360 name and removed Curascript in Specialty Pharmacy section.
1/2014	Updated. To include Mekinist™ and Tafinlar®.
1/2013	New Policy, effective 1/1/2013.

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7. Xalkori® [package insert]. New York, NY: Pfizer Labs.: 2012.
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15. Lynparza ™ [package insert]. Wilmington, DE: AstraZeneca Pharmaceuticals LP, Inc.: 12/2014.
16. Opdivo ® [package insert]. Princeton, NJ: Bristol-Myers Squibb Company, Inc.: 3/2015.
17. Farydak ® [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation.: 2/2015.
18. Cotellic ™ [package insert]. South San Francisco, CA: Genentech, Inc.: 11/2015.
19. Alecensa ® [package insert]. South San Francisco, CA: Genentech, Inc.: 12/2015.
20. Venclexta ™ [package insert]. North Chicago, IL: AbbVie Inc.: 4/2016.
21. Idhifa ® [package insert]. Summit, NJ: Celgene Corporation.: 8/2017.
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24. Tibsovo ® [package insert]. Cambridge, MA: Agios Pharmaceuticals, Inc.: 7/2018.
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28. Vitrakvi ® [package insert]. Stamford, CT: Loxo Oncology, Inc..: 12/2018
29. Vizimpro ® [package insert]. New York, NY: Pfizer Labs.: 10/2018
30. Xospata ® [package insert]. Northbrook, IL: Astellas Pharma US, Inc.: 11/2018
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32. Iressa ® [package insert]. Wilmington, DE: AstraZeneca Pharmaceuticals LP, Inc.: 8/2018.
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43. Tepmetko® [package insert]. Rockland, MA: EMD Serono, Inc.: 2/2021.
44. Lumakras ™ [package insert] Thousand Oaks, CA: Amgen Inc.: 6/2021.
45. Truseltiq ™ [package insert] Brisbane, CA: QED Therapeutics, Inc.: 6/2021.
46. Alunbrig ™ [package insert]. Lexington, MA: Takeda Pharmaceuticals America, Inc.: 9/2021.
47. Exkivity ™ [package insert]. Lexington, MA: Takeda Pharmaceuticals America, Inc.: 9/2021.
48. Lytgobi ™ [package insert]. Princeton, NJ: Taiho Oncology, Inc.: 9/2022.
49. Jaypirca ™ [package insert]. Indianapolis, IN: Lilly USA, LLC,: 1/2023.
50. Orserdu ® [package insert]. New York, NY: Stemline Therapeutics, Inc.: 2/2023.
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Endnotes

1. Based on BCBSA Technology Evaluation Center Specialty Pharmacy Combined Capacity (SPCC) Report #11-2011 Vemurafenib (Zelboraf™), reviewed September 2011.
2. Based on BCBSA Technology Evaluation Center Specialty Pharmacy Combined Capacity (SPCC) Report #13-2011 Crizotinib (Xalkori®), reviewed October 2011.

To request prior authorization using the Massachusetts Standard Form for Medication Prior Authorization Requests (eForm), click the link below:

http://www.bluecrossma.com/common/en_US/medical_policies/023%20E%20Form%20medication%20prior%20auth%20instruction%20prn.pdf