Select Oral Oncology Drugs

Policy # 00642
Original Effective Date: 01/01/2019
Current Effective Date: 07/12/2021

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc.(collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

When Services May Be Eligible for Coverage

Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- *Benefits are available in the member's contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

Based on review of available data, the Company may consider cabozantinib (Cabometyx™)‡, brand and generic imatinib (Gleevec®)‡, lenalidomide (Revlimid®)‡, dasatinib (Sprycel®)‡, and sunitinib (Sutent®)‡ for the treatment of cancer to be **eligible for coverage.****

Patient Selection Criteria

Coverage eligibility for cabozantinib (Cabometyx), brand and generic imatinib (Gleevec), lenalidomide (Revlimid), dasatinib (Sprycel), and sunitinib (Sutent) will be considered when the following criteria are met for the requested drug:

- For Cabometyx requests
  - Patient has a diagnosis of renal cell carcinoma (RCC) that is relapsed or stage IV; OR
  - Patient has a diagnosis of non-small cell lung cancer (NSCLC) with rearranged during transfection (RET) gene rearrangements; OR
  - Patient has a diagnosis of hepatocellular carcinoma that has been previously treated with at least one tyrosine kinase inhibitor therapy (e.g., sorafenib [Nexavar®]‡, lenvatinib [Lenvima™‡]); OR
  - Patient has a diagnosis of Ewing sarcoma or osteosarcoma; AND
    - Patient has tried at least one previous systemic regimen; OR
  - Patient has a diagnosis of Gastrointestinal Stromal Tumor (GIST); AND all of the following:
    - Patient has previously tried one of imatinib (Gleevec tablets, generic) or avapritinib (Ayvakit®)‡; AND

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        - Patient has previously tried all of the following: sunitinib (Sutent), (regorafenib) (Stivarga®)‡, and ripretinib (Gavreto™)‡.

- For Gleevec and generic imatinib requests
    - Patient has a diagnosis of Philadelphia chromosome positive (Ph+) acute lymphoblastic leukemia (ALL); OR
    - Patient has a diagnosis of Philadelphia chromosome positive (Ph+) chronic myeloid leukemia (CML); OR
    - Patient has a diagnosis of dermatofibrosarcoma protuberans (DFSP); OR
    - Patient has a diagnosis of gastrointestinal stromal tumor (GIST); OR
    - Patient has a diagnosis of hypereosinophilic syndrome (HES) and/or chronic eosinophilic leukemia (CEL); OR
    - Patient has a diagnosis of aggressive systemic mastocytosis (ASM); OR
    - Patient has a diagnosis of myelodysplastic/myeloproliferative disease (MDS/MPD) [e.g. polycythemia vera, myelofibrosis]; AND
        - The condition is associated with platelet-derived growth factor receptor (PDGFR) gene rearrangements; OR
    - Patient has a diagnosis of chordoma; OR
    - Patient has a diagnosis of unresectable, or advanced fibromatosis (Desmoid tumors); OR
    - Patient has a diagnosis of chronic graft versus host disease (GVHD); AND
        - Patient has tried at least one conventional systemic treatment for GVHD (e.g. corticosteroids, cyclosporine, tacrolimus, mycophenolate); OR
    - Patient has a diagnosis of metastatic myeloma; AND
        - Patient has c-Kit-positive advanced/recurrent or metastatic melanoma; OR
    - Patient has a diagnosis of pigmented villonodular synovitis/tenosynovial giant cell tumor (PVNS/TGCT); AND
        - Patient has tried and failed (e.g. intolerance or inadequate response) pexidartinib (Turalio®)‡ unless there is clinical evidence or patient history that suggests the use of Turalio will be ineffective or cause an adverse reaction to the patient; OR
    - Patient has a diagnosis of Acquired Immune Deficiency Syndrome (AIDS)-Related Kaposi's sarcoma; AND

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        - Patient has tried and failed (i.e. intolerance or inadequate response) at least one other regimen for this condition (e.g. liposomal doxorubicin, paclitaxel, pomalidomide [Pomalyst®]‡, or thalidomide [Thalomid®]‡); AND
        - Patient has relapsed or refractory disease; OR
    - Patient has a diagnosis of myeloid/lymphoid neoplasms with eosinophilia; AND
        - Patient is ≥18 years of age; AND
        - Patient meets ONE of the following:
            - The tumor has an *ABL1* rearrangement; OR
            - The tumor has an *FIP1L1-PDGFRA* or *PDGFRB* rearrangement; AND
    - If the request is for brand Gleevec: the patient has tried and failed (e.g. intolerance or inadequate response) GENERIC imatinib unless there is clinical evidence or patient history that suggests the use of GENERIC imatinib will be ineffective or cause an adverse reaction to the patient (e.g. difference in dyes, fillers, or preservatives). *(Note: this specific patient selection criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met).*
- For Revlimid requests
    - Patient has a diagnosis of mantle cell lymphoma (MCL); OR
    - Patient has a diagnosis of multiple myeloma (MM); OR
    - Patient has a diagnosis of marginal zone lymphoma; OR
    - Patient has a diagnosis of myelodysplastic syndrome (MDS); AND meets ONE of the following
        - Patient has symptomatic anemia; OR
        - Patient has transfusion-dependent anemia; OR
        - Patient has anemia that is not controlled with an erythroid stimulating agent (e.g. epoetin [Epogen®/Procrit®]‡ or darbepoetin [Aranesp®])‡; OR
    - Patient has a diagnosis of refractory or progressive Castleman's Disease; OR
    - Patient has a diagnosis of diffuse large B cell lymphoma; AND
        - Patient has tried at least one other medication treatment regimen (e.g., RCHOP, dose-adjusted EPOCH [etoposide, prednisone, vincristine, cyclophosphamide, doxorubicin] + rituximab, RCEPP [rituximab, cyclophosphamide, etoposide, prednisone, procarbazine], DHAP [dexamethasone, cisplatin, cytarabine] ± rituximab, and Treanda ± rituximab); OR

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- Patient has a diagnosis of follicular lymphoma; AND
  - Patient is using Revlimid in combination with rituximab; OR
  - Patient has tried at least one prior therapy (e.g. Treanda®‡ [bendamustine injection] plus rituximab; Treanda plus Gazyvia®‡ [obinutuzumab]; CHOP plus Gazyva or rituximab; chlorambucil with or without rituximab; cyclophosphamide with or without rituximab; Gazyvia; Copiktra™‡ [duvelisib]; Aliqopa®‡ [copanlisib]; or Zydelig®‡ [idelalisib]); OR
- Patient has a diagnosis of relapsed or refractory classical Hodgkin lymphoma (i.e. nodular sclerosis, mixed cellularity, lymphocyte depleted, and lymphocyte-rich subtypes of Hodgkin lymphoma); AND
- Patient has a diagnosis of myelofibrosis; AND
  - Patient has anemia according to the prescriber; AND
  - Serum erythropoietin levels are $\geq$500 mU/mL; OR
- Patient has a diagnosis of systemic light chain amyloidosis; OR
- Patient has a diagnosis of T-Cell Leukemia/Lymphoma; AND
  - Patient has tried at least one other chemotherapy regimen (e.g. Adcetris plus CHP [cyclophosphamide, doxorubicin, and prednisone], CHOP [cyclophosphamide, doxorubicin, vincristine, and prednisone], CHOEP [cyclophosphamide, doxorubicin, vincristine, etoposide, and prednisone], dose-adjusted EPOCH [etoposide, prednisone, vincristine, cyclophosphamide, and doxorubicin], HyperCVAD [cyclophosphamide, vincristine, doxorubicin, and dexamethasone] alternating with high-dose methotrexate and cytarabine, and belinostat [Beleodaq®])‡; OR
- Patient has a diagnosis of Acquired Immune Deficiency (AIDS)-related Kaposi's Sarcoma; AND
  - Patient has tried at least one regimen or therapy (e.g., liposomal doxorubicin, paclitaxel, pomalidomide [Pomalyst], or thalidomide [Thalomid]); AND
  - Patient has relapsed or refractory disease; OR
- Patient has a diagnosis of Central Nervous system lymphoma (primary) that is relapsed or refractory; OR
- Patient has a diagnosis of Langerhans Cell Histiocytosis; OR
- Patient has a diagnosis of peripheral T-cell lymphoma (e.g., peripheral T-cell lymphoma not otherwise specified [PTCL-NOS], angioimmunoblastic T-cell lymphoma [AITL], enteropathy-associated T-cell lymphoma [EATL], monomorphic

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epitheliotropic intestinal T-cell lymphoma [MEITL], nodal peripheral T-cell lymphoma [nodal PTCL] with T-follicular helper [TFH] phenotype, follicular T-cell lymphoma [FTCL], and hepatosplenic gamma-delta T-cell lymphomas); AND
    - Patient is $\geq$18 years of age; AND
    - Patient has tried at least one other regimen (e.g., Beleodaq [belinostat], Adcetris [brentuximab vedotin], DHAP [dexamethasone, cisplatin, cytarabine], ESHAP [etoposide, methylprednisolone, cytarabine, cisplatin], GDP [gemcitabine, dexamethasone, cisplatin], GemOX [gemcitabine, oxaliplatin]; ICE [ifosfamide, carboplatin, etoposide], or Istodax [romidepsin]); OR
  - Patient has a diagnosis of POEMS (polyneuropathy, organomegaly, endocrinopathy, monoclonal protein, skin changes) syndrome; AND
    - Patient is $\geq$18 years of age; AND
    - Use of Revlimid is in combination with dexamethasone.
- For Sprycel requests
  - Patient has a diagnosis of Philadelphia chromosome positive (Ph+) acute lymphoblastic leukemia (ALL); OR
  - Patient has a diagnosis of Philadelphia chromosome positive (Ph+) chronic myeloid leukemia (CML); OR
  - Patient has a diagnosis of chondrosarcoma or chordoma; OR
  - Patient has a diagnosis of gastrointestinal stromal tumor (GIST) and both of the following:
    - Patient has tried imatinib (Gleevec); AND
    - Patient has tried sunitinib (Sutent); AND
    - Patient has tried regorafenib (Stivarga®)‡; OR
  - Patient has a diagnosis of myeloid/lymphoid neoplasms with eosinophilia; AND
    - Patient is $\geq$18 years of age; AND
    - The tumor has an *ABL1* rearrangement.
- For Sutent requests
  - Patient has a diagnosis of gastrointestinal stromal tumor (GIST) AND one of the following:
    - Sutent will be used as a single agent AND the patient has tried imatinib; OR
    - Sutent will be used in combination with everolimus (Afinitor®)‡ ; AND the patient meets all of the following criteria:

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- ❖ Patient has tried imatinib (Gleevec); AND
- ❖ Patient has tried Sutent monotherapy; AND
- ❖ Patient has tried Stivarga; OR

- o Patient has a diagnosis of renal cell carcinoma (RCC) AND one of the following:
  - ▪ The patient is at high risk of recurrent RCC following nephrectomy and Sutent is used for adjuvant therapy; OR
  - ▪ The patient has advanced RCC; OR
- o Patient has a diagnosis of advanced, unresectable neuroendocrine tumor; OR
- o Patient has a diagnosis of alveolar soft part sarcoma (ASPS); OR
- o Patient has a diagnosis of angiosarcoma; OR
- o Patient has a diagnosis of recurrent chordoma; OR
- o Patient has a diagnosis of differentiated (i.e. papillary, follicular, and Hürthle cell) thyroid carcinoma that is refractory to radioactive iodine therapy; OR
- o Patient has a diagnosis of medullary thyroid carcinoma that is refractory to vandetanib (Caprelsa®)‡, or cabozantinib (Cometriq®)‡ treatment; OR
- o Patient has a diagnosis of recurrent or progressive meningioma; OR
- o Patient has a diagnosis of solitary fibrous tumor/hemangiopericytoma; OR
- o Patient has a diagnosis of thymic carcinoma that is refractory to chemotherapy (e.g., carboplatin/paclitaxel) or radiation therapy.

When Services Are Considered Not Medically Necessary

Based on review of available data, the Company considers the use of brand Gleevec when the patient has not tried and failed (e.g. intolerance or inadequate response) generic imatinib to be **not medically necessary.****

When Services Are Considered Investigational

Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers the use of cabozantinib (Cabometyx), brand and generic imatinib (Gleevec), lenalidomide (Revlimid), dasatinib (Sprycel), and sunitinib (Sutent) when patient selection criteria are not met for the requested drug (except those designated **not medically necessary****) to be **investigational.***

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Background/Overview

Many cancers can be treated with oral therapies in addition to or instead of traditional intravenous chemotherapy infusions. These oral treatments are typically administered daily until disease progression or unacceptable toxicity and can be associated with increased life expectancy and quality of life in patients with cancer. Dosing information as well as descriptions of possible adverse drug reactions can be found in the FDA-approved package insert for the respective drug. Many of these drugs are commonly used for oncology indications beyond those approved by the FDA. The National Comprehensive Cancer Network (NCCN) provides evidence-based guidelines regarding the appropriate treatment options for each type of cancer.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

Cabometyx is FDA-approved for the treatment of patients with advanced renal cell carcinoma, for the first-line treatment of patients with advanced renal cell carcinoma in combination with nivolumab, and for the treatment of patients with hepatocellular carcinoma who have been previously treated with sorafenib (Nexavar).

Gleevec is FDA-approved for the treatment of newly diagnosed Philadelphia chromosome positive (Ph+) chronic myeloid leukemia (CML); Ph+ CML in blast crisis, accelerated phase, or chronic phase after interferon-alpha therapy; adult patients with relapsed or refractory Ph+ acute lymphoblastic leukemia (ALL); pediatric patients with newly diagnosed Ph+ ALL; adult patients with myelodysplastic/myeloproliferative diseases associated with PDGFR gene re-arrangements; adult patients with aggressive systemic mastocytosis without the D816V c-Kit mutation or with c-Kit mutational status unknown; adult patients with hypereosinophilic syndrome (HES) and/or chronic eosinophilic leukemia (CEL); adult patients with unresectable, recurrent, and/or metastatic dermatofibrosarcoma protuberans, patients with Kit positive unresectable and/or metastatic gastrointestinal stromal tumor (GIST); and adjuvant treatment of adult patients following complete gross resection of Kit positive GIST.

Revlimid is FDA approved for treatment of multiple myeloma in combination with dexamethasone; as maintenance therapy in patients with multiple myeloma following autologous hematopoietic stem cell transplantation; for treatment of patients with transfusion-dependent anemia due to low or intermediate-1-risk myelodysplastic syndromes associated with a deletion 5q cytogenetic

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abnormality with or without additional cytogenetic abnormalities; for the treatment of adult patients with mantle cell lymphoma whose disease has relapsed or progressed after two prior therapies, one of which included bortezomib; for the treatment of previously treated follicular lymphoma in combination with a rituximab product; and for the treatment of previously treated marginal zone lymphoma in combination with a rituximab product.

Sprycel is FDA approved for the treatment of adult patients with newly diagnosed Philadelphia chromosome-positive (Ph+) chronic myeloid leukemia (CML) in chronic phase; for the treatment of chronic, accelerated, or myeloid or lymphoid blast phase Ph+ CML with resistance or intolerance to prior therapy including imatinib; for treatment of Ph+ acute lymphoblastic leukemia (ALL) with resistance or intolerance to prior therapy; and for the treatment of pediatric patients with Ph+ CML in chronic phase or newly diagnosed Ph+ ALL in combination with chemotherapy.

Sutent is FDA approved for the treatment of adult patients with gastrointestinal stromal tumors (GIST) after disease progression on or intolerance to imatinib; for the treatment of adult patients with advanced renal cell carcinoma; for the adjuvant treatment of adult patients at high risk of recurrent renal cell carcinoma following nephrectomy; and for the treatment of progressive, well-differentiated pancreatic neuroendocrine tumors in adult patients with unresectable locally advanced or metastatic disease.

Rationale/Source

This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. Food and Drug Administration approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, Blue Cross and Blue Shield Association technology assessment program (TEC) and other non-affiliated technology evaluation centers, reference to federal regulations, other plan medical policies, and accredited national guidelines.

The criteria in this policy are based on FDA approved indications for each included drug as well as evidence-based recommendations from the NCCN and are designed to ensure the most appropriate therapy for each patient.

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References

1. Cabometyx [package insert]. Exelixis, Inc. South San Francisco, CA. January 2021.
2. Gleevec [package insert]. Novartis. East Hanover, NJ. October 2020.
3. Revlimid [package insert]. Celgene. Summit, NJ. April 2020.
4. Sprycel [package insert]. Bristol Myers Squibb. Princeton, NJ. March 2021.
5. Sutent [package insert]. Pfizer. New York, NY. October 2020.
6. Oncology—Cabometyx Prior Authorization Policy. Express Scripts. February 2021.
7. Oncology—Imatinib (Gleevec) Prior Authorization Policy. Express Scripts. April 2021.
8. Oncology—Revlimid Prior Authorization Policy. Express Scripts. April 2021.
9. Oncology—Sprycel Prior Authorization Policy. Express Scripts. April 2021.
10. Oncology—Sutent Prior Authorization Policy. Express Scripts. June 2020.

Policy History

Original Effective Date: 01/01/2019
Current Effective Date: 07/12/2021

10/04/2018 Medical Policy Committee review
10/17/2018 Medical Policy Implementation Committee approval. New policy.
01/10/2019 Medical Policy Committee review
01/23/2019 Medical Policy Implementation Committee approval. Removed Xtandi from the policy.
03/07/2019 Medical Policy Committee review
03/20/2019 Medical Policy Implementation Committee approval. Added new indication for Cabometyx to criteria.
05/02/2019 Medical Policy Committee review
05/15/2019 Medical Policy Implementation Committee approval. Updated criteria for Gleevec, Ibrance, Revlimid, and Sprycel to reflect changes in guidelines.
08/01/2019 Medical Policy Committee review
08/14/2019 Medical Policy Implementation Committee approval. Updated criteria for Revlimid to reflect guideline changes for indication.
08/01/2019 Medical Policy Committee review
08/14/2019 Medical Policy Implementation Committee approval. Updated criteria for Revlimid to reflect guideline changes for indication.
05/07/2020 Medical Policy Committee review

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05/13/2020	Medical Policy Implementation Committee approval. Updated criteria for Revlimid to include coverage for AIDS-related Kaposi's Sarcoma and relapsed/refractory CNS lymphoma and updated criteria for myelofibrosis. Criteria for imatinib were updated to require a trial of the new standard of care, Turalio, prior to imatinib approval for the rare condition, tenosynovial giant cell tumor per NCCN.
06/03/2021	Medical Policy Committee review
06/09/2021	Medical Policy Implementation Committee approval. Updated criteria for Cabometyx to reflect FDA approval for first line treatment of patients with advanced renal cell carcinoma in combination with nivolumab. Additionally, added coverage for patients with Ewing sarcoma, osteosarcoma and GIST based on guideline updates. Added coverage for Gleevec and its generic for adults with myeloid/lymphoid neoplasms with eosinophilia. Removed Ibrance from policy. Added coverage for Revlimid for patients with Langerhans Cell Histiocytosis, peripheral T-cell lymphoma, and POEMS syndrome. Added coverage for Sprycel for adults with myeloid/lymphoid neoplasms with eosinophilia.

Next Scheduled Review Date: 06/2022

*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
    1. Consultation with the Blue Cross and Blue Shield Association technology assessment program (TEC) or other nonaffiliated technology evaluation center(s);
    2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or

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3. Reference to federal regulations.

**Medically Necessary (or "Medical Necessity") - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

A. In accordance with nationally accepted standards of medical practice;
B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and
C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, "nationally accepted standards of medical practice" means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

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NOTICE: If the Patient's health insurance contract contains language that differs from the BCBSLA Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.

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