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Subject: Imatinib (Imkeldi) Oral Solution

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Position Statement	Dosage/ Administration	Billing/Coding	Reimbursement	Program Exceptions	Definitions
Related Guidelines	Other	References	Updates		

DESCRIPTION:

Imatinib (Imkeldi) oral solution was approved by the US Food and Drug Administration (FDA) in November 2024. It is the first commercially available liquid formulation of imatinib. It shares the same FDA-approved indications as imatinib tablets (Gleevec and generics). Imkeldi, as an 80 mg/mL oral solution and using a graduated oral syringe, may allow for more precise dosing in pediatric patients who require a dosage based on body surface area (BSA). Of note, the package labeling for imatinib tablets includes directions in which the product may be dispersed in a glass of water or apple juice for patients unable to swallow a whole tablet. Imatinib tablet (as brand Gleevec) was the first tyrosine kinase inhibitor (TKI) to receive approval by the US FDA for the treatment of persons with chronic myeloid leukemia (CML) in chronic phase in 2001. Following initial approval, imatinib was approved in 2002 for the treatment of metastatic and/or unresectable malignant gastrointestinal stromal tumors (GIST) and in 2006 for treatment of five rare diseases: dermatofibrosarcoma protuberans (DFSB), Philadelphia chromosome-positive (Ph+) acute lymphocytic leukemia (ALL), certain types of myelodysplastic/myeloproliferative disorders (MDS/MPD), hypereosinophilic syndrome/chronic eosinophilic leukemia (HES/CEL), and aggressive systemic mastocytosis (ASM). The FDA granted orphan designation to imatinib for the treatment of CML and GIST in 2001; and for the treatment of Ph+ ALL, DFSB, systemic mastocytosis without the D816V c-kit mutation, idiopathic hypereosinophilic syndrome including acute and chronic eosinophilic leukemia, and MDS/MPD associated with platelet-derived growth factor gene re-arrangements in 2005. Clinical practice guidelines from the National Comprehensive Cancer Network (NCCN) provide recommendations for the use of imatinib in a variety of settings, including FDA-approved indications. Additional off-label uses supported by NCCN include treatment of [chordoma](#), a form of bone cancer, melanoma, certain soft tissue sarcomas, and lymphoblastic lymphoma, which is a type of non-Hodgkin's lymphoma (NHL).

POSITION STATEMENT:

Comparative Effectiveness

The FDA has deemed the drug(s) or biological product(s) in this coverage policy to be appropriate for self-administration or administration by a caregiver (i.e., not a healthcare professional). Therefore, coverage (i.e., administration) in a provider-administered setting such as an outpatient hospital, ambulatory surgical suite, physician office, or emergency facility is not considered medically necessary.

Initiation of imatinib (Imkeldi) oral solution **meets the definition of medical necessity** when **ALL** of the following criteria are met:

A. **ONE** of the following to support clinical use is met (“1”, “2”, or “3”):

1. **BOTH** of the following are met regarding FDA labeling or NCCN Compendium (“a” and “b”):

a. **EITHER** of the following (indication and usage) [“i” or ii”]:

- i. Member is diagnosed with a condition that is consistent with an indication listed in the imatinib oral solution FDA-approved prescribing information (or package insert) **AND** member meets any additional requirements listed in the “Indications and Usage” section of the FDA-approved prescribing information (or package insert)
- ii. Indication **AND** usage is recognized in NCCN Drugs and Biologics Compendium as a Category 1 or 2A recommendation (see Table 2)

b. **EITHER** of the following (diagnostic testing) [“i” or ii”]:

- i. The requested indication for imatinib oral solution requires genetic/specific diagnostic testing per the FDA labeling* or NCCN Compendium, **AND BOTH** of the following are met:
 - The genetic/specific diagnostic testing has been completed
 - The results of the testing indicate imatinib oral solution therapy is appropriate – documentation must be submitted
- ii. The requested indication for imatinib oral solution does **NOT** require specific genetic/diagnostic testing per FDA labeling or NCCN Compendium

**FDA Companion Diagnostics: <https://www.fda.gov/medical-devices/vitro-diagnostics/list-cleared-or-approved-companion-diagnostic-devices-vitro-and-imaging-tools>*

2. Imatinib oral solution is designated as an orphan drug by the FDA for the requested indication, **AND** the indication is not included in the FDA labeling or the NCCN compendium as a 1 or 2A recommendation (i.e., “Designated”) [orphan drug designations can be found at <http://www.accessdata.fda.gov/scripts/opdlisting/oopd/>]
3. The indication and usage is supported by the results of **TWO** or more published clinical studies – the prescriber must submit full text copies of each article

NOTE:

- Case reports, posters, and abstracts (including published meeting abstracts) are **NOT** accepted as evidence to support use

- Clinical studies must be supportive of use for a similar patient population (e.g., indication, diagnosis, disease severity, genetic or tumor mutations) and for the intended treatment plan, including any concomitant therapy

B. **EITHER** of the following (“1” or “2”)**:

1. **BOTH** of the following (“a” and “b”):

- a. The member is a pediatric patient (less than 18 years of age) whose dosage is based on body surface area (BSA) [i.e., dosage of 340 mg/m² daily]
- b. The resulting daily dosage cannot be adequately achieved using 100 and 400 mg tablets [for example - a child with a BSA of 0.8 m² and a calculated daily dose of 272 mg]

2. **BOTH** of the following (“a” and “b”):

- a. The member is unable to swallow a whole imatinib tablet due to functional impairment or their age – documentation of the member’s inability to swallow must be submitted
- b. Dispersing imatinib tablets in water or beverage (50 mL of fluid per 100 mg) and administering as a suspension is **NOT** an appropriate option for the member – rationale for not being able to use a suspension prepared from imatinib tablets must be submitted

***Step therapy requirement does **NOT** apply if a prior health plan paid for the medication - documentation of a paid claim within the past 90 days must be submitted*

C. The dosage of imatinib mesylate oral solution does not exceed the maximum FDA-approved dose and frequency with the following exceptions (“1” or “2”):

1. Dose and frequency for the indication are supported by standard reference compendia (see NCCN Compendium or other compendia in Table 3)
2. Dose and frequency for the indication are supported by the results of **TWO** or more published clinical studies – the prescriber must submit full text copies of each article

NOTE: Dose ranging studies, case reports, posters, and abstracts (including published meeting abstracts) are not accepted as evidence to support use

D. The month’s supply of imatinib oral solution will be achieved using the fewest number of 140 mL bottles (11,200 mg total per bottle) required for the prescribed dosage

Approval duration: 6 months

Continuation of imatinib (Imkeldi) oral solution **meets the definition of medical necessity** when **ALL** of the following criteria are met:

A. Imatinib oral solution has been previously approved by Florida Blue or another health plan in the past 2 years, **OR** the member has previously met **ALL** indication-specific criteria

B. **EITHER** of the following (“1” or “2”)**:

1. **BOTH** of the following (“a” and “b”):

- a. The member is a pediatric patient (less than 18 years of age) whose dosage is based on body surface area (BSA) [i.e., dosage of 340 mg/m² daily]

- b. The resulting daily dosage cannot be adequately achieved using 100 and 400 mg tablets [for example - a child with a BSA of 0.8 m² and a calculated daily dose of 272 mg]

2. **BOTH** of the following (“a” and “b”):

- a. The member is unable to swallow a whole imatinib tablet due to functional impairment or their age – documentation of the member’s inability to swallow must be submitted
- b. Dispersing imatinib tablets in water or beverage (50 mL of fluid per 100 mg) and administering as a suspension is **NOT** an appropriate option for the member – rationale for not being able to use a suspension prepared from imatinib tablets must be submitted

***Step therapy requirement does **NOT** apply if a prior health plan paid for the medication - documentation of a paid claim within the past 90 days must be submitted*

- C. The dosage of imatinib oral solution does not exceed the maximum FDA-approved dose and frequency with the following exceptions:
- i. Dose and frequency for the indication are supported by standard reference compendia (see NCCN Compendium or Table 3)
- ii. Dose and frequency for the indication are supported by the results of **TWO** or more published clinical studies – the prescriber must submit full text copies of each article
- NOTE:** Dose ranging studies, case reports, posters, and abstracts (including published meeting abstracts) are not accepted as evidence to support use
- D. The month’s supply of imatinib oral solution will be achieved using the fewest number of 140 mL bottles (11,200 mg total per bottle) required for the prescribed dosage

Approval duration: 1 year

DOSAGE/ADMINISTRATION:

THIS INFORMATION IS PROVIDED FOR INFORMATIONAL PURPOSES ONLY AND SHOULD NOT BE USED AS A SOURCE FOR MAKING PRESCRIBING OR OTHER MEDICAL DETERMINATIONS. PROVIDERS SHOULD REFER TO THE MANUFACTURER’S FULL PRESCRIBING INFORMATION FOR DOSAGE GUIDELINES AND OTHER INFORMATION RELATED TO THIS MEDICATION BEFORE MAKING ANY CLINICAL DECISIONS REGARDING ITS USAGE.

FDA-approved:

Imatinib oral solution is indicated for the treatment of:

- Newly diagnosed adult and pediatric patients with Philadelphia chromosome positive chronic myeloid leukemia (Ph+ CML) in chronic phase.
- Patients with Philadelphia chromosome positive chronic myeloid leukemia (Ph+ CML) in blast crisis (BC), accelerated phase (AP), or in chronic phase (CP) after failure of interferon-alpha therapy.
- Adult patients with relapsed or refractory Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ ALL).
- Pediatric patients with newly diagnosed Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ ALL) in combination with chemotherapy.

- Adult patients with myelodysplastic/myeloproliferative diseases (MDS/MPD) associated with platelet-derived growth factor receptor (PDGFR) gene re-arrangements.
- Adult patients with aggressive systemic mastocytosis (ASM) 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) who have the FIP1L1-PDGFR α fusion kinase (mutational analysis or fluorescence in situ hybridization [FISH] demonstration of CHIC2 allele deletion) and for patients with HES and/or CEL who are FIP1L1-PDGFR α fusion kinase negative or unknown.
- Adult patients with unresectable, recurrent and/or metastatic dermatofibrosarcoma protuberans (DFSP).
- Patients with Kit (CD117) positive unresectable and/or metastatic malignant gastrointestinal stromal tumors (GIST).
- Adjuvant treatment of adult patients following resection of Kit (CD117) positive GIST.

Dosage:

- Adults with Ph+ CML CP: 400 mg/day
- Adults with Ph+ CML AP or BC: 600 mg/day
- Pediatrics with Ph+ CML CP: 340 mg/m²/day
- Adults with Ph+ ALL: 600 mg/day
- Pediatrics with Ph+ ALL: 340 mg/m²/day
- Adults with MDS/MPD: 400 mg/day
- Adults with ASM: 100 mg/day or 400 mg/day
- Adults with HES/CEL: 100 mg/day or 400 mg/day
- Adults with DFSP: 800 mg/day
- Adults with metastatic and/or unresectable GIST: 400 mg/day
- Adjuvant treatment of adults with GIST: 400 mg/day
- Patients with mild to moderate hepatic impairment: 400 mg/day
- Patients with severe hepatic impairment: 300 mg/day

All doses of Imkeldi should be taken with a meal and a large glass of water. Doses of 400 mg or 600 mg should be administered once daily, whereas a dose of 800 mg should be administered as 400 mg twice a day. Imkeldi is intended for oral use only. It is important that Imkeldi be measured with an accurate measuring device. A household teaspoon is not an accurate measuring device. A pharmacist can provide an appropriate press-in bottle adapter and oral dispensing syringe and can provide instructions for measuring the correct dose

Drug Availability:

- Imkeldi oral solution 80 mg/mL is supplied as 140 mL of clear yellow to brownish yellow colored solution with a strawberry flavor in an amber PET bottle with a child resistant tamper-evident closure.
- Store at 20°C to 25°C (68°F to 77°F); excursions permitted between 15°C and 30°C (59°F and 86°F) [see USP Controlled Room Temperature]. Store and dispense in original container only. Any open bottle should be discarded after 30 days.

PRECAUTIONS:

CONTRAINDICATIONS

- None

BOXED WARNING:

- None

WARNINGS

- **Fluid Retention and Edema:** Edema and severe fluid retention have occurred. Weigh patients regularly and manage unexpected rapid weight gain by drug interruption and diuretics.
- **Hematologic Toxicity:** Cytopenias, particularly anemia, neutropenia, and thrombocytopenia, have occurred. Manage with dose reduction, dose interruption, or discontinuation of treatment. Perform complete blood counts weekly for the first month, biweekly for the second month, and periodically thereafter.
- **Congestive Heart Failure and Left Ventricular Dysfunction:** Severe congestive heart failure and left ventricular dysfunction have been reported, particularly in patients with comorbidities and risk factors. Monitor and treat patients with cardiac disease or risk factors for cardiac failure.
- **Hepatotoxicity:** Severe hepatotoxicity, including fatalities may occur. Assess liver function before initiation of treatment and monthly thereafter or as clinically indicated. Monitor liver function when combined with chemotherapy known to be associated with liver dysfunction.
- **Hemorrhage:** Grade 3/4 hemorrhage has been reported in clinical studies in patients with newly diagnosed CML and with GIST. GI tumor sites may be the source of GI bleeds in GIST.
- **Gastrointestinal Disorders:** Gastrointestinal (GI) perforations, some fatal, have been reported.
- **Hypereosinophilic Cardiac Toxicity:** Cardiogenic shock/left ventricular dysfunction has been associated with the initiation of Imkeldi in patients with conditions associated with high eosinophil levels (e.g., HES, MDS/MPD, and ASM).
- **Dermatologic Toxicities:** Bullous dermatologic reactions (e.g., erythema multiforme and Stevens-Johnson syndrome) have been reported with the use of Imkeldi.

- **Hypothyroidism:** Hypothyroidism has been reported in thyroidectomy patients undergoing levothyroxine replacement. Closely monitor TSH levels in such patients.
- **Embryo-Fetal Toxicity:** Can cause fetal harm. Advise females of reproductive potential of the potential risk to the fetus, and to use effective contraception.
- **Growth Retardation in Children and Adolescents:** Growth retardation occurring in children and pre-adolescents receiving Imkeldi has been reported. Close monitoring of growth in children under Imkeldi treatment is recommended.
- **Tumor Lysis Syndrome:** Close monitoring is recommended.
- **Impairments Related to Driving and Using Machinery:** Motor vehicle accidents have been reported in patients receiving imatinib. Caution patients about driving a car or operating machinery.
- **Renal Toxicity:** A decline in renal function may occur in patients receiving Imkeldi. Evaluate renal function at baseline and during therapy, with attention to risk factors for renal dysfunction.
- **Measuring Device:** Advise patients to measure Imkeldi with an accurate milliliter measuring device. Inform patients that a household teaspoon is not an accurate measuring device and could lead to overdosage, which can result in serious adverse reactions. Advise patients to ask their pharmacist to recommend an appropriate press-in bottle adapter and oral dispensing syringe and for instructions for measuring the correct dose.

HCPCS Coding

J8999	Prescription drug, oral, chemotherapeutic, Not Otherwise Specified
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ICD-10 Diagnosis Codes That Support Medical Necessity

C43.0	Malignant melanoma of lip
C43.10 – C43.12	Malignant melanoma of eyelid, including canthus
C43.20 – C43.22	Malignant melanoma of ear and external auricular canal
C43.30 – C43.39	Malignant melanoma of other and unspecified parts of face
C43.4	Malignant melanoma of scalp and neck
C43.51 – C43.59	Malignant melanoma trunk
C43.60 – C43.62	Malignant melanoma of upper limb, including shoulder
C43.70 – C43.72	Malignant melanoma of lower limb, including hip
C43.8	Malignant melanoma of overlapping sites of skin
C43.9	Malignant melanoma of skin, unspecified
C44.90	Unspecified malignant neoplasm of skin, unspecified
C46.0 - C46.9	Kaposi's sarcoma
C47.8	Malignant neoplasm of overlapping sites of peripheral nerves and autonomic nervous system
D48.1	Neoplasm of uncertain behavior of connective and other soft tissue
C49.4	Malignant neoplasm of connective and soft tissue of abdomen
C49.8	Malignant neoplasm of overlapping sites of connective and soft tissue
C49.9	Malignant neoplasm of connective and soft tissue, unspecified

C49.A0 – C49.A9	Gastrointestinal stromal tumor
C72.0	Malignant neoplasm of spinal cord
C72.1	Malignant neoplasm of cauda equina
C79.31	Secondary malignant neoplasm of brain
C80.0	Disseminated malignant neoplasm, unspecified
C80.1	Malignant (primary) neoplasm, unspecified
C83.50	Lymphoblastic (diffuse) lymphoma, unspecified site
C83.51	Lymphoblastic (diffuse) lymphoma, lymph nodes of head, face, and neck
C83.52	Lymphoblastic (diffuse) lymphoma, intrathoracic lymph nodes
C83.53	Lymphoblastic (diffuse) lymphoma, intra-abdominal lymph nodes
C83.54	Lymphoblastic (diffuse) lymphoma, lymph nodes of axilla and upper limb
C83.55	Lymphoblastic (diffuse) lymphoma, lymph nodes of inguinal region and lower limb
C83.56	Lymphoblastic (diffuse) lymphoma, intrapelvic lymph nodes
C83.57	Lymphoblastic (diffuse) lymphoma, spleen
C83.58	Lymphoblastic (diffuse) lymphoma, lymph nodes of multiple sites
C83.59	Lymphoblastic (diffuse) lymphoma, extranodal and solid organ sites
C91.00	Acute lymphoblastic leukemia not having achieved remission
C91.01	Acute lymphoblastic leukemia, in remission
C91.02	Acute lymphoblastic leukemia, in relapse
C92.10	Chronic myeloid leukemia, bcr/abl-positive, not having achieved remission
C92.11	Chronic myeloid leukemia, bcr/abl-positive, in remission
C92.12	Chronic myeloid leukemia, bcr/abl-positive, in relapse
C93.10	Chronic myelomonocytic leukemia, not having achieved remission
C93.12	Chronic myelomonocytic leukemia, in relapse
C96.20	Malignant mast cell neoplasm, unspecified
C96.21	Aggressive systemic mastocytosis
C96.22	Mast cell sarcoma
C96.29	Other malignant mast cell neoplasm
D47.02	Systemic mastocytosis
D48.1	Neoplasm of uncertain behavior of connective and other soft tissue
D72.110 - D72.119	Hypereosinophilic syndrome [HES]
D89.811	Chronic graft-versus-host disease
D89.812	Acute on chronic graft-versus-host disease
D89.813	Graft-versus-host disease, unspecified
T86.09	Other complications of bone marrow transplant

REIMBURSEMENT INFORMATION:

Refer to section entitled [POSITION STATEMENT](#).

PROGRAM EXCEPTIONS:

Federal Employee Program (FEP): Follow FEP guidelines.

State Account Organization (SAO): Follow SAO guidelines.

Medicare Advantage Products: No National Coverage Determination (NCD) and/or Local Coverage Determination (LCD) were found at the time of the last guideline review date.

Medicare Part D: Florida Blue has delegated to Prime Therapeutics authority to make coverage determinations for the Medicare Part D services referenced in this guideline.

If this Medical Coverage Guideline contains a step therapy requirement, in compliance with Florida law 627.42393, members or providers may request a step therapy protocol exemption to this requirement if based on medical necessity. The process for requesting a protocol exemption can be found at [Coverage Protocol Exemption Request](#).

DEFINITIONS:

None

RELATED GUIDELINES:

[Allogeneic Bone Marrow and Stem Cell Transplantation, 02-38240-01](#)

[Asciminib \(Scemblix\) Tablets, 09-J4000-22](#)

[Bosutinib \(Bosulif\) Tablets, 09-J1000-84](#)

[Nilotinib \(Tasigna\) Capsules, 09-J1000-48](#)

[Oral Oncology Medications, 09-J3000-65](#)

OTHER:

Table 1: CML Risk Scores

Score	Calculation	Risk Definition by Calculation
Sokal score	$\text{Exp } 0.0116 \times (\text{age} - 43.4) + (\text{spleen size} - 7.51) + 0.188 \times [(\text{platelet count}/700)^2 - 0.562] + 0.0887 \times (\text{blast cells} - 2.10)$	<ul style="list-style-type: none">• Low: <0.8• Intermediate: 0.8 to 1.2• High: >1.2
Hasford (EURO) score	$[0.666 \text{ when age } \geq 50 + (0.042 \times \text{spleen size}) + 1.0956 \text{ when platelet count } \geq 1,500 \times 10^3/\text{L} + (0.0584 \times \text{blast cells}) + 0.2039 \text{ when basophils } \geq 3\% + (0.0413 \times \text{eosinophils})] \times 1,000$	<ul style="list-style-type: none">• Low: ≤ 780• Intermediate: >780 to 1,480• High: >1,480
EUTOS long-term survival (ELTS) score	$0.0025 \times (\text{age}/10)^3 + 0.0615 \times \text{spleen size} + 0.1052 \times \text{blast cells} + 0.4104 \times (\text{platelet count}/1,000)^{-0.5}$	<ul style="list-style-type: none">• Low: ≤ 1.5680• Intermediate: >1.5680 to ≤ 2.2185• High: >2.2185

Age is in years. Spleen is in centimeters below the costal margin (maximum distance). Blast cells, eosinophils, and basophils are in percent of peripheral blood differential. All factors must be collected prior to any treatment.

Online calculator for Sokal and Hasford (EURO) scores can be found at: https://www.leukemia-net.org/content/leukemias/cml/euro_and_sokal_score/index_eng.html

Online calculator for the ELTS score can be found at: https://www.leukemia-net.org/content/leukemias/cml/elts_score/index_eng.html

Table 2

NCCN Categories of Evidence Consensus	
Category 1	Based upon high-level evidence; there is uniform NCCN consensus that the intervention is appropriate
Category 2A	Based upon lower-level evidence, there is uniform NCCN consensus that the intervention is appropriate
Category 2B	Based upon lower-level evidence, there NCCN consensus that the intervention is appropriate
Category 3	Based upon any level of evidence, there is major NCCN disagreement that the intervention is appropriate

Table 3

Other Compendia	
Compendium	Covered Uses
AHFS-DI	Narrative text is supportive
Clinical Pharmacology	Narrative text is supportive
Lexicomp	Evidence rating A, B or G
Thomson Micromedex DrugDex	Meets requirements for BOTH of the following: <ul style="list-style-type: none"> Strength of recommendation: Class I (Recommended) or IIa (Recommended, In Most Cases) Efficacy: Class I (Effective) or IIa (Evidence Favors Efficacy)
AHFS-DI - American Hospital Formulary Service Drug Information	

Table 4

Lexicomp Recommendation Ratings	
A	Consistent evidence from well-performed randomized, controlled trials or overwhelming evidence of some other form (e.g., results of the introduction of penicillin treatment) to support the off-label use. Further research is unlikely to change confidence in the estimate of benefit.
B	Evidence from randomized, controlled trials with important limitations (inconsistent results, methodological flaws, indirect or imprecise), or very strong evidence of some other research design. Further research (if performed) is likely to have an impact on confidence in the estimate of benefit and risk and may change the estimate.

C	Evidence from observational studies (e.g., retrospective case series/reports providing significant impact on patient care), unsystematic clinical experience, or from potentially flawed randomized, controlled trials (e.g., when limited options exist for condition). Any estimate of effect is uncertain.
G	Use has been substantiated by inclusion in at least one evidence-based or consensus-based clinical practice guideline.

Table 5

Thomson Micromedex DrugDex Recommendation Ratings: Strength of Recommendation		
Class I	Recommended	The given test or treatment has been proven to be useful, and should be performed or administered
Class IIa	Recommended, in most cases	The given test or treatment is generally considered to be useful and is indicated in most cases.
Class IIb	Recommended in some cases	The given test or treatment may be useful, and is indicated in some, but not most, cases
Class III	Not recommended	The given test or treatment is not useful and should be avoided
Class Indeterminate	Evidence Inconclusive	

Table 6

Thomson Micromedex DrugDex Recommendation Ratings: Efficacy		
Class I	Effective	Evidence and/or expert opinion suggests that a given drug treatment for a specific indication is effective
Class IIa	Evidence favors efficacy	Evidence and/or expert opinion is conflicting as to whether a given drug treatment for a specific indication is effective, but the weight of evidence and/or expert opinion favors efficacy.
Class IIb	Evidence is inconclusive	Evidence and/or expert opinion is conflicting as to whether a given drug treatment for a specific indication is effective, but the weight of evidence and/or expert opinion argues against efficacy.
Class III	Ineffective	Evidence and/or expert opinion suggests that a given drug treatment for a specific indication is ineffective

REFERENCES:

1. Clinical Pharmacology powered by ClinicalKey [Internet]. Tampa, FL: Elsevier.; 2025. Available at: <https://www.clinicalkey.com/pharmacology/>. Accessed 01/28/25.
2. Imkeldi (imatinib oral solution) [package insert]. Shorla Oncology Inc. Cambridge, MA: November 2024.

3. Gleevec (imatinib) [package insert]. Novartis Pharmaceuticals Corporation. East Hanover, NJ: March 2024.
4. Micromedex Healthcare Series [Internet Database]. Greenwood Village, Colo: Thomson Healthcare. Updated periodically. Accessed 01/28/25.
5. National Comprehensive Cancer Network. Cancer Guidelines. Cancer Guidelines and Drugs and Biologics Compendium. Accessed 01/28/25.

COMMITTEE APPROVAL:

This Medical Coverage Guideline (MCG) was approved by the Florida Blue Pharmacy Policy Committee on 02/12/25.

GUIDELINE UPDATE INFORMATION:

03/15/25	New Medical Coverage Guideline.
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