CLINICAL GUIDELINES FOR MEDICAL NECESSITY

MEDICAL POLICY

Imatinib Mesylate (Gleevec®)

Version: 1.0

EFFECTIVE DATE: 12/1/2024

NantHealth® | Eviti®

Please note the following:

Imatinib Mesylate (Gleevec®)

Note: For Medicare members/enrollees, to ensure consistency with the Medicare National Coverage Determinations (NCD) and Local Coverage Determinations (LCD), all applicable NCDs, LCDs, and Medicare Coverage Articles should be reviewed prior to applying the criteria set forth in this clinical policy. Please refer to the CMS website at http://www.cms.gov for additional information.

Note: For Medicaid members/enrollees, circumstances when state Medicaid coverage provisions conflict with the coverage provisions within this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

Imatinib Mesylate (Gleevec): Discussion

Imatinib mesylate is a derivative of 2-phenylamino-pyrimidine and acts as a protein and tyrosine kinase inhibitor. It was initially developed to target the platelet-derived growth factor receptor (PDGFR). Imatinib mesylate also inhibits other protein tyrosine kinases, such as c-kit (associated with gastrointestinal stromal tumors) and the BCR-ABL fusion protein (linked to Philadelphia chromosome-positive chronic myelogenous leukemia). When these kinases are constitutively activated, either through mutations or other mechanisms, they can lead to cancer. By blocking this continuous activation, imatinib mesylate has been shown to induce programmed cell death in cancer cells without further differentiation. As a therapeutic agent, imatinib mesylate works by competitively inhibiting the ATP binding site of the ABL kinase, leading to the apoptosis of leukemic cells.[1]

Imatinib mesylate has serious adverse reactions which include edema, congestive heart failure, left ventricular dysfunction, and gastrointestinal disorders. Toxicities related to imatinib mesylate include hematologic, renal, dermatologic, and liver.

Imatinib mesylate is approved by the Food and Drug Administration (FDA) for acute lymphoblastic leukemia, chronic myeloid leukemia, dermatofibrosarcoma protuberans, gastrointestinal stromal tumors, hypereosinophilic syndrome (HES), chronic eosinophilic leukemia, myelodysplastic/myeloproliferative diseases, pediatric acute lymphoblastic leukemia, and systemic mastocytosis.[2]

The National Comprehensive Cancer Network (NCCN) endorses imatinib mesylate in the following cancer types: acute lymphoblastic leukemia, bone, chronic myeloid leukemia, gastrointestinal stromal tumors (GIST), hematopoietic cell transplantation, Kaposi sarcoma, myeloid/lymphoid neoplasms with eosinophilia and tyrosine kinase gene fusions, cutaneous melanoma, pediatric acute lymphoblastic leukemia, soft tissue, and systemic mastocytosis.[3,4,5,6,7,8,9,10,11,12,13,14]

Imatinib Mesylate: Definitions

- **BCR-ABL1 gene** - A translocated fusion oncoprotein that defines chronic myeloid leukemia and results when ABL1 gene encodes a non-receptor tyrosine kinase on chromosome 9, and BCR which is a breakpoint cluster region, encodes on chromosome 22.[15]
- **National Comprehensive Cancer Network (NCCN)** - An alliance of more than 30 leading cancer centers devoted to patient care, research, and education. The NCCN guidelines are utilized for Radiation Therapy and Medical Oncology standards. NCCN consensus clinical standards are periodically updated and NantHealth, Inc. reviews these and updates its policies within a timely manner.
- **Food and Drug Administration (FDA)** - The FDA is responsible for protecting the public health by assuring the safety, efficacy, and security of human and veterinary drugs, biological products, medical devices, our nation's food supply, cosmetics, and products that emit radiation.

Imatinib Mesylate: Policy

Note: Coverage of imatinib mesylate will be provided for an FDA-approved indication or National Comprehensive Cancer Network (NCCN) guidelines when it is a Category 1, 2A, or 2B recommendation or when all criteria are met.

Imatinib Mesylate will be considered for coverage when the following criteria are met:

Acute Lymphoblastic Leukemia

1. At least 18 years of age; AND
2. Prescribed by or in consultation with an oncologist; AND

For **FDA** required criteria coverage:

3. Adult patients with relapsed or refractory Philadelphia chromosome-positive acute lymphoblastic leukemia (Ph+ ALL)[2]; OR

For **NCCN** required criteria coverage:

4. Therapy as a TKI in combination with blinatumomab for Philadelphia chromosome-positive B-ALL (AYA without substantial comorbidities and adults) during frontline induction therapy; OR
5. Therapy as a component of TKI with EsPhALL
   a) Induction (cyclophosphamide, cytarabine, dexamethasone, doxorubicin, mercaptopurine, pegaspargase, thioguanine, vincristine)
   b) Consolidation (cyclophosphamide, cytarabine, daunorubicin, dexamethasone, etoposide, ifosfamide, high-dose methotrexate, pegaspargase, vincristine); OR
6. Therapy as a component of TKI for one of the following:
   a) Dose-adjusted HyperCVAD: induction/consolidation (hyperfractionated cyclophosphamide, mesna, vincristine, doxorubicin, dexamethasone, IT

b) Methotrexate, IT cytarabine alternating with high-dose methotrexate, leucovorin, dose-adjusted cytarabine, IT methotrexate, IT cytarabine)
c) CALGB 10701 - induction (cyclophosphamide, daunorubicin, dexamethasone, vincristine)
d) CALGB 10701 - consolidation (cytarabine, etoposide); OR

7. As a component of TKI with corticosteroid; OR
8. Therapy as a component of TKI plus vincristine plus dexamethasone
   a) Induction - vincristine + dexamethasone with IT chemotherapy (methotrexate, cytarabine, hydrocortisone)
   b) Induction 2 - methotrexate, leucovorin, cytarabine with IT chemotherapy (methotrexate, cytarabine, hydrocortisone)
   c) Interphase - methotrexate PO, mercaptopurine with IT chemotherapy (methotrexate, cytarabine, hydrocortisone)
   d) Consolidation odd cycles - vincristine, dexamethasone, cyclophosphamide, doxorubicin
   e) Consolidation even cycles - high-dose methotrexate, leucovorin, cytarabine
   f) Maintenance (if minimal/measurable residual disease negative): prednisone, vincristine; OR
9. Therapy as a component of TKI with other multiagent therapy for one of the following:
   a) Induction (cyclophosphamide, daunorubicin, prednisone, vincristine)
   b) Consolidation (cytarabine, high-dose methotrexate, methylprednisolone); OR
10. Philadelphia chromosome-positive B-ALL (AYA without substantial comorbidities and adults) during frontline therapy and relapsed or refractory therapy if not previously given, as a component of TKI with EWALL for one of the following:
    a) Induction (cyclophosphamide, dexamethasone, vincristine)
    b) Consolidation (cytarabine, high-dose methotrexate, pegaspargase); OR
11. Philadelphia chromosome-positive B-ALL (AYA without substantial comorbidities and adults) during frontline therapy as a TKI for one of the following:
    a) Single agent if unfit for additional therapies
    b) In combination with blinatumomab
    c) In combination with inotuzumab ozogamicin if persistent, rising minimal or measurable residual disease (MRD) is present; OR
12. Philadelphia chromosome-positive B-ALL (AYA without substantial comorbidities and adults) during maintenance therapy as a TKI for one of the following:
    a) Single agent if unfit for additional therapies if minimal/measurable residual disease (MRD) negative
    b) Single agent if previously received blinatumomab plus TKI if MRD negative
    c) Single agent post-hematopoietic stem cell transplant when feasible
    d) In combination with POMP: (vincristine and prednisone with or without methotrexate and mercaptopurine) for MRD negative (if not already included in a multi-part regimen); OR
13. Philadelphia chromosome-positive B-ALL during relapsed or refractory (R/R) therapy as a TKI for one of the following:
    a) Single agent
    b) In combination with blinatumomab
    c) In combination with inotuzumab ozogamicin.

Note:

1. Imatinib mesylate use in first-line should be restricted to those who cannot tolerate broader acting TKIs.
2. Blinatumomab plus TKI is preferred in consolidation regardless of MRD status for those who have not previously received blinatumomab.[3]

Bone Cancer – Chordoma

1. At least 18 years of age; AND
2. Prescribed by or in consultation with an oncologist; AND

For **NCCN** required criteria coverage:

3. Treatment of recurrent conventional or chondroid chordoma for one of the following:
   a) Single agent therapy
   b) In combination with cisplatin
   c) In combination with sirolimus.[4]

Chronic Myeloid Leukemia

1. Prescribed by or in consultation with an oncologist; AND

For **FDA** required criteria coverage:

2. Newly diagnosed adult and pediatric patients with Philadelphia chromosome positive chronic myeloid leukemia (Ph plus CML) in chronic phase; OR
3. Patients with Philadelphia chromosome positive chronic myeloid leukemia (Ph plus CML) in blast crisis (BC), accelerated phase (AP), or in chronic phase (CP) after failure of interferon-alpha therapy[2]; OR

For **NCCN** required criteria coverage:

4. At least 18 years of age; AND
5. Primary treatment as a single agent for newly diagnosed chronic phase CML (Philadelphia chromosome or BCR-ABL1 positive) in patients for one of the following:
   a) A low-risk score
   b) An intermediate or high-risk score; OR
6. Continued imatinib mesylate treatment for BCR-ABL1 transcript levels for one of the following:
   a) ≤0.1% at any response milestone
   b) >0.1- to 1% at 3 or 6 months
   c) >0.1- to 1% at 12 months (≤1% optimal if treatment goal is long-term survival; ≤0.1% optimal if treatment goal is treatment-free remission)
   d) >1% to 10% at 3 or 6 months
   e) >1 to 10% at 12 months if CCyR is achieved (patients with more than 50% reduction compared to baseline or minimally above the 10% cutoff can continue the same dose of TKI for another 3 months)

f) >10% at 3 months; OR

7. Used if a second generation (2G) or third generation (3G) TKI is contraindicated for one of the following:
   a) Primary treatment of CML in accelerated phase as a single agent (not recommended for patients with disease progression on prior TKI therapy)
   b) In combination with induction chemotherapy as primary treatment for CML in lymphoid blast phase or myeloid blast phase. Acute lymphoblastic leukemia-type induction chemotherapy is recommended for lymphoid blast phase. Acute myeloid leukemia-type induction chemotherapy is recommended for myeloid blast phase
   c) In combination with steroids as primary treatment for CML in lymphoid blast phase if not a candidate for induction chemotherapy
   d) As primary treatment for CML in myeloid blast phase as a single agent if not a candidate for induction chemotherapy
   e) As maintenance therapy with consolidation chemotherapy for non-candidates for allogeneic hematopoietic stem cell transplant (HCT) in remission for blast phase CML (BP-CML); OR
8. Used as a single agent as one of the following:
   a) As post-allogeneic hematopoietic stem cell transplant (HCT) therapy for at least one year in patients with prior accelerated or blast phase with complete cytogenetic response (CCYR)
   b) As post-allogeneic HCT additional therapy in patients with molecular relapse (BCR-ABL1 transcript positive) following CCYR
   c) As post-allogeneic HCT additional therapy in patients with relapse or less than CCyR.[5]

Dermatofibrosarcoma Protuberans

1. At least 18 years of age; AND
2. Prescribed by or in consultation with an oncologist; AND

For **FDA** required criteria coverage:

3. Adult patients with unresectable, recurrent or metastatic disease[2]; OR

For **NCCN** required criteria coverage:

4. Single agent neoadjuvant treatment for one of the following:
   a) Unresectable disease
   b) Borderline resectable disease
   c) Patients in whom resection with negative margins may result in unacceptable functional or cosmetic outcomes; OR
5. Single agent treatment for recurrent disease for one of the following:
   a) Unresectable disease
   b) Unacceptable functional or cosmetic outcomes following resection.[6]

Gastrointestinal Stromal Tumors

1. At least 18 years of age; AND
2. Prescribed by or in consultation with an oncologist; AND

For **FDA** required criteria coverage:

3. Patients with Kit (CD117) positive unresectable metastatic malignant gastrointestinal stromal tumors; OR
4. Adjuvant treatment of adult patients following resection of Kit (CD117) positive GIST[2]; OR

For **NCCN** required criteria coverage:

5. Neoadjuvant therapy as a single agent to decrease surgical morbidity for GIST with imatinib-sensitive KIT or PDGFRA mutations (including D842V) that are resectable with significant morbidity; OR

Note: Although mutational analysis is recommended (other than rare circumstances, family history, etc.), it is appropriate to start neoadjuvant imatinib mesylate pending confirmation of the mutational analysis.

6. Single agent for GIST with imatinib-sensitive KIT or PDGFRA mutations for one of the following: (excluding PDGFRA exon 18 mutations that are insensitive to imatinib mesylate, including D842V)
   a) Adjuvant treatment following complete resection (R0/R1) of primary GIST if no neoadjuvant imatinib mesylate given to patients with significant risk of recurrence (intermediate or high risk if patient has an imatinib-sensitive mutation)
   b) Adjuvant treatment as continuation of imatinib mesylate, to be considered if completely resected (R0/R1) primary GIST after neoadjuvant imatinib mesylate given to patients with significant risk of recurrence
   c) First-line therapy for GIST with gross residual disease (R2 resection), unresectable primary disease, tumor rupture, or recurrent/metastatic disease; OR

   Note:
   1. PDGFRA mutation excludes PDGFRA exon 18 mutations that are insensitive to imatinib mesylate.
   2. Life-long systemic therapy is recommended for TKI-sensitive GIST.

7. Continued treatment as a single agent (if previously treated with standard dose imatinib) for one of the following:
   a) Limited progression with or without dose escalation
   b) Patients with a performance status of 0-2 and generalized (widespread and systemic) progression with dose escalation; OR
8. Therapy in combination with everolimus for gross residual disease (R2 resection), unresectable primary disease, tumor rupture, or recurrent/metastatic disease after progression on approved therapies (imatinib mesylate, sunitinib, regorafenib, and standard dose ripretinib); OR

9. First-line therapy in combination with binimetinib for SDH-deficient GIST with gross residual disease (R2 resection), unresectable primary disease, tumor rupture, or recurrent/metastatic disease and as continued treatment for limited progression.

Note:

1. Discontinuing TKI therapy, even in the setting of progressive disease, may accelerate the pace of disease progression and worsens the symptoms of life-long systemic therapy.
2. Imatinib mesylate reintroduction may be considered for palliation of symptoms if previously tolerated and effective as part of best supportive care.[7]

Hematopoietic Cell Transplantation

1. At least 18 years of age; AND
2. Prescribed by or in consultation with an oncologist; AND

For **NCCN** required criteria coverage:

3. Additional therapy for chronic graft-versus-host disease (cGVHD) in conjunction with systemic corticosteroids following no response (steroid-refractory disease) to first-line therapy options.[8]

Hypereosinophilic Syndrome (HES) and/or Chronic Eosinophilic Leukemia

1. At least 18 years of age; AND
2. Prescribed by or in consultation with an oncologist; AND

For **FDA** required criteria coverage:

3. Adult patients who have the FIP1L1-PDGFRα fusion kinase (mutational analysis or fluorescence in situ hybridization [FISH] demonstration of CHIC2 allele deletion) and with FIP1L1-PDGFRα fusion kinase negative or unknown.[2]

Kaposi Sarcoma

1. At least 18 years of age; AND
2. Prescribed by or in consultation with an oncologist; AND

For **NCCN** required criteria coverage:

3. Subsequent systemic therapy, given alone (no HIV) or with antiretroviral therapy (ART) for people with HIV (PWH), for relapsed or refractory advanced, cutaneous, oral, visceral, or nodal disease that has progressed on or not and responded to first-line systemic therapy which progressed on alternate first-line systemic therapy.[9]

Myeloid/Lymphoid Neoplasms with Eosinophilia and Tyrosine Kinase Gene Fusions

1. At least 18 years of age; AND
2. Prescribed by or in consultation with an oncologist; AND

For **NCCN** required criteria coverage:

3. In combination with corticosteroids for patients with symptoms and signs of cardiac involvement including troponinemia, abnormal ECHO findings for myeloid, lymphoid neoplasms with eosinophilia, and the FIP1L1-PDGFRA or PDGFRB rearrangement in chronic phase or blast phase; OR
4. In combination with ALL or AML- type induction or as a single agent in patients with blast phase disease where FIP1L1-PDGFRA or PDGFRB rearrangement is discovered after induction chemotherapy; OR
5. ABL1 rearrangement in chronic phase or blast phase; OR
6. In combination with ALL or AML-type induction chemotherapy and followed by consideration of allogeneic HCT for ABL1 rearrangement in blast phase.[10]

Myelodysplastic/Myeloproliferative Diseases

1. At least 18 years of age; AND
2. Prescribed by or in consultation with an oncologist; AND

For **FDA** required criteria coverage:

3. Associated with platelet-derived growth factor receptor (PDGFR) gene re-arrangements.[2]

Melanoma - Cutaneous

1. At least 18 years of age; AND
2. Prescribed by or in consultation with an oncologist; AND

For **NCCN** required criteria coverage:

3. Single agent for metastatic or unresectable tumors with activating mutations of KIT as second-line or subsequent therapy for disease progression, intolerance, or projected risk of progression with BRAF-targeted therapy.[11]

Pediatric Acute Lymphoblastic Leukemia

1. At least 18 years of age; AND
2. Prescribed by or in consultation with an oncologist; AND

For **FDA** required criteria coverage:

3. Newly diagnosed Ph+ ALL in combination with chemotherapy[2]; OR

For **NCCN** required criteria coverage:

4. Induction therapy as a component for one of the following:
   a) Standard arm of COG AALL1631 (based on COG AALL1122/EsPhALL regimen) with EsPhALL backbone + imatinib for BCR-ABL1-positive B-ALL
   b) COG AALL0622 regimen + imatinib mesylate for BCR-ABL1-positive ALL; OR
5. Consolidation therapy as a component of the standard arm of COG AALL1631 (based on COG AALL1122/EsPhALL regimen) with EsPhALL backbone + imatinib for BCR-ABL1-positive B-ALL; OR
6. Consolidation therapy in combination with blinatumomab for BCR-ABL1-positive B-ALL with high risk and less than complete response or minimal residual disease positive (MRD+) at end of consolidation; OR
7. Relapsed or refractory BCR-ABL1-positive B-ALL in combination with one of the following regimens:
   a) UKALL R3
   b) COG AALL01P2
   c) ALL-REZ BFM 90
   d) COG AALL07P1
   e) Clofarabine-containing
   f) Fludarabine-containing
   g) High-dose cytarabine-based; OR
8. As part of a TKI-based regimen for relapsed or refractory T-ALL with ABL-class translocation.[12]

Soft Tissue Sarcoma

1. At least 18 years of age; AND
2. Prescribed by or in consultation with an oncologist; AND

Desmoid Tumors (Aggressive Fibromatosis)

For **NCCN** required criteria coverage:

3. Primary or subsequent-line treatment for intra-abdominal/retroperitoneal, abdominal wall, pelvic, trunk extremity, head and neck, intrathoracic tumors, or treatment of gross residual disease (R2 resection) in abdominal wall, pelvic, trunk extremity, head and neck, intrathoracic tumors as a single agent for one of the following:
   a) Ongoing progression with potential morbidity or significant symptoms in anatomic location where progression would not be morbid
   b) Documented progression in anatomic location where progression would be morbid
   c) No documented progression in anatomic location where progression would be morbid if concerns for morbidity or significant symptoms; OR

Dermatofibrosarcoma Protuberans (DFSP) with Fibrosarcomatous Transformation/ Pigmented Villonodular Synovitis/Tenosynovial Giant Cell Tumor

4. Single-agent therapy.[13]

Systemic Mastocytosis

1. At least 18 years of age; AND
2. Prescribed by or in consultation with an oncologist; AND

For **FDA** required criteria coverage:

3. Adult patients with aggressive systemic mastocytosis (ASM) without the D816V c-Kit mutation or with c-Kit mutational status unknown[2]; OR

For **NCCN** required criteria coverage:

4. Single agent for first-line and second-line treatment of aggressive systemic mastocytosis (for KIT D816V mutation negative or unknown; well-differentiated SM; [WDSM]; eosinophilia is present with FIP1L1-PDGFRA fusion gene).[14]

Authorization Period and Renewal Criteria

1. Initial Authorization Period: 12 months
2. Renewal Criteria: No evidence of disease progression or unacceptable toxicity
3. Renewal Authorization Period: 12 months

Imatinib Mesylate: References

1. P. Flynn et al. Imatinib. https://www.ncbi.nlm.nih.gov/books/NBK551676/. Accessed December 4, 2024.
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14. National Comprehensive Cancer Network. Systemic Mastocytosis. https://www.nccn.org/professionals/physician_gls/pdf/mastocytosis.pdf. Accessed December 4, 2024.
15. National Library of Medicine. Chronic Myelogenous Leukemia. https://www.ncbi.nlm.nih.gov/books/NBK531459/. Accessed December 4, 2024.

Imatinib Mesylate: Coding (CPT®, ICD 10, and HCPCS)

Procedure codes appearing in medical policy documents are only included as a general reference. This list may not be all-inclusive and is subject to updates. In addition, the codes listed are not a guarantee of payment. CPT codes are available through the AMA.

Code	Description
C41.2	Malignant neoplasms of the vertebral column
C43.9	Malignant melanoma of the skin
C46.9	Kaposi sarcoma
D47.2	Systemic mastocytosis
D48.110-D48.119	Desmoid tumors

C49.A0	Gastrointestinal stromal tumors
C49.10-C49.12, C49.20-C49.22, C49.8-C49.9,	Pigmented villonodular synovitis/tenosynovial giant cell tumor
C49.2	Dermatofibrosarcoma protuberans
C91.0	Malignant neoplasm of lymphoid, hematopoetic, and related issues
C94.6	Myelodysplastic/myeloproliferative diseases
C94.8-C94.82, C95.1, C95.10-C95.12, C96.Z, C96.9	Myeloid/lymphoid neoplasms with eosinophilia and tyrosine kinase gene fusions
D72.118, C94.8	Hypereosinophilic syndrome (HES) and/or chronic eosinophilic leukemia
D89.811-D89.813, T86.09	Hematopoietic cell transplantation
S0088	Imatinib mesylate

Imatinib Mesylate: Revision and Review History

No.	Description	Date(s)
1	Original Effective Date:	12/1/2024
2	Policy Review Dates:	
3	Policy Revision Dates:	
4	Department Owner:	Medical Affairs
5	NH Advisory Committee:	12/21/2024
6	Revision Changes:	