PRIOR AUTHORIZATION POLICY

POLICY: Oncology – Imatinib Prior Authorization Policy
- Gleevec® (imatinib tablets– Novartis, generic)

REVIEW DATE: 05/01/2024

OVERVIEW

Imatinib, a tyrosine kinase inhibitor (TKI), is indicated for the following uses:[1,2]
Acute lymphoblastic leukemia (ALL), Philadelphia chromosome positive (Ph+), in adults with relapsed or refractory disease.

ALL, newly diagnosed and Ph+, in combination with chemotherapy in pediatric patients.

Aggressive systemic mastocytosis, without the D816V c-Kit mutation or with unknown c-Kit mutational status, in adults.

Chronic myeloid leukemia (CML), newly diagnosed and Ph+, chronic phase in adult and pediatric patients.

CML, Ph+, in blast phase, accelerated phase, or in chronic phase in patients after failure of interferon alfa therapy.

Dermatofibrosarcoma protuberans in adults with unresectable, current, and/or metastatic disease.

Gastrointestinal stromal tumors (GIST), in patients with KIT (CD117) positive unresectable and/or metastatic malignant disease.

GIST, Kit (CD117) positive, as adjuvant treatment of adults following resection.

Hypereosinophilic syndrome and/or chronic eosinophilic leukemia, in adults who have the FIP1L1-PDGFR alpha fusion kinase (mutation analysis or fluorescence in situ hybridization demonstration of CICH2 allele deletion) and for patients with hypereosinophilic syndrome and/or chronic eosinophilic leukemia who are FIP1l1-PDGFR alpha fusion kinase negative or unknown.

Myelodysplastic/myeloproliferative diseases, associated with platelet-derived growth factor receptor (PDGFR) gene rearrangements in adults.

Guidelines

Imatinib is addressed in guidelines from National Comprehensive Cancer Network (NCCN):

ALL: NCCN guidelines for adults and adolescents (version 4.2023 – February 5, 2024) recommend imatinib for Ph+ disease in many different clinical circumstances (e.g., induction, consolidation therapy, maintenance, or relapsed or refractory disease) [category 2A].3 NCCN guidelines for pediatric ALL (version 5.2024 – April 3, 2024) feature imatinib prominently (category 2A) in a variety of clinical scenarios.4

Bone Cancer: NCCN guidelines (version 2.2024 – March 12, 2024) recommend imatinib either as monotherapy or as "other recommended regimens" or in combination with cisplatin or Rapamune® (sirolimus tablets) for chordoma as "useful in certain circumstances" (both category 2A).5

CML: NCCN guidelines (version 2.2024 – December 5, 2023) state that for patients with chronic phase CML with a low-risk score, the primary "preferred" treatment recommendations includes a first-generation TKI (imatinib) or a second-generation TKI (Bosulif® [bosutinib tablets], Sprycel® [dasatinib tablets], or Tasigna® [nilotinib capsules] {all category 1}).6 For patients with chronic phase CML with an intermediate- or high-risk score, a second-generation TKI is preferred (Bosulif, Sprycel, or Tasigna [all category 1]); imatinib is an listed as "other recommended regimen" (category 2A); imatinib is also recommended for other clinical scenarios (category 2A).

Dermatofibrosarcoma Protuberans: NCCN guidelines (version 1.2024 – November 9, 2023) state to consider neoadjuvant imatinib for unresectable disease, borderline resectable disease, and in patients whom resection with negative margins may result in unacceptable functional or cosmetic outcomes (category 2A) and for recurrent disease in cases where the disease is unresectable, or unacceptable functional or adverse cosmetic outcomes may occur with resection (category 2A).7

GIST: NCCN guidelines (version 1.2024 – March 8, 2024) recommend imatinib as a "preferred regimen" for first-line therapy (category 1) in various scenarios (e.g., for sensitive mutations or for PDGFRA exon 18 mutations [excluding the D842V mutation) and is recommended in other clinical scenarios (e.g., neoadjuvant and adjuvant therapy)[category 2A].8

Graft-Versus-Host Disease (GVHD): NCCN guidelines for hematopoietic cell transplantation (version 1.2024 – April 26, 2024) address GVHD.9 Imatinib is cited as one of many therapies recommended for steroid-refractory, chronic GVHD (category 2A).

Kaposi Sarcoma: NCCN guidelines (version 1.2024 – November 7, 2023) recommend imatinib for subsequent systemic therapy for relapsed/refractory therapy as "useful in certain circumstances." 10 First-line systemic therapy options are liposomal doxorubicin as "preferred regimen" and paclitaxel.

Melanoma: Cutaneous: NCCN guidelines (version 2.2024 – April 3, 2024) recommend imatinib as second-line or subsequent therapy for metastatic or unresectable disease for tumors with activating mutations of KIT as "useful in certain circumstances" (category 2A).11

Myelodysplastic Syndromes: NCCN guidelines (version 1.2024 – February 12, 2024) note that data have demonstrated that patients with chronic myelomonocytic leukemia who have PDGFRβ may respond well to imatinib.12

Myeloid/Lymphoid Neoplasms with Eosinophilia and Tyrosine Kinase Gene Fusions: NCCN guidelines (version 1.2024 – December 21, 2023) recommend imatinib for patients with ABL1 rearrangements in the chronic phase or blast phase (category 2A).13 Imatinib is also recommended for certain situations where the tumor has an FIP1L1-PDGFRA or PDGFRB rearrangement (category 2A). Imatinib is also recommended for treatment in combination with ALL- or acute myeloid leukemia-type induction chemotherapy followed by allogeneic hematopoietic stem cell transplantation (if eligible) for lymphoid, myeloid or mixed lineage neoplasms with eosinophilia and ABL1 rearrangement in blast phase (category 2A).

Soft Tissue Sarcomas: NCCN guidelines (version 1.2024 – April 26, 2024) recommend imatinib for desmoid tumors (aggressive fibromatosis) as a "preferred regimen" (category 2A). For dermatofibrosarcoma protuberans with fibrosarcomatous transformation, imatinib is recommended as a "preferred regimen" (category 2A). For pigmented villonodular synovitis/tenosynovial giant cell tumor, imatinib is recommended as "useful in certain circumstances" (category 2A).14

Systemic Mastocytosis: NCCN guidelines (version 1.2023 – May 24, 2023,) recommend imatinib for aggressive systemic mastocytosis (for KIT D816V mutation negative or unknown; well differentiated systemic mastocytosis; eosinophilia is present with FIP1L1-PDGFRA fusion gene) as "useful in certain circumstances" (category 2A).15

Policy Statement

Prior Authorization is recommended for prescription benefit coverage of imatinib tablets. All approvals are provided for the duration noted below.

Automation: None.

Recommended Authorization Criteria

Coverage of imatinib is recommended in those who meet one of the following criteria:

FDA-Approved Indications

Acute Lymphoblastic Leukemia. Approve for 1 year if the patient has Philadelphia chromosome-positive acute lymphoblastic leukemia.

Aggressive Systemic Mastocytosis. Approve for 1 year if the patient is ≥ 18 years of age.

Chronic Myeloid Leukemia. Approve for 1 year if the patient has Philadelphia chromosome-positive chronic myeloid leukemia.

Dermatofibrosarcoma Protuberans. Approve for 1 year if the patient is ≥ 18 years of age.

Gastrointestinal Stromal Tumors. Approve for 1 year.

Hypereosinophilic Syndrome and/or Chronic Eosinophilic Leukemia. Approve for 1 year if the patient is ≥ 18 years of age.

Myelodysplastic/Myeloproliferative Disease. Approve for 1 year if the patient meets BOTH of the following (A and B):

Patient is ≥ 18 years of age; AND

The condition is associated with platelet-derived growth factor receptor (PDGFR) gene rearrangements.

Other Uses with Supportive Evidence

Chordoma. Approve for 1 year.

Desmoid Tumors (Aggressive Fibromatosis. Approve for 1 year

Graft-Versus-Host Disease, Chronic. Approve for 1 year if the patient has tried at least one conventional systemic treatment for graft-versus-host disease.

Note: Examples include corticosteroids (methylprednisolone, prednisone); cyclosporine; tacrolimus; mycophenolate mofetil; Imbruvica (ibrutinib capsules, tablets, and oral suspension); low-dose methotrexate; sirolimus; Rezurock (belumosudil tablets); and Jakafi (ruxolitinib tablets).

Kaposi Sarcoma. Approve for 1 year if the patient meets ALL of the following (A, B and C):

Patient is ≥ 18 years of age; AND

Patient has tried at least one medication; AND

Note: Examples include liposomal doxorubicin, paclitaxel, Pomalyst (pomalidomide capsules), lenalidomide, etoposide, and Thalomid (thalidomide capsules).

Patient has relapsed or refractory disease.

Melanoma, Cutaneous. Approve for 1 year if the patient meets ALL of the following (A, B, C, and D):

Patient is ≥ 18 years of age; AND

Patient has metastatic or unresectable disease; AND

Patient has an activating KIT mutation; AND

Patient has tried at least one systemic regimen.

Note: Examples of a systemic regimen include: Opdivo (nivolumab intravenous infusion) + Yervoy (ipilimumab intravenous infusion), Opdivo + Opdualag (nivolumab/relatlimab-rmbw intravenous infusion), Keytruda (pembrolizumab intravenous infusion), Opdivo, Tafinlar (dabrafenib capsules and tablets for suspension) + Mekinist (trametinib tablets), Zelboraf (vemurafenib tablets) + Cotellic (cobimetinib tablets), Braftovi (encorafenib capsules) + Mektovi (binimetinib tablets).

Myeloid/Lymphoid Neoplasms with Eosinophilia. Approve for 1 year if the patient meets BOTH of the following (A and B):

Patient is ≥ 18 years of age; AND

Patient meets ONE of the following (i or ii):

The tumor has an ABL1 rearrangement; OR

The tumor has an FIP1L1-PDGFRA or PDGFRB rearrangement.

Pigmented Villonodular Synovitis/Tenosynovial Giant Cell Tumor. Approve for 1 year if the patient meets ONE of the following (A or B):

Patient has tried Turalio (pexidartinib capsules); OR

Patient cannot take Turalio, according to the prescriber.

Note: Examples of reasons for not being able to take Turalio include patients with elevated liver enzymes or concomitant use of medications that are associated with hepatotoxicity.

Conditions Not Recommended for Approval

Coverage of imatinib is not recommend in the following situations:

Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

References

Gleevec® tablets [prescribing information]. East Hanover, NJ: Novartis; March 2024.

Imatinib tablets [prescribing information]. Cranbury, NJ: Sun; Sept 2022.

The NCCN Acute Lymphoblastic Leukemia Clinical Practice Guidelines in Oncology (version 4.2023 – February 5, 2024). © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on April 29, 2024.

The NCCN Pediatric Acute Lymphoblastic Leukemia Clinical Practice Guidelines in Oncology (version 5.2024 – April 3, 2024). © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on April 29, 2024.

The NCCN Bone Cancer Clinical Practice Guidelines in Oncology (version 2.2024 – March 12, 2024). © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on April 29, 2024.

The NCCN Chronic Myeloid Leukemia Clinical Practice Guidelines in Oncology (version 2.2024 – December 5, 2023). © 2023 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on April 29, 2024.

The NCCN Dermatofibrosarcoma Protuberans Clinical Practice Guidelines in Oncology (version 1.2024 – November 9, 2023 © 2023 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on April 29, 2024.

The NCCN Gastrointestinal Stromal Tumors Clinical Practice Guidelines in Oncology (version 1.2024 – March 8, 2024). © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on April 29, 2024.

The NCCN Hematopoietic Cell Transplantation (HCT) Clinical Practice Guidelines in Oncology (version 1.20234 – April. 26, 2024). © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on April 29, 2024.

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The NCCN Soft Tissue Sarcoma Clinical Practice Guidelines in Oncology (version 1.2024 – April 26, 2024). © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on April 29, 2024.

The NCCN Systemic Mastocytosis Clinical Practice Guidelines in Oncology (version 3.2024 – April 24, 2024). © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on April 29, 2024.