PRIOR AUTHORIZATION POLICY

POLICY: Oncology – Imatinib Products Prior Authorization Policy
- Gleevec® (imatinib tablets– Novartis, generic)
- Imkeldi® (imatinib oral solution – Shorla Oncology)

REVIEW DATE: 03/25/2026

INSTRUCTIONS FOR USE

THE FOLLOWING COVERAGE POLICY APPLIES TO HEALTH BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. CERTAIN CIGNA COMPANIES AND/OR LINES OF BUSINESS ONLY PROVIDE UTILIZATION REVIEW SERVICES TO CLIENTS AND DO NOT MAKE COVERAGE DETERMINATIONS. REFERENCES TO STANDARD BENEFIT PLAN LANGUAGE AND COVERAGE DETERMINATIONS DO NOT APPLY TO THOSE CLIENTS. COVERAGE POLICIES ARE INTENDED TO PROVIDE GUIDANCE IN INTERPRETING CERTAIN STANDARD BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. PLEASE NOTE, THE TERMS OF A CUSTOMER'S PARTICULAR BENEFIT PLAN DOCUMENT [GROUP SERVICE AGREEMENT, EVIDENCE OF COVERAGE, CERTIFICATE OF COVERAGE, SUMMARY PLAN DESCRIPTION (SPD) OR SIMILAR PLAN DOCUMENT] MAY DIFFER SIGNIFICANTLY FROM THE STANDARD BENEFIT PLANS UPON WHICH THESE COVERAGE POLICIES ARE BASED. FOR EXAMPLE, A CUSTOMER'S BENEFIT PLAN DOCUMENT MAY CONTAIN A SPECIFIC EXCLUSION RELATED TO A TOPIC ADDRESSED IN A COVERAGE POLICY. IN THE EVENT OF A CONFLICT, A CUSTOMER'S BENEFIT PLAN DOCUMENT ALWAYS SUPERSEDES THE INFORMATION IN THE COVERAGE POLICIES. IN THE ABSENCE OF A CONTROLLING FEDERAL OR STATE COVERAGE MANDATE, BENEFITS ARE ULTIMATELY DETERMINED BY THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT. COVERAGE DETERMINATIONS IN EACH SPECIFIC INSTANCE REQUIRE CONSIDERATION OF 1) THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT IN EFFECT ON THE DATE OF SERVICE; 2) ANY APPLICABLE LAWS/REGULATIONS; 3) ANY RELEVANT COLLATERAL SOURCE MATERIALS INCLUDING COVERAGE POLICIES AND; 4) THE SPECIFIC FACTS OF THE PARTICULAR SITUATION. EACH COVERAGE REQUEST SHOULD BE REVIEWED ON ITS OWN MERITS. MEDICAL DIRECTORS ARE EXPECTED TO EXERCISE CLINICAL JUDGMENT WHERE APPROPRIATE AND HAVE DISCRETION IN MAKING INDIVIDUAL COVERAGE DETERMINATIONS. WHERE COVERAGE FOR CARE OR SERVICES DOES NOT DEPEND ON SPECIFIC CIRCUMSTANCES, REIMBURSEMENT WILL ONLY BE PROVIDED IF A REQUESTED SERVICE(S) IS SUBMITTED IN ACCORDANCE WITH THE RELEVANT CRITERIA OUTLINED IN THE APPLICABLE COVERAGE POLICY, INCLUDING COVERED DIAGNOSIS AND/OR PROCEDURE CODE(S). REIMBURSEMENT IS NOT ALLOWED FOR SERVICES WHEN BILLED FOR CONDITIONS OR DIAGNOSES THAT ARE NOT COVERED UNDER THIS COVERAGE POLICY (SEE "CODING INFORMATION" BELOW). WHEN BILLING, PROVIDERS MUST USE THE MOST APPROPRIATE CODES AS OF THE EFFECTIVE DATE OF THE SUBMISSION. CLAIMS SUBMITTED FOR SERVICES THAT ARE NOT ACCOMPANIED BY COVERED CODE(S) UNDER THE APPLICABLE COVERAGE POLICY WILL BE DENIED AS NOT COVERED. COVERAGE POLICIES RELATE EXCLUSIVELY TO THE ADMINISTRATION OF HEALTH BENEFIT PLANS. COVERAGE POLICIES ARE NOT RECOMMENDATIONS FOR TREATMENT AND SHOULD NEVER BE USED AS TREATMENT GUIDELINES. IN CERTAIN MARKETS, DELEGATED VENDOR GUIDELINES MAY BE USED TO SUPPORT MEDICAL NECESSITY AND OTHER COVERAGE DETERMINATIONS.

CIGNA NATIONAL FORMULARY COVERAGE:

OVERVIEW

Imatinib, a tyrosine kinase inhibitor (TKI), is indicated for the following uses:[1,2,3]
- **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

The National Comprehensive Cancer Network (NCCN) Compendium recommends use of imatinib for the indications listed in the FDA-Approved Indications and Other Uses with Supportive Evidence sections.[4]

POLICY STATEMENT

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

- **Gleevec® (imatinib tablets - Novartis, generic)**
- **Imkeldi® (imatinib oral solution – Shorla Oncology)**

is(are) covered as medically necessary when the following criteria is(are) met for FDA-approved indication(s) or other uses with supportive evidence (if applicable):

FDA-Approved Indications

1. **Acute Lymphoblastic Leukemia.** Approve for 1 year if the patient meets ONE of the following (A or B):
   A) Patient has Philadelphia chromosome-positive acute lymphoblastic leukemia; OR
   B) Patient has *ABL*-class translocation.

2. **Systemic Mastocytosis.** Approve for 1 year if the patient meets BOTH of the following (A and B)
   A) Patient is ≥ 18 years of age; AND
   B) The disease is *KIT* D816V mutation negative or unknown.

3. **Chronic Myeloid Leukemia.** Approve for 1 year if the patient meets ONE of the following (A or B):
   A) Patient has Philadelphia chromosome-positive chronic myeloid leukemia; OR
   B) Patient has *BCR::ABL1*-mutation positive chronic myeloid leukemia.

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

5. **Gastrointestinal Stromal Tumors.** Approve for 1 year.

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

7. **Myelodysplastic/Myeloproliferative Disease.** Approve for 1 year if the patient meets BOTH of the following (A and B):
   A) Patient is ≥ 18 years of age; AND
   B) The condition is associated with platelet-derived growth factor receptor (*PDGFR*) gene rearrangements.

Other Uses with Supportive Evidence

8. **Chordoma.** Approve for 1 year.

9. **Desmoid Tumors (Aggressive Fibromatosis).** Approve for 1 year.

10. **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 of a systemic treatment include corticosteroids (methylprednisolone, prednisone); cyclosporine; tacrolimus; mycophenolate mofetil; Imbruvica (ibrutinib capsules, tablets, and oral suspension); low-dose methotrexate; sirolimus; Niktimvo (axatilimab-csfr intravenous infusion); Rezurock (belumosudil tablets); and Jakafi (ruxolitinib tablets).

11. **Kaposi Sarcoma.** Approve for 1 year if the patient meets ALL of the following (A and B):
    A) Patient is ≥ 18 years of age; AND
    B) Patient meets ONE of the following (i or ii):
       i. Patient meets BOTH of the following (a and b):
          a) Patient has tried at least one medication; AND
          Note: Examples include liposomal doxorubicin, paclitaxel, pomalidomide, lenalidomide, etoposide, and Thalomid (thalidomide capsules).
          b) Patient has relapsed or refractory disease; OR
       ii. Patient has Kaposi sarcoma-associated herpesvirus (KSHV)-associated inflammatory cytokine syndrome.
          Note: KSHV-associated inflammatory cytokine syndrome is also known as Kaposi sarcoma inflammatory cytokine syndrome (KICS).

12. **Melanoma, Cutaneous.** Approve for 1 year if the patient meets ALL of the following (A, B, C, and D):
    A) Patient is ≥ 18 years of age; AND
    B) Patient has metastatic or unresectable disease; AND
    C) Patient has an activating *KIT* mutation; AND
    D) Patient has tried at least one systemic regimen.
    Note: Examples of a systemic regimen include: Opdivo (nivolumab intravenous infusion) + Yervoy (ipilimumab intravenous infusion), Opdualag

(nivolumab/relatlimab-rmbw intravenous infusion), Keytruda (pembrolizumab intravenous infusion), Opdivo, Tafinlar (dabrafenib capsules and tablets for suspension) + Mekinist (trametinib tablets and oral solution), Zelboraf (vemurafenib tablets) + Cotellic (cobimetinib tablets), Braftovi (encorafenib capsules) + Mektovi (binimetinib tablets).

13. Myeloid/Lymphoid Neoplasms with Eosinophilia. Approve for 1 year if the patient meets BOTH of the following (A and B):
- **A)** Patient is ≥ 18 years of age; AND
- **B)** Patient meets ONE of the following (i or ii):
  - **i.** The tumor has an *ABL1* rearrangement; OR
  - **ii.** The tumor has an *FIP1L1-PDGFRA* or *PDGFRB* rearrangement.

14. Pigmented Villonodular Synovitis/Tenosynovial Giant Cell Tumor. Approve for 1 year if the patient meets ONE of the following (A or B):
- **A)** Patient has tried Turalio (pexidartinib capsules) or Romvimza (vimseltinib capsules); OR
- **B)** Patient cannot take Turalio or Romvimza, according to the prescriber.
  Note: Examples of reasons for not being able to take Turalio or Romvimza include patients with elevated liver enzymes or concomitant use of medications that are associated with hepatotoxicity.

CONDITIONS NOT COVERED

- **Gleevec® (imatinib tablets - Novartis, generic)**
- **Imkeldi® (imatinib oral solution – Shorla Oncology)**

is(are) considered not medically necessary for ANY other use(s); criteria will be updated as new published data are available.

REFERENCES

1. Gleevec® tablets [prescribing information]. East Hanover, NJ: Novartis; March 2024.
2. Imatinib tablets [prescribing information]. Cranbury, NJ: Sun; Sept 2022.
3. Imkeldi oral solution [prescribing information]. Cambridge, MA: Shorla Oncology; November 2024.
4. The NCCN Drugs & Biologics Compendium. © 2026 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on March 18, 2026. Search term: imatinib.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	No criteria changes.	05/01/2024
Selected Revision	A new formulation of imatinib (Imkeldi [imatinib oral solution]) was added to the policy with the same criteria as imatinib. The name of the policy was changed to "Imatinib Products Prior Authorization Policy."	01/08/2025
Annual Revision	**Acute Lymphoblastic Leukemia:** The following option for approval was added, "patient has *ABL1*-class translocation." **Chronic Myeloid Leukemia**: The following option for approval was added, "patient has *BCR::ABL1*-positive chronic myeloid leukemia."	03/26/2025

	Graft-Versus-Host Disease, Chronic: Niktimvo (axatilimab-csfr intravenous infusion) was added to the examples of a systemic treatment in the Note. **Melanoma, Cutaneous:** The following example of systemic regimen in the Note was modified from Opdivo + Opdualag (nivolumab/relatlimab-rmbw intravenous infusion) to Opdualag (nivolumab/relatlimab-rmbw intravenous infusion). **Pigmented Villonodular Synovitis/Tenosynovial Giant Cell Tumor:** Romvimza (vimseltinib capsules) was added as an option of a medication that patient has to try or that patient cannot take. Romvimza was added to the Note as well.	
Annual Revision	**Systemic Mastocytosis**: The qualifier of "Aggressive" was removed from the condition of approval. The requirement that the disease is *KIT* D816V mutation negative or unknown was added. **Kaposi Sarcoma:** An option for approval was added for a patient that has Kaposi sarcoma-associated herpesvirus (KSHV)-associated inflammatory cytokine syndrome. A Note was added which states that KSHV-associated inflammatory cytokine syndrome is also known as Kaposi sarcoma inflammatory cytokine syndrome (KICS).	03/25/2026