Mass General Brigham
Health Plan

Imkeldi (imatinib) oral solution
Effective 05/01/2025

Plan	☐ MassHealth UPPL ☒Commercial/Exchange	**Program Type**	☒ Prior Authorization ☐ Quantity Limit ☐ Step Therapy
Benefit	☒ Pharmacy Benefit ☐ Medical Benefit		
Specialty Limitations	This medication has been designated specialty and must be filled through a contracted specialty pharmacy.		
Contact Information	**Medical and Specialty Medications** All Plans | Phone: 877-519-1908 | Fax: 855-540-3693		
	Non-Specialty Medications All Plans | Phone: 800-711-4555 | Fax: 844-403-1029		
Exceptions	N/A		

Overview

Imkeldi (imatinib) oral solution is a kinase inhibitor 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 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 Ph+ acute lymphoblastic leukemia (ALL)
- Pediatric patients with newly diagnosed 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-PDGFRα 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 FIP1LI-PDGFRα fusion kinase negative or unknown
- Adult patients with unresectable, recurrent, 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

Coverage Guidelines

Authorization may be granted for members new to the plan within the past 90 days who are currently receiving treatment with the requested medication, excluding when the product is obtained as samples or via manufacturer's patient assistance programs

OR

Authorizations may be granted when all the following criteria are met:

1. Member has had a trial and failure, intolerance or contraindication to imatinib tablet or a clinical rationale why the member cannot administer imatinib tablet is provided

Continuation of Therapy

Requests for reauthorization will be approved when the following criteria are met:

1. Member had had a positive response to therapy and does not show evidence of disease progression or toxicity

Limitations

1. Initial and reauthorization requests will be approved for 12 months.
2. The following quantity limitations apply:

Drug Name	Quantity Limit
Imkeldi oral solution	10 mL/day

References

1. Imkeldi (imatinib) oral solution [prescribing information]. Cambridge, MA: Shorla Oncology Inc.; November 2024.

Review History

02/12/2025 – Created for February P&T. Effective 05/01/2025.