

POLICY NUMBER UM_ONC_1177	SUBJECT Gleevec (imatinib mesylate)	DEPT/PROGRAM UM Dept	PAGE 1 OF 3
DATES COMMITTEE REVIEWED 09/09/11, 01/09/13, 01/08/14, 06/09/15, 06/08/16, 04/08/20	APPROVAL DATE April 8, 2020	EFFECTIVE DATE April 24, 2020	COMMITTEE APPROVAL DATES (latest version listed last) 09/09/11, 01/09/13, 01/08/14, 06/09/15, 06/08/16, 04/08/20
PRIMARY BUSINESS OWNER: UM APPROVED BY: Dr. Andrew Hertler	COMMITTEE/BOARD APPROVAL Utilization Management Committee		
URAC STANDARDS HUM 1	NCQA STANDARDS UM 2	ADDITIONAL AREAS OF IMPACT	
CMS REQUIREMENTS	STATE/FEDERAL REQUIREMENTS	APPLICABLE LINES OF BUSINESS All	

I. PURPOSE

To define and describe the accepted indications for Gleevec (imatinib mesylate) usage in the treatment of cancer, including FDA approved indications, and off-label indications.

New Century is responsible for processing all medication requests from network ordering providers. Medications not authorized by New Century may be deemed as not approvable and therefore not reimbursable.

The use of this drug must be supported by one of the following: FDA approved product labeling, CMS-approved compendia, National Comprehensive Cancer Network (NCCN), American Society of Clinical Oncology (ASCO) clinical guidelines, or peer-reviewed literature that meets the requirements of the CMS Medicare Benefit Policy Manual Chapter 15.

II. INDICATIONS FOR USE/INCLUSION CRITERIA

1. PREFERRED MEDICATION GUIDANCE FOR INITIAL REQUEST:

- When health plan Medicaid coverage provisions- including any applicable PDLs (Preferred Drug Lists)- conflict with the coverage provisions in this drug policy, health plan Medicaid coverage provisions take precedence per the **Preferred Drug Guidelines OR**
- When health plan Exchange coverage provisions- including any applicable PDLs (Preferred Drug Lists)- conflict with the coverage provisions in this drug policy, health plan Exchange coverage provisions take precedence per the **Preferred Drug Guidelines OR**
- For Health Plans that utilize NCH UM Oncology Clinical Policies as the initial clinical criteria, the **Preferred Drug Guidelines shall follow NCH L1 Pathways** when applicable, otherwise shall follow NCH drug policies: **Error! Hyperlink reference not valid. AND**
- Continuation requests of previously approved non-preferred medication are not subject to this provision **AND**
- When available, generic alternatives are preferred over brand-name drugs.

2. Chronic myeloid leukemia (CML)

- NOTE: In the absence of a resistant mutation (i.e. a mutation that confers resistance to imatinib), the preferred agent for initial therapy is IMATINIB.**
- Imatinib use is supported in all phases of CML, including before and after marrow transplant.

3. Philadelphia Chromosome + Acute lymphoblastic leukemia (ALL)



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- a. **NOTE: Per NCH Policy & NCH Pathway the preferred tyrosine kinase inhibitor for this disease, is IMATINIB, unless the member is intolerant to/has disease that is refractory to Imatinib.**
- b. Gleevec (Imatinib) may be used as a single agent or in combination with chemotherapy for initial or subsequent therapy of Philadelphia chromosome + ALL.
4. **Bone Cancer – Chordoma**
 - a. Gleevec (imatinib mesylate) is being used as single-agent therapy or in combination with cisplatin or sirolimus for the treatment of recurrent chordoma.
5. **Melanoma**
 - a. The member has metastatic or unresectable melanoma with activating mutations of C-KIT.
6. **Myelodysplastic syndrome (MDS)**
 - a. The member has MDS or myeloproliferative disease associated with PDGFR (platelet-derived growth factor receptor) gene rearrangements (i.e. Chronic myelomonocyte leukemia, atypical chronic myeloid leukemia, juvenile myelomonocyte leukemia).
7. **Gastrointestinal stromal tumors (GIST)**
 - a. **NOTE: The preferred agent, per NCH Pathway & NCH Policy, for primary or initial therapy is IMATINIB.**
 - b. The member has a diagnosis of CD117 (Kit) positive GIST AND Gleevec (imatinib mesylate) is being used as **ONE** of the following:
 - i. As primary or subsequent therapy **OR**
 - ii. Preoperative/postoperative therapy **OR**
 - iii. As therapy for unresectable/metastatic disease.
8. **Dermatofibrosarcoma protuberans (DFSP)**
 - a. The member has DFSP positive for t(17;22) translocation **AND**
 - b. Gleevec (imatinib mesylate) is being used as one of the following:
 - i. As adjuvant therapy in members with positive surgical margins following excision
 - ii. For recurrent or metastatic disease.
9. **Hypereosinophilic syndrome (HES) or Chronic eosinophilic leukemia (CEL)**
 - a. The member has a diagnosis of HES or CEL with a positive test for FIP1L1-PDGFR alpha fusion kinase.
10. **Pigmented Villonodular Synovitis/Tenosynovial Giant Cell Tumor (PVNS/TGCT)**
 - a. The member has PVNS/TGCT and Gleevec (imatinib mesylate) is being used as single agent.
11. **Systemic mastocytosis (SM)**
 - a. The member has aggressive SM without D816V c-Kit mutation or if eosinophilia is present with FIP1L1-PDGFR alpha fusion gene.

III. EXCLUSION CRITERIA

1. Disease progression on Gleevec (imatinib).



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2. Dosing exceeds single dose limit of Gleevec (imatinib mesylate) 800 mg.
3. Do not exceed 240 (100 mg) tablets/month, or 60 (400 mg) tablets/month .
4. Treatment exceeds the maximum 36 months duration limit for adjuvant GIST.
5. Indications not supported by CMS recognized compendia or acceptable peer reviewed literature.

IV. MEDICATION MANAGEMENT

Please refer to the FDA label/package insert for details regarding these topics.

V. APPROVAL AUTHORITY

1. Review – UM Department
2. Final Approval – UM Committee

VI. ATTACHMENTS

None

VII. REFERENCES

1. Gleevec prescribing information. Novartis Pharmaceuticals Corporation East Hanover, New Jersey. 2019.
2. Clinical Pharmacology Elsevier Gold Standard. 2020.
3. Micromedex® Healthcare Series: Thompson Micromedex, Greenwood Village, Co. 2020.
4. National Comprehensive Cancer Network. Cancer Guidelines and Drugs and Biologics Compendium. 2020.