Drug Policy:

Gleevec™ (imatinib mesylate)

POLICY NUMBER UM ONC_1177	**SUBJECT** Gleevec™ (imatinib mesylate)		**DEPT/PROGRAM** UM Dept	**PAGE 1 of 5**
DATES COMMITTEE REVIEWED 09/09/11, 01/09/13, 01/08/14, 06/09/15, 06/08/16, 04/08/20, 02/10/21, 11/15/21	**APPROVAL DATE** November 15, 2021	**EFFECTIVE DATE** November 29, 2021	**COMMITTEE APPROVAL DATES** 09/09/11, 01/09/13, 01/08/14, 06/09/15, 06/08/16, 04/08/20, 02/10/21, 11/15/21	
PRIMARY BUSINESS OWNER: UM		**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** Commercial, Exchange, Medicaid	

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 Health (NCH) is responsible for processing all medication requests from network ordering providers. Medications not authorized by NCH 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

A. PREFERRED MEDICATION GUIDANCE FOR INITIAL REQUEST:

1. 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
2. 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

3. 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 AND
4. Continuation requests of previously approved, non-preferred medication are not subject to this provision AND
5. When available, generic alternatives are preferred over brand-name drugs.

B. Chronic myeloid leukemia (CML)

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

C. Philadelphia Chromosome + Acute lymphoblastic leukemia (ALL)

1. NOTE: Per NCH Policy & NCH Pathway the preferred tyrosine kinase inhibitor for this disease, is generic IMATINIB, unless the member is intolerant to/has disease that is refractory to imatinib.
2. Imatinib may be used as a single agent or in combination with chemotherapy for initial or subsequent therapy of Philadelphia chromosome + ALL.

D. Bone Cancer – Chordoma

1. Imatinib is being used as single-agent therapy or in combination with cisplatin or sirolimus for the treatment of recurrent chordoma.

E. Melanoma

1. The member has metastatic or unresectable melanoma with activating mutations of C-KIT.

F. Myelodysplatic syndrome (MDS)

1. 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).

G. Gastrointestinal stromal tumors (GIST)

1. NOTE: The preferred agent, per NCH Pathway & NCH Policy, for adjuvant therapy (for surgically resected disease) and for primary/initial therapy of unresectable/recurrent/metastatic disease is generic IMATINIB.
2. The member has a diagnosis of CD117 (Kit) positive GIST AND Imatinib is being used as ONE of the following:
    a. As primary or subsequent therapy for metastatic/unresectable/recurrent disease OR
    b. For preoperative (neoadjuvant)/postoperative (adjuvant) therapy of resected disease.

H. Dermatofribrosarcoma protuberans (DFSP)

1. The member has DFSP positive for t(17;22) translocation AND
2. Imatinib is being used as one of the following:
    a. As adjuvant therapy in members with positive surgical margins following excision
    b. For recurrent or metastatic disease.

I. Hypereosinophilic syndrome (HES) or Chronic eosinophilic leukemia (CEL)

1. The member has a diagnosis of HES or CEL with a positive test for FIPL1L-PDGFR alpha fusion kinase.

J. Pigmented Villonodular Synovitis/Tenosynovial Giant Cell Tumor (PVNS/TGCT)

1. The member has PVNS/TGCT and Gleevec (imatinib mesylate) is being used as single agent.

K. Systemic mastocytosis (SM)

1. The member has aggressive SM without D816V c-Kit mutation or if eosinophilia is present with FIP1L1-PDGFRA fusion gene.

III. EXCLUSION CRITERIA

A. Disease progression on Gleevec (imatinib).

B. Dosing exceeds single dose limit of Gleevec (imatinib mesylate) 800 mg.

C. Do not exceed 240 (100 mg) tablets/month or 60 (400 mg) tablets/month.

D. Treatment exceeds the maximum 36 months duration limit for adjuvant GIST.

E. Investigational use of Gleevec (imatinib mesylate) with an off-label indication that is not sufficient in evidence or is not generally accepted by the medical community. Sufficient evidence that is not supported by CMS recognized compendia or acceptable peer reviewed literature is defined as any of the following:

1. Whether the clinical characteristics of the patient and the cancer are adequately represented in the published evidence.
2. Whether the administered chemotherapy/biologic therapy/immune therapy/targeted therapy/other oncologic therapy regimen is adequately represented in the published evidence.
3. Whether the reported study outcomes represent clinically meaningful outcomes experienced by patients. Generally, the definition of Clinically Meaningful outcomes are those recommended by ASCO, e.g., Hazard Ratio of < 0.80 and the recommended survival benefit for OS and PFS should be at least 3 months.
4. Whether the experimental design, in light of the drugs and conditions under investigation, is appropriate to address the investigative question. (For example, in some clinical studies, it may be unnecessary or not feasible to use randomization, double blind trials, placebos, or crossover).
5. That non-randomized clinical trials with a significant number of subjects may be a basis for supportive clinical evidence for determining accepted uses of drugs.
6. That case reports are generally considered uncontrolled and anecdotal information and do not provide adequate supportive clinical evidence for determining accepted uses of drugs.
7. That abstracts (including meeting abstracts) without the full article from the approved peer-reviewed journals lack supporting clinical evidence for determining accepted uses of drugs.

IV. MEDICATION MANAGEMENT

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

V. APPROVAL AUTHORITY

A. Review – Utilization Management Department

B. Final Approval – Utilization Management Committee

VI. ATTACHMENTS

A. None

VII. REFERENCES

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R. Medicare Benefit Policy Manual Chapter 15 Covered Medical and Other Health Services: https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c15.pdf.