Cigna National Preferred Formulary Coverage Policy

Effective Date .................................. 1/1/2021
Next Review Date................................. 1/1/2022
Coverage Policy Number ...................... NPF004

Formulary Exception
Oncology – Gleevec (imatinib mesylate tablet for oral use)

Table of Contents

NPF Coverage Policy ................................. 1
References ............................................. 3
Last Revision Details ................................. 3

Related Coverage Resources

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. 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.

NPF Coverage Policy

Cigna covers imatinib mesylate (Gleevec™) tablets as medically necessary when the following criteria are met:

Documentation: Documentation is required for use of generic imatinib as noted in the criteria as [documentation required]. Documentation may include, but is not limited to, chart notes, prescription claims records, prescription receipts and/or other information.

Approval Duration: All approvals are provided for 1 year.

Criteria

1. Acute Lymphoblastic Leukemia (ALL) That is Philadelphia Chromosome Positive (Ph+). Approve if the individual has tried generic imatinib mesylate tablets AND cannot take generic imatinib mesylate tablets due to a formulation difference in the inactive ingredient(s) [e.g., difference in dyes, fillers, preservatives] between the brand and the bioequivalent generic product which, per the prescribing physician, would result in a significant allergy or serious adverse reaction [documentation required].

2. Chronic Myeloid Leukemia (CML) That is Philadelphia Chromosome Positive (Ph+). Approve if the individual has tried generic imatinib mesylate tablets AND cannot take generic imatinib mesylate tablets due
to a formulation difference in the inactive ingredient(s) [e.g., difference in dyes, fillers, preservatives] between the brand and the bioequivalent generic product which, per the prescribing physician, would result in a significant allergy or serious adverse reaction [documentation required].

3. Dermatofibrosarcoma Protuberans (DFSP). Approve if the individual has tried generic imatinib mesylate tablets AND cannot take generic imatinib mesylate tablets due to a formulation difference in the inactive ingredient(s) [e.g., difference in dyes, fillers, preservatives] between the brand and the bioequivalent generic product which, per the prescribing physician, would result in a significant allergy or serious adverse reaction [documentation required].

4. Gastrointestinal Stromal Tumors (GIST). Approve if the individual has tried generic imatinib mesylate tablets AND cannot take generic imatinib mesylate tablets due to a formulation difference in the inactive ingredient(s) [e.g., difference in dyes, fillers, preservatives] between the brand and the bioequivalent generic product which, per the prescribing physician, would result in a significant allergy or serious adverse reaction [documentation required].

5. Hypereosinophilic Syndrome (HES) and/or Chronic Eosinophilic Leukemia (CEL). Approve if the individual has tried generic imatinib mesylate tablets AND cannot take generic imatinib mesylate tablets due to a formulation difference in the inactive ingredient(s) [e.g., difference in dyes, fillers, preservatives] between the brand and the bioequivalent generic product which, per the prescribing physician, would result in a significant allergy or serious adverse reaction [documentation required].

6. Mastocytosis, Aggressive Systemic Mastocytosis (ASM): Approve if the individual has tried generic imatinib mesylate tablets AND cannot take generic imatinib mesylate tablets due to a formulation difference in the inactive ingredient(s) [e.g., difference in dyes, fillers, preservatives] between the brand and the bioequivalent generic product which, per the prescribing physician, would result in a significant allergy or serious adverse reaction [documentation required].

7. Myelodysplastic/Myeloproliferative Disease (MDS/MPD) [e.g., Polycythemia Vera, Myelofibrosis]: Approve if the individual meets the following criteria (A and B):
   A. The condition is associated with Platelet-Derived Growth Factor Receptor (PDGFR) gene rearrangements; AND
   B. The individual has tried generic imatinib mesylate tablets AND cannot take generic imatinib mesylate tablets due to a formulation difference in the inactive ingredient(s) [e.g., difference in dyes, fillers, preservatives] between the brand and the bioequivalent generic product which, per the prescribing physician, would result in a significant allergy or serious adverse reaction [documentation required].

8. Acquired Immune Deficiency Syndrome (AIDS)-Related Kaposi’s Sarcoma: Approve if the individual meets the following criteria (A, B and C):
   A. The individual has tried at least one regimen or therapy; AND
   Note: Examples include liposomal doxorubicin, paclitaxel, Pomalyst® [pomalidomide capsules], Revlimid® (lenalidomide capsules), etoposide, and Thalomid® [thalidomide capsules]).
   B. The individual has relapsed or refractory disease; AND
   C. The individual has tried generic imatinib mesylate tablets AND cannot take generic imatinib mesylate tablets due to a formulation difference in the inactive ingredient(s) [e.g., difference in dyes, fillers, preservatives] between the brand and the bioequivalent generic product which, per the prescribing physician, would result in a significant allergy or serious adverse reaction [documentation required].

9. Chordoma: Approve if the individual has tried generic imatinib mesylate tablets AND cannot take generic imatinib mesylate tablets due to a formulation difference in the inactive ingredient(s) [e.g., difference in dyes, fillers, preservatives] between the brand and the bioequivalent generic product which, per the prescribing physician, would result in a significant allergy or serious adverse reaction [documentation required].

10. Fibromatosis (Desmoid Tumors): Approve if the individual meets the following criteria (A and B):
    A. The individual has advanced or unresectable fibromatosis (desmoid tumors); AND
B. The individual has tried generic imatinib mesylate tablets AND cannot take generic imatinib mesylate tablets due to a formulation difference in the inactive ingredient(s) [e.g., difference in dyes, fillers, preservatives] between the Brand and the bioequivalent generic product which, per the prescribing physician, would result in a significant allergy or serious adverse reaction [documentation required].

11. Graft Versus Host Disease (GVHD), Chronic: Approve if the individual meets the following criteria (A and B):
   A. The individual has tried at least one conventional systemic treatment for graft versus host disease; AND
   Note: Examples include corticosteroids (methylprednisolone, prednisone); cyclosporine, tacrolimus, mycophenolate mofetil, Imbruvica® (ibrutinib capsules and tablets); low-dose methotrexate; sirolimus; and Jakafi® (ruxolitinib tablets).
   B. The individual has tried generic imatinib mesylate tablets AND cannot take generic imatinib mesylate tablets due to a formulation difference in the inactive ingredient(s) [e.g., difference in dyes, fillers, preservatives] between the Brand and the bioequivalent generic product which, per the prescribing physician, would result in a significant allergy or serious adverse reaction [documentation required].

12. Metastatic Melanoma: Approve if the individual meets the following criteria (A and B):
   A. The individual has c-Kit-positive advanced/recurrent or metastatic melanoma; AND
   B. The individual has tried generic imatinib mesylate tablets AND cannot take generic imatinib mesylate tablets due to a formulation difference in the inactive ingredient(s) [e.g., difference in dyes, fillers, preservatives] between the Brand and the bioequivalent generic product which, per the prescribing physician, would result in a significant allergy or serious adverse reaction [documentation required].

13. Pigmented Villonodular Synovitis/Tenosynovial Giant Cell Tumor (PVNS/TGCT): Approve if the individual meets the following criteria (A and B):
   A. The individual meets one of the following (i or ii):
      i. The individual has tried Turalio (pexidartinib capsules); OR
      ii. According to the prescriber, the individual cannot take Turalio; AND
      Note: Examples of reasons for not being able to take Turalio include individuals with elevated liver enzymes or concomitant use of medications that are associated with hepatotoxicity.
   B. The individual has tried generic imatinib mesylate tablets AND cannot take generic imatinib mesylate tablets due to a formulation difference in the inactive ingredient(s) [e.g., difference in dyes, fillers, preservatives] between the Brand and the bioequivalent generic product which, per the prescribing physician, would result in a significant allergy or serious adverse reaction [documentation required].

Conditions Not Covered
Any other exception is considered not medically necessary.

References

Last Revision Details

<table>
<thead>
<tr>
<th>Annual revision</th>
<th>Criteria was updated to match Gleevec PA criteria:</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Acquired Immune Deficiency Syndrome-Related Kaposi’s Sarcoma: The criteria that requires a trial of one regimen now states “at least one regimen or therapy” and the alternatives are now listed as a note instead of in the criteria.</td>
<td></td>
</tr>
<tr>
<td>2. Graft Versus Host Disease, Chronic: The criteria that requires a trial of one conventional systemic treatment was changed to state “at least one” and the alternatives are now listed as a note instead of in the criteria.</td>
<td></td>
</tr>
<tr>
<td>04/27/2020</td>
<td></td>
</tr>
</tbody>
</table>
3. Pigmented Villonodular Synovitis/Tenosynovial Giant Cell Tumor: Criteria were added that the patient has tried Turalio or according to the prescriber the patient cannot take Turalio. A note was added that reasons for not being able to take Turalio include patients with elevated liver enzymes or concomitant use of medications that are associated with hepatotoxicity.