FORMULARY EXCEPTION POLICY

POLICY: Oncology – Gleevec® (imatinib mesylate tablets for oral use – Novartis)

DATE EFFECTIVE: 3/20/2019

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
Coverage of brand Gleevec tablets are recommended in those who meet the following criteria:

FDA-Approved Indications

1. Acute Lymphoblastic Leukemia (ALL) That is Philadelphia Chromosome Positive (Ph+). Approve if the patient 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 patient 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 patient 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 patient 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 patient 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 patient 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 patient meets the following criteria (A and B):
   A. The condition is associated with Platelet-Derived Growth Factor Receptor (PDGFR) gene rearrangements; AND
   B. The patient 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 patient meets the following criteria (A, B and C):
   A. The patient has tried one regimen (e.g., liposomal doxorubicin, paclitaxel, Pomalyst® [pomalidomide capsules], and Thalomid® [thalidomide capsules]); AND
   B. The patient has relapsed or refractory disease; AND
   C. The patient 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 patient 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 patient meets the following criteria (A and B):
    A. The patient has advanced or unresectable fibromatosis (desmoid tumors); AND
    B. The patient 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 patient meets the following criteria (A and B):
    A. The patient has tried one conventional systemic treatment for graft versus host disease (e.g., corticosteroids [methylprednisolone, prednisone], cyclosporine, tacrolimus, mycophenolate mofetil, Imbruvica® [ibrutinib capsules]); AND
    B. The patient 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].
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12. Metastatic Melanoma: Approve if the patient meets the following criteria (A and B):
   A. The patient has c-Kit-positive advanced/recurrent or metastatic melanoma; AND
   B. The patient 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 patient 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].

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<thead>
<tr>
<th>HISTORY</th>
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<tr>
<td><strong>Type of Revision</strong></td>
<td><strong>Summary of Changes</strong></td>
<td><strong>Date</strong></td>
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<tr>
<td>New policy</td>
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<td>7/1/2018</td>
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<tr>
<td>Annual revision</td>
<td>Criteria were developed for patients with AIDS-related Kaposi Sarcoma to approve if the patient has tried one systemic therapy.</td>
<td>3/20/2019</td>
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