VENTURA COUNTY
HEALTH CARE PLAN

FORMULARY EXCEPTION POLICY

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

DATE EFFECTIVE: 4/27/2020

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 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 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 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 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]**.

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 meets the following criteria (A and B):
    - **A.** The patient meets one of the following (i or ii):
      - **i.** The patient has tried Turalio (pexidartinib capsules); OR
      - **ii.** According to the prescriber, the patient cannot take Turalio; AND

      Note: Examples of reasons for not being able to take Turalio include patients with elevated liver enzymes or concomitant use of medications that are associated with hepatoxicity.
    - **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]**.

HISTORY

Type of Revision	Summary of Changes	Date
New policy	--	7/1/2018
Annual revision	Criteria were developed for patients with AIDS-related Kaposi Sarcoma to approve if the patient has tried one systemic therapy.	3/20/2019
Annual revision	Criteria was updated to match Gleevec PA criteria: 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. 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. 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.	04/27/2020