VENTURA COUNTY
HEALTH CARE PLAN

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]**.

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]**.

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