

nilotinib (TASIGNA)

Diagnosis Considered for Coverage:

- Chronic Myeloid Leukemia (CML)
- Gastrointestinal Stromal Tumor (GIST)
- Acute Lymphoblastic Leukemia (ALL)
- Myeloid, lymphoid, or mixed lineage neoplasms
- Tenosynovial giant cell tumor (TGCT) or pigmented villonodular synovitis (PVNS)

Coverage Criteria:

For Chronic Myelogenous Leukemia (CML):

- *Firstline therapy request:* Intolerance or contraindication (including contraindicated mutations per NCCN) to imatinib (Gleevec), **and**
- Dose does not exceed 800 mg per day.

For diagnosis of gastrointestinal stromal tumor (GIST):

- Being used as subsequent therapy after disease progression with all of the following:
 - imatinib (Gleevec),
 - Sutent (sunitinib) or Sprycel (dasatinib),
 - Stivarga (regorafenib),
 - Qinlock (ripretinib),**and**
- Being used as a single agent, **and**
- Dose does not exceed 800 mg per day.

For diagnosis of Acute Lymphoblastic Leukemia (ALL):

- Patient is Philadelphia Chromosome positive, **and**
- Intolerance or contraindication (including contraindicated mutations per NCCN) to imatinib (Gleevec), **and**
- Dose does not exceed 800 mg per day.

For diagnosis of myeloid, lymphoid, or mixed lineage neoplasms:

- Provider attestation of eosinophilia, **and**
- Provider attestation of ABL1 rearrangement, **and**
- Dose does not exceed 800 mg per day.

For diagnosis of tenosynovial giant cell tumor:

- Being used as a single agent therapy, **and**
- Dose does not exceed 800 mg per day.

Coverage Duration: one year

Effective Date: 3/1/2023