

Specialty Pharmacy Program

Tasigna® (nilotinib)

DESCRIPTION

Tasigna is an oral tyrosine kinase inhibitor indicated for the treatment of chronic myelogenous leukemia in adults who have resistance or intolerance to previous treatment that included Gleevec (imatinib).

APPROVAL DURATION

Approval duration: 1 year

APPROVAL CRITERIA

FDA-Approved Indication(s)

1. Treatment of chronic phase and accelerated phase Philadelphia chromosome positive chronic myelogenous leukemia in adult patients resistant or intolerant to prior therapy that included imatinib.

Off-Label Indication(s)

Requests for off-label use of Tasigna will be reviewed and approved when sufficiently supported by evidence from major compendia, published peer-reviewed medical literature, nationally accepted practice guidelines, or expert consensus statements. The major compendia that are recognized include AHFS® Drug Information, Thomson Micromedex®, National Comprehensive Cancer Network Drugs and Biologics Compendium™, and Clinical Pharmacology.