

# TASIGNA, DANZITEN (nilotinib)

## **Pre - PA Allowance**

None

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## **Prior-Approval Requirements**

## Tasigna only

Age 1 year of age and older

## **Diagnoses**

Patient must have **ONE** of the following:

- 1. Chronic myeloid leukemia (CML)
  - a. Patient MUST have tried ONE of the preferred products (generic Sprycel: dasatinib or generic Gleevec: imatinib) unless the patient has a valid medical exception (e.g., inadequate treatment response, intolerance, contraindication)
- 2. Chronic myeloid leukemia (CML) with hematopoietic stem cell transplant (HSCT)
  - a. In combination with induction therapy
- 3. Ph+ Acute lymphoblastic leukemia (ALL)
- 4. Ph+ Acute lymphoblastic leukemia (ALL) post hematopoietic stem cell transplant (HSCT)
  - a. After achieving complete response to induction therapy

#### **AND ALL** of the following for **ALL** above indications:

- Confirmed by molecular testing by the detection of the Ph chromosome or BCR-ABL gene prior to initiation of therapy
- 2. If the patient has had prior therapy with a TKI then **ONE** of the following requirements must be met:
  - a. Member experienced resistance to prior therapy with TKI
    - Results from mutational testing are negative for the T315I mutation
  - Member experienced toxicity or intolerance to prior therapy with a TKI
- 5. Gastrointestinal stromal tumor (GIST)



# TASIGNA, DANZITEN (nilotinib)

 Disease progression after prior therapy with imatinib, sunitinib or regorafenib

### **Danziten only**

Age 18 years of age and older

## **Diagnosis**

Patient must have the following:

- 1. Chronic myeloid leukemia (CML)
  - a. Confirmed by molecular testing by the detection of the Ph chromosome or BCR-ABL gene prior to initiation of therapy
  - b. Patient **MUST** have tried **ONE** of the preferred products (generic Sprycel: dasatinib or generic Gleevec: imatinib) unless the patient has a valid medical exception (e.g., inadequate treatment response, intolerance, contraindication)

#### **AND ONE** of the following:

- 1. Newly diagnosed with chronic phase
- 2. Resistant to or intolerant to prior therapy that included imatinib

## **Prior - Approval Limits**

## Quantity

Tasigna	
Strength	Quantity
50 mg	504 capsules per 84 days <b>OR</b>
150 mg	336 capsules per 84 days <b>OR</b>
200 mg	336 capsules per 84 days

Danziten	
Strength	Quantity
71 mg	336 tablets per 84 days <b>OR</b>
95 mg	336 tablets per 84 days

#### **Duration** 12 months



# TASIGNA, DANZITEN (nilotinib)

# Prior – Approval Renewal Requirements

### Tasigna only

Age 1 year of age and older

## **Diagnoses**

Patient must have **ONE** of the following:

- 1. Chronic myeloid leukemia (CML)
- 2. Chronic myeloid leukemia (CML) with hematopoietic stem cell transplant (HSCT)
- 3. Ph+ Acute lymphoblastic leukemia (ALL)
- 4. Ph+ Acute lymphoblastic leukemia (ALL) post hematopoietic stem cell transplant (HSCT)
- 5. Gastrointestinal stromal tumor (GIST)

### **Danziten only**

**Age** 18 years of age and older **Diagnosis** 

Patient must have the following:

1. Chronic myeloid leukemia (CML)

## Prior - Approval Renewal Limits

Same as above