

### **Pre - PA Allowance**

None

### **Prior-Approval Requirements**

### <u>Tasigna only</u>

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:
  - 1. 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
      - i. Results from mutational testing are negative for the T315I mutation
    - b. Member experienced toxicity or intolerance to prior therapy with a TKI
  - 5. Gastrointestinal stromal tumor (GIST)



# TASIGNA, DANZITEN

(nilotinib)

a. 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 OR
150 mg	336 capsules per 84 days OR
200 mg	336 capsules per 84 days

Danziten	
Strength	Quantity
71 mg	336 tablets per 84 days OR
95 mg	336 tablets per 84 days

#### **Duration** 12 months



(nilotinib)

### Prior – Approval *Renewal* Requirements

### <u>Tasigna only</u>

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