TASIGNA

<table>
<thead>
<tr>
<th>Brand Name</th>
<th>Generic Name</th>
<th>Length of Authorization</th>
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<tbody>
<tr>
<td>Tasigna</td>
<td>nilotinib</td>
<td>Calendar Year</td>
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Approvable Criteria:

1. Tasigna is being prescribed by, or in consultation with, an oncologist; **AND**
2. Member is 18 years of age or older; **AND**
3. Member has a documented diagnosis of Philadelphia chromosome positive (Ph+) chronic myelogenous leukemia (CML); **AND**
   - **For Resistant or Intolerant Chronic Phase and Accelerated Phase Ph+ CML:** Member has tried and failed or is contraindicated/intolerant to Gleevec (imatinib), **OR**
   - **For Newly Diagnosed Ph+ CML in Chronic Phase:** No trial and failure required.

Approvable Duration: Calendar Year.

Note:

- Gleevec (imatinib) resistance is defined as failure to achieve a complete hematologic response (by 3 months), cytogenetic response (by 6 months), or major cytogenic response (by 12 months) or progression of disease after a previous cytogenic or hematologic response.
- Gleevec (imatinib) intolerance is defined as discontinuation of treatment due to toxicity.

Dosage and Administration:

- **Resistant or Intolerant Ph+ CML-CP and CML-AP:** 400 mg orally BID.
- **Newly Diagnosed Ph+ CML-CP:** 300 mg orally BID.*

**QL = 112 x 28 DAYS**

**SELF-ADMINISTERED – RX ONLY**

**SPECIALTY PHARMACY PRODUCT**

For Baptist Health Plan to recognize a chemotherapy regimen as an accepted approach to treatment it must be included in the National Comprehensive Cancer Network® Clinical Practice Guidelines in Oncology (NCCN Guidelines®).

*References:
- Tasigna (nilotinib) prescribing information. East Hanover, NJ: Novartis Pharmaceuticals Corporation; 2012 May.