**Tasigna® (nilotinib)**
(Oral)

Last Review Date: 08/01/2017  
Date of Origin: 11/01/2012  

I. **Length of Authorization**

Coverage will be provided for six months and may be renewed.

II. **Dosing Limits**

A. **Quantity Limit (max daily dose) [Pharmacy Benefit]**:
   - Tasigna 150 mg capsules: 4 capsules per day
   - Tasigna 200 mg capsules: 4 capsules per day

B. **Max Units (per dose and over time) [Medical Benefit]**:
   - 800 mg per day

III. **Initial Approval Criteria**

Coverage is provided in the following conditions:

**Chronic Myelogenous Leukemia (CML) †**

- Patient is at least 18 years old: **AND**
- Patient’s disease is confirmed by either a Philadelphia chromosome-positive (Ph+) or BCR-ABL1 positive laboratory test result: **AND**
- Chronic or accelerated phase disease †
  - Patient is resistant, or intolerant, or had an inadequate response to prior tyrosine kinase inhibitor (TKI) therapies, consisting of a 3 month trial or longer, with any of the following: omacetaxine, imatinib, bosutinib, ponatinib, dasatinib, etc.
- Primary Treatment †
  - Used as single agent for newly diagnosed chronic phase disease †: **OR**
  - Used as single agent for myeloid blast phase or accelerated phase disease: **OR**
  - In combination with steroids for lymphoid blast phase disease: **OR**
  - In combination with induction chemotherapy for lymphoid or myeloid blast phase disease
• **Switch Therapy ‡**
  - Initial therapy was one of the following: imatinib or dasatinib; **AND**
  - Patient has *BCR-ABL1* transcript levels:
    - 0.1% to <1% at >12 months
    - 1% to 10% at 12 or >12 months
    - >10% at any response milestone

• **Continued Therapy ‡**
  - Patient has *BCR-ABL1* transcript levels:
    - <0.1% at any response milestone
    - 0.1% to <1% at any response milestone
    - 1% to 10% at 3, 6, or 12 months
    - >10% at 3 months

• **Post-allogeneic hematopoietic stem cell transplant (HCT) ‡**
  - Used in patients with a complete cytogenetic response (CCyR) for accelerated or blast phase disease; **OR**
  - Used in patients with molecular relapse (BCR-ABL1 transcript positive) following CCyR; **OR**
  - Used in patients with relapse or those who are not in CCyR

• **Used in disease with any of the following *BCR-ABL* KD mutations:** F317L/V/I/C, T315A, or V299L ‡

  - Patient has documented resistance or intolerance to prior therapy including imatinib (Gleevec)
    - Does not apply to newly diagnosed Philadelphia chromosome-positive (Ph+) chronic myeloid leukemia (CML) in chronic phase

**Acute Lymphoblastic Leukemia (ALL) ‡**

• **Patients disease is Philadelphia chromosome-positive (Ph+); **AND**

• **Relapsed-Refractory Treatment**
  - Used as a single agent therapy; **OR**
  - Used in combination with an induction therapy not previously used; **OR**
  - Used in patients with any of the following *BCR-ABL1* KD mutations: F317L/V/I/C, T315A, or V299L

• **Induction Treatment**
  - Patient’s age is at least 15 years old; **AND**
  - Used in combination with corticosteroids; **OR**
  - Used in combination with dexamethasone and vincristine; **OR**
  - Used as a component of cyclophosphamide, daunorubicin, vincristine and prednisone
• Maintenance Treatment
  o Used in combination with vincristine and prednisone: OR
  o Used in patients who are post-hematopoietic stem cell transplant

**Gastrointestinal stromal tumors (GIST) ‡**

• Patient is at least 18 years old: AND
• Patient’s disease is progressive after prior therapies, consisting of a 3 month trial or longer, with at least ONE of the following: imatinib, regorafenib or sunitinib

† FDA Approved Indication(s); ‡ Compendia Approved Indication(s)

**IV. Renewal Criteria**

Coverage can be renewed based upon the following criteria:

• Patient continues to meet criteria from section III: AND
• Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include the following: electrolyte abnormalities (hypomagnesemia, hypokalemia); cardiac toxicity (long QT syndrome); myelosuppression (neutropenia, thrombocytopenia, anemia); metabolic toxicity (increase lipase, pancreatitis); hepatotoxicity (severe changes in liver function tests); AND
• Patient has been adherent to therapy: AND

**Acute lymphoblastic leukemia (ALL) only:**

• Treatment response or stabilization of disease as indicated by CBC, bone marrow cytogenic analysis, QPCR, or FISH

**Chronic Myelogenous Leukemia (CML) only:**

• Treatment response as indicated by one of the following BCR-ABL1 (IS) transcript levels:
  o \( \leq 10\% \) at 3 months; OR
  o \( \leq 10\% \) at 6 months; OR
  o \( < 1\% \) at 12 months; OR
  o \( < 0.1\% \) beyond 12 months

  **NOTE:** cytogenetic assessment of response may be used if quantitative RT-PCR (QPCR) using International Scale (IS) for \textit{BCR-ABL1} is not available

**Gastrointestinal stromal tumors (GIST) only:**

• Tumor response with stabilization of disease or decrease in size of tumor or tumor spread

**V. Dosage/Administration**

<table>
<thead>
<tr>
<th>Indication</th>
<th>Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Maintenance Treatment</td>
<td></td>
</tr>
<tr>
<td>Gastrointestinal stromal tumors (GIST) ‡</td>
<td></td>
</tr>
</tbody>
</table>
Chronic Myelogenous Leukemia (CML) | 300 – 400 mg orally twice daily
Acute Lymphoblastic Leukemia (ALL) | 400 mg orally twice daily
Gastrointestinal stromal tumors (GIST) | 400 mg orally twice daily

VI. Billing Code/Availability Information

Jcode:
- J8999: Prescription drug, oral, chemotherapeutic, NOS
NDC:
- Tasigna 150 mg capsule -00078-0592-xx
- Tasigna 200 mg capsule-00078-0526-xx

VII. References


2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) for nilotinib hydrochloride monohydrate. National Comprehensive Cancer Network, 2017. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc.” To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed June 2017.

3. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) for Acute Lymphoblastic Leukemia. 1.2017. National Comprehensive Cancer Network, 2017. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc.” To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed June 2017.

4. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) for Chronic Myelogenous Leukemia 2.2017. National Comprehensive Cancer Network, 2017. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc.” To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed June 2017.

Appendix 1 – Covered Diagnosis Codes

<table>
<thead>
<tr>
<th>ICD-10</th>
<th>ICD-10 Description</th>
<th>Details</th>
</tr>
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<tbody>
<tr>
<td>C49.4</td>
<td>Malignant neoplasm of connective and soft tissue of abdomen</td>
<td></td>
</tr>
<tr>
<td>C49.8</td>
<td>Malignant neoplasm of overlapping sites of connective and soft tissue</td>
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</tr>
<tr>
<td>C49.9</td>
<td>Malignant neoplasm of connective and soft tissue, unspecified</td>
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</tr>
<tr>
<td>C91.00</td>
<td>Acute lymphoblastic leukemia not having achieved remission</td>
<td></td>
</tr>
<tr>
<td>C91.01</td>
<td>Acute lymphoblastic leukemia, in remission</td>
<td></td>
</tr>
<tr>
<td>C91.02</td>
<td>Acute lymphoblastic leukemia, in relapse</td>
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</tr>
<tr>
<td>C92.10</td>
<td>Chronic myeloid leukemia, BCR/ABL-positive, not having achieved remission</td>
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<tr>
<td>C92.11</td>
<td>Chronic myeloid leukemia, BCR/ABL-positive, in remission</td>
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</tr>
<tr>
<td>C92.12</td>
<td>Chronic myeloid leukemia, BCR/ABL-positive, in relapse</td>
<td></td>
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</table>

Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD) and Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. They can be found at: http://www.cms.gov/medicare-coverage-database/search/advanced-search.aspx. Additional indications may be covered at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD): N/A

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<tr>
<th>Jurisdiction</th>
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<th>Contractor</th>
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<tbody>
<tr>
<td>E (1)</td>
<td>CA, HI, NV, AS, GU, CNMI</td>
<td>Noridian Healthcare Solutions, LLC</td>
</tr>
<tr>
<td>F (2 &amp; 3)</td>
<td>AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ</td>
<td>Noridian Healthcare Solutions, LLC</td>
</tr>
<tr>
<td>5</td>
<td>KS, NE, IA, MO</td>
<td>Wisconsin Physicians Service Insurance Corp (WPS)</td>
</tr>
<tr>
<td>6</td>
<td>MN, WI, IL</td>
<td>National Government Services, Inc. (NGS)</td>
</tr>
<tr>
<td>H (4 &amp; 7)</td>
<td>LA, AR, MS, TX, OK, CO, NM</td>
<td>Novitas Solutions, Inc.</td>
</tr>
<tr>
<td>8</td>
<td>MI, IN</td>
<td>Wisconsin Physicians Service Insurance Corp (WPS)</td>
</tr>
<tr>
<td>N (9)</td>
<td>FL, PR, VI</td>
<td>First Coast Service Options, Inc.</td>
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<td>J (10)</td>
<td>TN, GA, AL</td>
<td>Cahaba Government Benefit Administrators, LLC</td>
</tr>
<tr>
<td>M (11)</td>
<td>NC, SC, WV, VA (excluding below)</td>
<td>Palmetto GBA, LLC</td>
</tr>
<tr>
<td>L (12)</td>
<td>DE, MD, PA, NJ, DC (includes Arlington &amp; Fairfax counties and the city of Alexandria in VA)</td>
<td>Novitas Solutions, Inc.</td>
</tr>
<tr>
<td>K (13 &amp; 14)</td>
<td>NY, CT, MA, RI, VT, ME, NH</td>
<td>National Government Services, Inc. (NGS)</td>
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<tr>
<td>15</td>
<td>KY, OH</td>
<td>CGS Administrators, LLC</td>
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