Market Applicability							
Market	**DC**	**GA**	**KY**	**MD**	**NJ**	**NY**	**WA**
Applicable	X	X	X	X	X	X	X

Tasigna (nilotinib)

Override(s)	Approval Duration
Prior Authorization Quantity Limit	1 year

Medications	Quantity Limit
Tasigna (nilotinib)	May be subject to quantity limit

APPROVAL CRITERIA

Requests for Tasigna (nilotinib) may be approved if the following criteria are met**:**

Individual has a diagnosis of one of the following:

I. Chronic Myeloid Leukemia (CML)
   A. Individual is 1 year of age or older (Label, NCCN 2A); **AND**
   B. Individual is newly diagnosed with chronic phase Philadelphia chromosome positive (Ph+) CML;
      OR
   C. Individual has chronic phase Ph+ CML which is resistant (i.e. relapsed/refractory) or intolerant to prior tyrosine-kinase therapy (TKI) therapy and does not have any of the following mutations: T315I, Y253H, E255K/V, F359V/C/I or G250E;

   OR
   D. Individual is 18 years of age or older (Label, NCCN 2A); **AND**
   E. Individual has chronic or accelerated phase Ph+ CML; **AND**
   F. Individual has disease which is resistant (i.e. relapsed/refractory) or intolerant to prior TKI therapy and does not have any of the following mutations: T315I, Y253H, E255K/V, F359V/C/I or G250E;

OR

II. Acute Lymphoblastic Leukemia (ALL) (NCCN 2A)
   A. Individual has a diagnosis of Ph+ ALL and is using in maintenance therapy; **AND**
   B. Individual is using in combination with vincristine and prednisone with or without methotrexate and mercaptopurine;
      OR
   C. Individual is using post-hematopoietic stem cell transplant;

Market Applicability							
Market	**DC**	**GA**	**KY**	**MD**	**NJ**	**NY**	**WA**
Applicable	X	X	X	X	X	X	X

OR

D. Individual has a diagnosis of Ph + ALL and is using in relapsed/refractory disease and does not have any of the following mutations: T315I, Y253H, E255K/V, F359V/C/I or G250E;

OR

E. Individual is using Tasigna (nilotinib) as a component of either induction therapy or in induction/consolidation therapy;

OR

III. Soft Tissue Sarcoma (NCCN 2A)

A. Individual is using for Gastrointestinal Stromal Tumors (GIST) for those no longer receiving benefit from imatinib, sunitinib, and regorafenib (NCCN 2A).

Note:

Tasigna (nilotinib) has black box warnings for QT prolongation and sudden death. ECGs to monitor the QTc, should be performed at baseline, seven days after initiation, following any dose adjustments, and periodically thereafter. The use of concomitant drugs known to prolong the QT interval and strong CYP3A4 inhibitors (e.g., ketoconazole, itraconazole, clarithromycin, atazanavir, indinavir, nefazodone, nelfinavir, ritonavir, saquinavir, telithromycin, voriconazole) should be avoided. Therapy should not be administered to individuals with hypokalemia, hypomagnesium, or long QT syndrome. Prior to administration and periodically during therapy, hypokalemia and hypomagnesemia should be monitored for and deficiencies corrected if occurs.

Key References:

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2020. URL: http://www.clinicalpharmacology.com. Updated periodically.
2. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm. 2020. Updated periodically.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2020; Updated periodically.
5. NCCN Clinical Practice Guidelines in Oncology™. © 2020 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: http://www.nccn.org/index.asp. 2020. Updated periodically.
    a. Acute Lymphoblastic Leukemia. V1.2020. Revised January 15, 2020.
    b. Chronic Myeloid Leukemia. V2.2020. Revised September 25, 2019.
    c. Soft Tissue Sarcoma. V4.2019. Revised September 12, 2019.