Market Applicability														
Market	**DC**	**FL & FHK**	**FL MMA**	**FL LTC**	**GA**	**KS**	**KY**	**MD**	**NJ**	**NV**	**NY**	**TN**	**TX**	**WA**
Applicable	X	X	NA	NA	X	NA	X	X	X	X	X	NA	NA	X

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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**:**

I. Individual has a diagnosis of Chronic myelogenous leukemia (CML);
AND
   A. Individual is 1 year of age or older; **AND**
   B. Individual is newly diagnosed with chronic phase Philadelphia chromosome positive (Ph+) CML; **OR**
   C. Individual has disease which is resistant or intolerant to prior tyrosine-kinase therapy (TKI) therapy;

   OR
   D. Individual is 18 years of age or older; **AND**
   E. Individual has chronic or accelerated phase Ph+ CML; **AND**
   F. Individual has disease which is resistant or intolerant to prior TKI therapy; **OR**
   G. Individual is using for Switch Therapy, Continued Therapy, or Post-allogenic hematopoietic stem cell transplant therapies (NCCN 2A);

OR

II. Individual has one of the following mutations: F317L/V/I/C, T315A, or V299L and results are confirmed (NCCN 2A);

OR

III. Individual has a diagnosis of Ph+ Acute Lymphoblastic Leukemia (ALL) (NCCN 2A);
AND
   A. Individual is 18 years of age or older (NCCN 2A); **AND**
   B. Individual is using in maintenance or relapsed/refractory disease (NCCN 2A); **OR**
   C. Individual is using in induction/consolidation therapy (NCCN 2A);

Market Applicability														
Market	**DC**	**FL & FHK**	**FL MMA**	**FL LTC**	**GA**	**KS**	**KY**	**MD**	**NJ**	**NV**	**NY**	**TN**	**TX**	**WA**
Applicable	X	X	NA	NA	X	NA	X	X	X	X	X	NA	NA	X

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OR

IV. Individual has a diagnosis of Soft Tissue Sarcoma (NCCN 2A);

AND

A. Individual is using for Gastrointestinal Stromal Tumors (GIST) in those no longer receiving benefit from imatinib, sunitinib, or 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.

State Specific Mandates		
State name	Date effective	Mandate details (including specific bill if applicable)
N/A	N/A	N/A

Key References:

Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2018. URL: http://www.clinicalpharmacology.com. Updated periodically.

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DrugPoints® System [Internet Database]. Greenwood Village, CO: Thomson Reuters (Healthcare) Inc. Updated periodically.

Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2018; Updated periodically.

Market Applicability														
Market	**DC**	**FL & FHK**	**FL MMA**	**FL LTC**	**GA**	**KS**	**KY**	**MD**	**NJ**	**NV**	**NY**	**TN**	**TX**	**WA**
Applicable	X	X	NA	NA	X	NA	X	X	X	X	X	NA	NA	X

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This policy does not apply to health plans or member categories that do not have pharmacy benefits, nor does it apply to Medicare. Note that market specific restrictions or transition-of-care benefit limitations may apply.