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

Iclusig (ponatinib)

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

Medications	Quantity Limit
Iclusig (ponatinib)	May be subject to quantity limit

APPROVAL CRITERIA

Requests for Iclusig (ponatinib) may be approved if the following criteria are met:

I. Individual has a diagnosis of one of the following:

A. Chronic, accelerated, or blast phase Chronic Myelogenous Leukemia (CML) or Philadelphia chromosome positive Acute Lymphoblastic Leukemia (ALL) where no other tyrosine kinase inhibitor therapy is indicated (e.g. is contraindicated, intolerant, or failed other prior TKI therapies); **OR**
B. Chronic Myelogenous Leukemia (CML) in chronic, accelerate or blast phase where CML is T315I-positive; **OR**
C. Chronic phase CML in individuals with resistance or intolerance to at least two prior kinase inhibitors; **OR**
D. Acute Lymphoblastic Leukemia (ALL) where ALL is T315I-positive, Philadelphia chromosome positive.

Iclusig (ponatinib) may not be approved for the following:

I. Individual is using for the treatment of those with newly diagnosed chronic phase CML.

Note:
Iclusig (ponatinib) has black box warnings for vascular occlusion, heart failure, and hepatotoxicity. Arterial and venous thrombosis and occlusions have occurred in at least 27% of Iclusig-treated individuals, including fatal myocardial infarction, stroke, stenosis of large arterial vessels of the brain, severe peripheral vascular disease, and the need for urgent revascularization procedures. Individuals with and without cardiovascular risk factors, including age 50 years or younger, experienced these events. Hepatotoxicity, liver failure, and death

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

have occurred with Iclusig. Hepatic function should be monitored and interruption of therapy may be necessary if hepatotoxicity is suspected.

Key References:

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2021. 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. 2021. 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.; 2021. Updated periodically.
5. NCCN Clinical Practice Guidelines in Oncology™. © 2021 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: http://www.nccn.org/index.asp. Accessed on January 15, 2021.
    a. Acute Lymphoblastic Leukemia. V2.2020. Revised October, 23, 2020.
    b. Chronic Myeloid Leukemia. V3.2021. Revised January 13, 2021.