Market Applicability/Effective Date														
Market	**FL & FHK**	**FL MMA**	**FL LTC**	**GA**	**KS**	**KY**	**LA**	**MD**	**NJ**	**NV**	**NY**	**TN**	**TX**	**WA**
Applicable	X	N/A	N/A	X	N/A	X	X	X	X	X	X	N/A	N/A	X

*FHK- Florida Healthy Kids

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. Acute Lymphoblastic Leukemia (ALL) where
   ALL is T315I-positive, Philadelphia chromosome positive. .

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 have occurred with Iclusig. Hepatic function should be monitored and interruption of therapy may be necessary if hepatotoxicity is suspected. Iclusig is not recommended for the treatment of patients with newly diagnosed chronic phase CML.

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

Market Applicability/Effective Date														
Market	**FL & FHK**	**FL MMA**	**FL LTC**	**GA**	**KS**	**KY**	**LA**	**MD**	**NJ**	**NV**	**NY**	**TN**	**TX**	**WA**
Applicable	X	N/A	N/A	X	N/A	X	X	X	X	X	X	N/A	N/A	X

*FHK- Florida Healthy Kids

Key References:

Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2017. URL: http://www.clinicalpharmacology.com. Updated periodically.

DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm. 7 2017.

DrugPoints® System (electronic version). Truven Health Analytics, Greenwood Village, CO. Updated periodically.

Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2017; Updated periodically.

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.