

**Iclusig (ponatinib)  
Effective 01/01/2021**

<b>Plan</b>	<input type="checkbox"/> MassHealth <input checked="" type="checkbox"/> MassHealth (PUF) <input type="checkbox"/> Commercial/Exchange	<b>Program Type</b>	<input checked="" type="checkbox"/> Prior Authorization <input checked="" type="checkbox"/> Quantity Limit <input type="checkbox"/> Step Therapy
<b>Benefit</b>	<input checked="" type="checkbox"/> Pharmacy Benefit <input type="checkbox"/> Medical Benefit (NLX)		
<b>Specialty Limitations</b>	This medication has been designated specialty and must be filled at a contracted specialty pharmacy.		
<b>Contact Information</b>	<b>Specialty Medications</b>		
	All Plans	Phone: 866-814-5506	Fax: 866-249-6155
	<b>Non-Specialty Medications</b>		
	MassHealth	Phone: 877-433-7643	Fax: 866-255-7569
	Commercial	Phone: 800-294-5979	Fax: 888-836-0730
	Exchange	Phone: 855-582-2022	Fax: 855-245-2134
	<b>Medical Specialty Medications (NLX)</b>		
	All Plans	Phone: 844-345-2803	Fax: 844-851-0882
<b>Exceptions</b>	N/A		

### Overview

Iclusig® (ponatinib) is a kinase inhibitor indicated for the:

- Treatment of adult patients with chronic phase, accelerated phase, or blast phase chronic myeloid leukemia (CML) or Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ ALL) for whom no other tyrosine kinase inhibitor (TKI) therapy is indicated.
- Treatment of adult patients with T315I-positive chronic myeloid leukemia (chronic phase, accelerated phase, or blast phase) or T315I-positive Ph+ ALL.

### Coverage Guidelines

Authorization may be reviewed on a case by case basis for members new to AllWays Health Partners who are currently receiving treatment with Iclusig, excluding when the product is obtained as samples or via manufacturer’s patient assistance programs

**OR**

Authorization may be granted if the member meets **ALL** following criteria and documentation has been submitted:

#### For Chronic Myelogenous Leukemia

Prescriber provides documentation of **ALL** of the following:

1. Appropriate diagnosis
2. Prescriber is a hematologist or oncologist
3. Appropriate dosing
4. **ONE** of the following:
  - a. Paid claim or physician documentation of inadequate response or adverse reaction to **TWO** of the following or a contraindication to **ALL** of the following:



- a. Bosulif<sup>®</sup> (bosutinib)
  - b. imatinib
  - c. Sprycel<sup>®</sup> (dasatinib)
  - d. Tassigna<sup>®</sup> (nilotinib)
- b. Confirmed T315I mutation

**For Acute Lymphoblastic Leukemia**

Prescriber provides documentation of **ALL** of the following:

- 1. Appropriate diagnosis
- 2. Prescriber is a hematologist or oncologist
- 3. Appropriate dosing
- 4. Paid claim or physician documentation of inadequate response or adverse reaction to **ONE** of the following or a contraindication to **ALL** of the following\*:
  - a. imatinib
  - b. Sprycel<sup>®</sup> (dasatinib)
  - c. Tassigna<sup>®</sup> (nilotinib)

*\*Documentation of contraindication to imatinib and dasatinib is sufficient for approval if request notes ponatinib to be used with hyper-CVAD regimen (nilotinib trial is not required)*

**Continuation of Therapy**

Reauthorization requires physician attestation of continuation of therapy and positive response to therapy.

**Limitations**

- 1. Initial approvals and reauthorizations will be granted for 6 months
- 2. The following quantity limits apply:

Iclusig 15mg tablets	60 tablets per 30 days
Iclusig 45mg tablets	30 tablets per 30 days

- 3.

**References**

- 1. Iclusig (ponatinib) [prescribing information]. Cambridge, MA: ARIAD Pharmaceuticals, Inc.; 01/2020.
- 2. Cortes JE, Kim D-W, Pinilla-Ibarz J, et al. Ponatinib efficacy and safety in Philadelphia chromosome-positive leukemia: final 5-year results of the phase 2 PACE trial. *Blood*. 2018;132(4):393-404.

**Review History**

10/9/2020: Created criteria to be in compliance with the Masshealth partial unified formulary requirements effective 1/1/21.

**Disclaimer**

AllWays Health Partners complies with applicable federal civil rights laws and does not discriminate or exclude people on the basis of race, color, national origin, age, disability, or sex.