ROCKY MOUNTAIN HEALTH PLANS®
We understand Colorado. We understand you.

UNIFORM PHARMACY PRIOR AUTHORIZATION REQUEST FORM

CONTAINS CONFIDENTIAL PATIENT INFORMATION

Complete this form in its entirety and send to Rocky Mountain Health Plans at 858-357-2538

☐ **Urgent**[1] ☐ **Non-Urgent**

Requested Drug Name: Iclusig® (ponatinib)

Patient Information:	**Prescribing Provider Information:**
Patient Name:	Prescriber Name:
Member/Subscriber Number:	Prescriber Fax:
Policy/Group Number:	Prescriber Phone:
Patient Date of Birth (MM/DD/YYYY):	Prescriber Pager:
Patient Address:	Prescriber Address:
Patient Phone:	Prescriber Office Contact:
Patient Email Address:	Prescriber NPI:
	Prescriber DEA:
Prescription Date:	Prescriber Tax ID:
	Specialty/Facility Name (If applicable):
	Prescriber Email Address:

Prior Authorization Request for Drug Benefit: ☐ New Request ☐ Reauthorization

Patient Diagnosis and ICD Diagnostic Code(s):

Drug(s) Requested (with J-Code, if applicable):

Strength/Route/Frequency:

Unit/Volume of Named Drug(s):

Start Date and Length of Therapy:

Location of Treatment: (e.g. provider office, facility, home health, etc.) including name, Type 2 NPI (if applicable), address and tax ID:

Clinical Criteria for Approval, Including other Pertinent Information to Support the Request, other Medications Tried, Their Name(s), Duration, and Patient Response:

Iclusig® (ponatinib)

Diagnosis (documentation supportive of diagnosis is required)

☐ CML (chronic, accelerated, or blast-phase)
☐ CML (T3151-positive, chronic, accelerated, or blast-phase)
☐ ALL (Philadelphia chromosome-positive)
☐ ALL (T3151-positive and Philadelphia chromosome-positive)
☐ Other (please state): _____

Clinical Consideration (for approval, please indicate and provide documentation of the following):

For ALL or CML (chronic, accelerated or blast-phase)

☐ Patient had resistance and/or intolerance to prior TKIs. [e.g. Gleevec® (imatinib), Sprycel® (dasatinib), Tasigna® (nilotinib), Bosulif® (bosutinib)]

☐ No other TKI therapy is indicated

☐ For ALL, documentation of PH+ status has also been provided

For T315I-positive ALL or CML

☐ Documentation of T315I mutation status has been provided

☐ For ALL, documentation of PH+ status has also been provided

Physician Specialty

☐ Oncologist

☐ Other (please state): _____

☐ For use in clinical trial? (If yes, provide trial name and registration number):

Drug Name (Brand Name and Scientific Name)/Strength:

Dose:	Route:	Frequency:
Quantity:	Number of Refills:	

Product will be delivered to: ☐ Patient's Home ☐ Physician Office Other:

Prescriber or Authorized Signature: Date:

Dispensing Pharmacy Name and Phone Number:

☐ **Approved** ☐ **Denied**

If denied, provide reason for denial, and include other potential alternative medications, if applicable, that are found in the formulary of the carrier:

1. A request for prior authorization that if determined in the time allowed for non-urgent requests could seriously jeopardize the life or health of the covered person or the ability of the covered person to regain maximum function, or subject the person to severe pain that cannot be adequately managed without the drug benefit contained in the prior authorization request

RMHP Formulary Coverage Policy

THIS INFORMATION IS NOT ALL-INCLUSIVE AND IS PROVIDED FOR INFORMATIONAL PURPOSES ONLY

Iclusig® (ponatinib)

CLASSIFICATION

- Antineoplastic Agent
- 3rd Generation Tyrosine Kinase Inhibitor

DESCRIPTION

- Iclusig is indicated for the treatment of adult patients with chronic, accelerated or blast phase chronic myeloid leukemia (CML) or Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ALL) that is resistant/intolerant to prior TKIs or where no other TKI therapy is indicated. It is also indicated for T315I-positive CML (chronic, accelerated or blast phase) or T315I-positive Ph+ALL.
- Approval and indication are only based on response rates. There are no trials to verify improvement in disease-related symptoms or increased survival.
- Iclusig was developed with a triple carbon-carbon bond on a substructure similar to imatinib. This structure was designed with intentions of targeting the T315I mutation that occurs in up to 20% of patients that have resistance to the other TKIs in the treatment of CML.
- NCCN guidelines call Iclusig a potent pan-BCR-ABL inhibitor with substantial activity in all phases of CML and a treatment option for patients with a T315I mutation or for patients with disease that has not responded to 2 or more TKI therapies.
- *Resistance* is defined as one of the following: no complete hematologic response (CHR) by 12 weeks (whether lost or never achieved); or no cytogenetic response by 24 weeks (i.e., 100% Ph positive [Ph+]) (whether lost or never achieved); or no major cytogenetic response (MCyR) by 52 weeks (i.e., ≥35% Ph+) (whether lost or never achieved); or progressive leukocytosis.
- *Intolerance* is defined as one of the following: 1) Grade 3-4 non-hematologic toxicity that does not resolve with adequate intervention; or 2) Grade 4 hematologic toxicity lasting more than 7 days; or 3) any Grade ≥ 2 toxicity that is unacceptable to the patient. Patients with NYHA class III or IV heart disease, active ischemia or other uncontrolled cardiac conditions were excluded.
- Chronic, accelerated or blast phases are classified based on the number of immature WBCs in the blood or bone marrow (chronic phase: <10% blasts; accelerated phase (AP): 10% to 19% blasts; blast phase: >20% blasts).
- TKIs available to treat CML include Gleevec® (imatinib – Novartis), Sprycel® (dasatinib – Bristol-Myers Squibb) and Tasigna® (nilotinib – Novartis), and Bosulif® (bosutinib – Pfizer). None of these TKIs have activity against the T315I mutation.

FORMULARY COVERAGE

Prior authorization:	Yes
Good Health Formulary:	Tier 3
Commercial Formulary:	Tier 3
Medicare Part D coverage:	Tier 5

COVERAGE CRITERIA

Iclusig® (ponatinib) meets the definition of **medical necessity** for all FDA approved indications, including the following:

- Documented diagnosis of chronic, accelerated or blast phase CML or Ph+ ALL that is resistant/intolerant to prior TKIs [e.g. Gleevec® (imatinib), Sprycel® (dasatinib), Tasigna® (nilotinib), Bosulif® (bosutinib)] or where no other TKI therapy is indicated.
- Documented diagnosis of T315I-positive CML (chronic, accelerated or blast phase) or T315I-positive Ph+ALL

Iclusig® (ponatinib) is considered **experimental** for the following:

- Any condition or diagnosis not FDA approved or Compendia supported

Required Provider Specialty:

- Approval is limited to Oncologist

DOSAGE/ADMINISTRATION

Adult Dosing (safety and efficacy has not been determined for pediatric patients less than 18 years):

- Chronic, accelerated or blast phase CML: 45mg PO daily
- Ph+ALL: 45mg PO daily
- See complete prescribing information for dose modifications.

PRECAUTIONS

- Black Box Warnings:
  - Vascular occlusion: arterial and venous thromboembolism and occlusions have occurred in 27% of Iclusig-treated patients, including fatal myocardial infarction, stroke, stenosis of large arterial vessels of the brain, severe peripheral vascular disease and the need for urgent revascularization procedures. Patients with and without cardiovascular risk factors experienced these events.
  - Heart failure, including fatalities, occurred in 8% of Iclusig-treated patients.
  - Hepatotoxicity, liver failure and death have occurred in Iclusig-treated patients. Monitor hepatic function prior to and during treatment. Interrupt and then reduce or discontinue Iclusig for hepatotoxicity.
- Precautions:
  - Treatment-emergent symptomatic hypertension including hypertensive crisis has been reported. Monitor and treat as clinically indicated.
  - Pancreatitis has been reported. Monitor serum lipase monthly. May require dose interruption, reduction or discontinuation.
  - Serious bleeding events, including fatalities, have been reported. Cerebral and gastrointestinal hemorrhages were the most commonly reported serious events. Interrupt Iclusig for serious or severe hemorrhage.
  - Serious fluid retention has been reported. Monitor for fluid retention; interrupt, reduce, or discontinue Iclusig
  - Cardiac arrhythmias including symptomatic bradyarrhythmias and supraventricular tachyarrhythmias have been reported. Monitor for signs and symptoms.

- Grade 3 or 4 myelosuppression occurred in 48% of patients treated with Iclusig. Thrombocytopenia, neutropenia, and anemia may require dose interruption or reduction. Monitor CBC.
- Tumor Lysis Syndrome has been reported. Ensure adequate hydration and correct high uric acid levels prior to initiating therapy with Iclusig.
- Based on Iclusig's mechanism of action, compromised wound healing could occur. Interrupt therapy at least 1 week prior to major surgery.
- Serious gastrointestinal perforation (fistula) has been reported. Interrupt therapy at least 1 week prior to major surgery.
- Ocular toxicity: conduct comprehensive eye exams at baseline and periodically during treatment
- Embryo-fetal toxicity: can cause fetal harm

Billing/Coding information

HCPCS Coding:

C9399	Unclassified drugs or biologicals (This code should only be used for drugs and biologicals that are approved by the FDA on or after January 1, 2004) (Hospital Outpatient Use ONLY)
J8999	Prescription drug, oral, chemotherapeutic, Not Otherwise Specified

COST

- AWP (January 2013):
  - Iclusig 45mg tablets (30): $11,496
  - Iclusig 45mg tablets (1): $383.20
  - Iclusig 15mg tablets (1): $191.60
- AWP (February 2015): Iclusig 15mg and 45 tablets (30): 13,536

COMMITTEE APPROVAL

- January 2013

GUIDELINE UPDATE INFORMATION

January 2013	Prior Authorization and Coverage Policy created
September 2015	Coverage Policy reviewed and updated

REFERENCES

- DRUGDEX®, accessed 1/12/2013, 9/22/15
- Product Information: Iclusig® (ponatinib) tablets, for oral use. Ariad Pharmaceuticals, Inc., Cambridge, MA. 12/2014.
- National Comprehensive Cancer Network, Inc. 2015. Chronic Myelogenous Leukemia. Version 1.2016. Accessed 9/22/2015.