STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

PONATINIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
PONATINIB HCL	ICLUSIG	39859		GPI-10 (2153187510)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of chronic myeloid leukemia (CML) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient had a mutational analysis prior to initiation AND Iclusig is appropriate per the NCCN guideline table for treatment recommendations based on BCR-ABL1 mutation profile *(Please see header CML-5 of the current NCCN guidelines)*

   If yes, continue to #2.
   If no, continue to #5.

2. Does the patient have T315I-positive CML (chronic phase, accelerated phase, or blast phase)?

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, continue to #3.

3. Does the patient have chronic phase (CP) chronic myeloid leukemia (CML) **AND** meet the following criterion?
   - The patient has a resistance or intolerance to at least TWO prior kinase inhibitors [e.g., Tasigna (nilotinib), Sprycel (dasatinib), Bosulif (bosutinib), Gleevec (imatinib)]

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, continue to #4.

4. Does the patient have accelerated phase (AP) or blast phase (BP) chronic myeloid leukemia (CML) **AND** meet the following criterion?
   - There are no other kinase inhibitors [e.g., Tasigna (nilotinib), Sprycel (dasatinib), Bosulif (bosutinib), Gleevec (imatinib)] indicated for the patient

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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PONATINIB

GUIDELINES FOR USE (CONTINUED)

5. Does the patient have a diagnosis of Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ ALL) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient meets ONE of the following:
     - The patient's cancer is positive for the T315I mutation
     - There are no other kinase inhibitors [e.g., Tasigna (nilotinib), Sprycel (dasatinib), Bosulif (bosutinib), Gleevec (imatinib)] indicated for the patient

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **PONATINIB (Iclusig)** requires the following rule(s) be met for approval:
   A. You have ONE of the following diagnoses:
      1. Chronic myeloid leukemia (CML: type of blood-cell cancer that begins in the bone marrow)
      2. Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ ALL) (type of white blood cell cancer)
   B. You are 18 years of age or older
   C. **If you have chronic myeloid leukemia, approval also requires:**
      1. You had a mutational analysis prior to initiation of therapy AND Iclusig is appropriate per the National Comprehensive Cancer Network (NCCN) guideline table for treatment recommendations based on BCR-ABL1 mutation (breakpoint cluster region-Abelson murine leukemia 1; a type of abnormal gene) profile
      2. You meet ONE of the following:
         a. You have T315I-positive (a genetic mutation) CML (chronic phase, accelerated phase, or blast phase)
         b. You have chronic phase CML AND have a resistance to or are not able to safely use at least TWO prior kinase inhibitor treatments such as Tasigna (nilotinib), Sprycel (dasatinib), Bosulif (bosutinib), Gleevec (imatinib)
         c. You have accelerated phase or blast phase CML AND there are no other kinase inhibitors, such as Tasigna (nilotinib), Sprycel (dasatinib), Bosulif (bosutinib), Gleevec (imatinib), that can be used for your disease
   D. **If you have Philadelphia chromosome positive acute lymphoblastic leukemia, approval also requires you meet ONE of the following:**
      1. Your cancer is positive for the T315I mutation (a type of abnormal gene)
      2. There are no other kinase inhibitors [e.g., Tasigna (nilotinib), Sprycel (dasatinib), Bosulif (bosutinib), Gleevec (imatinib)] indicated for the patient

   (Denial text continued on next page)

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PONATINIB

GUIDELINES FOR USE (CONTINUED)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Iclusig.

REFERENCES

- Iclusig [Prescribing Information]. Cambridge, MA: ARIAD Pharmaceuticals, Inc.; December 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 04/01/22

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