STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

IBRUTINIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
IBRUTINIB	IMBRUVICA	40745		GPI-10 (2153213300)	

GUIDELINES FOR USE

1. Is the request for Imbruvica (ibrutinib) 560 mg tablet?

   If yes, do not approve. (**Note:** This strength does not have an FDA-approved indication.)
   DENIAL TEXT: See the denial text at the end of the guideline.

   If no, continue to #2.

2. Does the patient have a diagnosis of chronic lymphocytic leukemia (CLL), small lymphocytic lymphoma (SLL), or Waldenstrom's macroglobulinemia (WM) **AND** meet the following criterion?
   - The patient is 18 years of age or older

   If yes, **approve for 12 months by GPID or GPI-14 for all of the following:**
   - **70 mg capsule: #1 per day.**
   - **140 mg capsule: #2 per day.**
   - **140 mg tablet: #1 per day.**
   - **280 mg tablet: #1 per day.**
   - **420 mg tablet: #1 per day.**
   - **70 mg/mL oral suspension: #7.2 mL per day.**

   If no, continue to #3.

3. Does the patient have a diagnosis of chronic graft versus host disease (cGVHD) and meet **ALL** of the following criteria?
   - The patient is 1 year of age or older
   - The patient has failed one or more lines of systemic therapy (e.g., prednisone, prednisolone, methylprednisolone)

   If yes, **approve for 12 months by GPID or GPI-14 for all of the following:**
   - **70 mg capsule: #1 per day.**
   - **140 mg capsule: #2 per day.**
   - **140 mg tablet: #1 per day.**
   - **280 mg tablet: #1 per day.**
   - **420 mg tablet: #1 per day.**
   - **70 mg/mL oral suspension: #7.2 mL per day.**

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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IBRUTINIB

GUIDELINES FOR USE (CONTINUED)

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 **IBRUTINIB (Imbruvica)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Chronic lymphocytic leukemia (CLL: a type of blood cancer)
   2. Small lymphocytic lymphoma (SLL: a type of blood cancer)
   3. Waldenstrom's macroglobulinemia (WM: a type of blood cancer)
   4. Chronic graft versus host disease (cGVHD: a type of immune disorder)

B. **If you have chronic lymphocytic leukemia, small lymphocytic lymphoma, or Waldenstrom's macroglobulinemia, approval also requires:**
   1. You are 18 years of age or older

C. **If you have chronic graft versus host disease, approval also requires:**
   1. You are 1 year of age or older
   2. You have failed one or more lines of systemic therapy (treatment spread through the blood, such as prednisone, prednisolone, methylprednisolone)

Note: Requests for Imbruvica (ibrutinib) 560mg tablet will not be approved. This strength does not have a Food and Drug Administration (FDA)-approved indication.

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 Imbruvica.

REFERENCES

- Imbruvica [Prescribing Information]. Horsham, PA: Janssen Biotech, Inc.; May 2023.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 08/01/23
Created: 01/14
Client Approval: 06/23
P&T Approval: 07/23