IBRUTINIB

Generic	Brand	HICL	GCN	Exception/Other
IBRUTINIB	IMBRUVICA	40745		

This drug requires a written request for prior authorization.

GUIDELINES FOR USE

1. Is the patient 18 years of age or older?

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

2. Does the patient have a diagnosis of mantle cell lymphoma (MCL) **AND** meet the following criterion?
   - Patient has received at least one prior therapy for mantle cell lymphoma (MCL)

   If yes, continue to #6.
   If no, continue to #3.

3. Does the patient have a diagnosis of chronic lymphocytic leukemia (CLL), small lymphocytic lymphoma (SLL), or Waldenström's macroglobulinemia (WM)?

   If yes, continue to #8.
   If no, continue to #4.

4. Does the patient have a diagnosis of marginal zone lymphoma (MZL) and meet **ALL** of the following criteria?
   - Patient requires systemic therapy
   - Patient has received at least one prior anti-CD20-based therapy (e.g., Rituxan)

   If yes, continue to #6.
   If no, continue to #5.

5. Does the patient have a diagnosis of chronic graft versus host disease (cGVHD) **AND** meet the following criteria?
   - The patient has failed one or more lines of systemic therapy (e.g., corticosteroids)

   If yes, continue to #8.
   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)

6. Is the request for Ibrutinib 140mg or 280mg tablets?

   If yes, continue to #7.
   If no, **approve for 12 months by GPID for all of the following strengths:**
   - **70mg capsule (GPID 44475) with a quantity limit of #1 capsule per day.**
   - **140mg capsule (GPID 35599) with a quantity limit of #2 capsules per day.**
   - **420mg tablet (GPID 44467) with a quantity limit of #1 tablet per day.**
   - **560mg tablet (GPID 44468) with a quantity limit of #1 tablet per day.**

7. Has the patient tried or have a contraindication to Ibrutinib 140mg capsules?

   If yes, **approve for 12 months by GPID (44465, 44466) (140mg, 280mg tablet) with a quantity limit of #1 per day. Please also enter approvals for all of the following:**
   - **70mg capsule (GPID 44475) with a quantity limit of #1 capsule per day.**
   - **140mg capsule (GPID 35599) with a quantity limit of #2 capsules per day.**
   - **420mg tablet (GPID 44467) with a quantity limit of #1 tablet per day.**
   - **560mg tablet (GPID 44468) with a quantity limit of #1 tablet per day.**

   If no, do not approve. **Please enter proactive approvals for 12 months by GPID for all of the following:**
   - **70mg capsule (GPID 44475) with a quantity limit of #1 capsule per day.**
   - **140mg capsule (GPID 35599) with a quantity limit of #2 capsules per day.**
   - **420mg tablet (GPID 44467) with a quantity limit of #1 tablet per day.**
   - **560mg tablet (GPID 44468) with a quantity limit of #1 tablet per day.**

   DENIAL TEXT: See the denial text at the end of the guideline.

8. Is the request for Ibrutinib 140mg or 280mg tablets?

   If yes, continue to #9.
   If no, **approve for 12 months by GPID for all of the following strengths:**
   - **70mg capsule (GPID 44475) with a quantity limit of #1 capsule per day.**
   - **140mg capsule (GPID 35599) with a quantity limit of #2 capsules per day.**
   - **420mg tablet (GPID 44467) with a quantity limit of #1 tablet per day.**

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GUIDELINES FOR USE (CONTINUED)

9. Has the patient tried or have a contraindication to Ibrutinib 140mg capsules**?**

If yes, **approve for 12 months by GPID (44465, 44466) (140mg, 280mg tablet) with a quantity limit of #1 per day. Please also enter approvals for all of the following:**
- **70mg capsule (GPID 44475) with a quantity limit of #1 capsule per day.**
- **140mg capsule (GPID 35599) with a quantity limit of #2 capsules per day.**
- **420mg tablet (GPID 44467) with a quantity limit of #1 tablet per day.**

If no, do not approve. **Please enter proactive approvals for 12 months by GPID for all of the following:**
- **70mg capsule (GPID 44475) with a quantity limit of #1 capsule per day.**
- **140mg capsule (GPID 35599) with a quantity limit of #2 capsules per day.**
- **420mg tablet (GPID 44467) with a quantity limit of #1 tablet per day.**

DENIAL TEXT: The guideline named **IBRUTINIB (Imbruvica)** requires a diagnosis of mantle cell lymphoma (MCL), chronic lymphocytic leukemia (CLL), small lymphocytic lymphoma (SLL), Waldenström's macroglobulinemia (WM), marginal zone lymphoma (MZL), or chronic graft versus host disease (cGVHD). Request for Ibrutinib 140mg or 280mg tablets requires a trial of or contraindication to Ibrutinib 140mg capsules. The following criteria must also be met:
- The patient is 18 years of age or older

For patients with mantle cell lymphoma (MCL), approval requires:
- Patient has received at least one prior therapy for mantle cell lymphoma (MCL)

For patients with marginal zone lymphoma (MZL), approval requires:
- Patient requires systemic therapy
- Patient has received at least one prior anti-CD20-based therapy (e.g., Rituxan)

For patients with chronic graft versus host disease (cGVHD), approval requires:
- The patient has failed one or more lines of systemic therapy (e.g., corticosteroids)

RATIONALE

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

REFERENCES

- Imbruvica [Prescribing Information]. Janssen Biotech, Inc.: Horsham, PA; January 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 02/25/19
Created: 01/14
Client Approval: 02/19
P&T Approval: 07/18