

Pharmacy Prior Authorization Form

Fax completed form to: 877.974.4411 toll free, or 616.942.8206

This form applies to: Commercial (Traditional) Commercial (Individual/Optimized)
 Medicaid

This request is: Urgent (life threatening) Non-Urgent (standard review)
 Urgent means the standard review time may seriously jeopardize the life or health of the patient or the patient's ability to regain maximum function.

Imbruvica[®] (ibrutinib)

Member

Last Name: _____ First Name: _____
 ID #: _____ DOB: _____ Gender: _____
 Primary Care Physician: _____
 Requesting Provider: _____ Prov. Phone: _____ Prov. Fax: _____
 Provider Address: _____
 Provider NPI: _____ Contact Name: _____
 Provider Signature: _____ Date: _____

Product Information

New request Continuation request

Drug product: Imbruvica 140mg tablet Imbruvica 280mg tablet Imbruvica 420mg tablet Imbruvica 560mg tablet
 Start date (or date of next dose): _____
 Date of last dose (if applicable): _____
 Dosing frequency: _____

Drug cost information

The wholesale acquisition cost per tablet is \$405.00. The annual cost of treatment with this drug may be more than \$163,000.

Precertification Requirements

Patient must meet the following criteria:

Must have a diagnosis of one of the following:

- a. Chronic lymphocytic leukemia (with or without 17p chromosome deletion)
- b. Small lymphocytic lymphoma (with or without 17p chromosome deletion)
- c. Mantle cell lymphoma previously treated with at least one prior therapy
- d. Marginal zone lymphoma previously treated with at least one anti-CD20-based therapy
- e. Waldenström's macroglobulinemia
- f. Classic chronic graft versus host disease (cGVHD) with all of the following:
 - i. Greater than 3 organs involved, OR, any single organ with severity score¹ > 2, lung involvement, OR persistent thrombocytopenia (platelet count less than 100,000/microL)
 - ii. Treatment failures with the following at optimized doses used in combination (failure indicated by disease progression in a previously unaffected organ, failure to improve after 1 month of combination therapy, inability to taper prednisone below 1mg/kg/day after 2 months, or patient is experiencing significant treatment-related toxicity):
 1. Systemic corticosteroid
 2. At least one additional immunosuppressant (e.g. tacrolimus, cyclosporine)
 - iii. Initial approval granted for 12 weeks, with continued 3 month approvals authorized if the patient:

- 1. Has documented (and sustains) at least a partial response (PR²) in at least one affected organ (with no progression in any other organ or site)
- iv. Discontinuation is expected when patients no longer require treatment, indicated by a complete response (CR²)
- v. Approved dosing is 420 mg daily.

¹Global Severity Grading of Chronic GvHD: NIH Consensus Criteria

²as defined per: Measuring Therapeutic Response in Chronic Graft-versus-Host Disease. National Institutes of Health Consensus Development Project on Criteria for Clinical Trials in Chronic Graft-versus-Host Disease: IV. The 2014 Response Criteria Working Group Report.

Note: Authorization for indications, dosing, or a route of administration not approved by the Food and Drug Administration (FDA) or recognized in CMS-accepted compendia (e.g. DrugDex, AHFS, U.S. Pharmacopeia, and also Clinical Pharmacology for oncology indications only) require supporting evidence for coverage. Please provide two published peer-reviewed literature articles supporting the appropriateness of the drug, the dosing of the drug, or the route of administration to be used for the identified indication.

Priority Health Precertification Documentation

1. What condition is this drug being requested for?

- Chronic lymphocytic leukemia (with or without 17p chromosome deletion)
- Small lymphocytic lymphoma (with or without 17p chromosome deletion)
- Mantle cell lymphoma previously treated with at least one prior therapy
- Marginal zone lymphoma previously treated with at least one anti-CD20-based therapy
- Waldenström's macroglobulinemia
- Chronic graft versus host disease (cGVHD)
- Other – the patient's condition is: _____

2. For marginal zone lymphoma: what previous treatment has the patient used?

(e.g. chemotherapy, Rituxan, Velcade, stem cell transplant)

Previous therapy: _____ Date: _____
 Previous therapy: _____ Date: _____
 Previous therapy: _____ Date: _____

3. For cGVHD (new requests), please provide the following:

- Diagnosis:
- Greater than 3 organs involved (specify) _____
 - Any single organ (specify) with severity score > 2 _____
 - Lung involvement
 - Persistent thrombocytopenia (provide platelet count) _____ Date: _____

Current/Prior Therapies:

Drug & dose: _____	Dates used: _____	Response: _____
Drug & dose: _____	Dates used: _____	Response: _____
Drug & dose: _____	Dates used: _____	Response: _____

4. For cGVHD (continuation), please provide documentation to support all the following:

- Partial response (PR) in at least one affected organ (specify) _____
- No progression in any other organ or site