

Applicable Drugs: Imbruvica (ibrutinib)

Preferred: N/A

Non-preferred: N/A

Date of Origin: 8/27/2019

Date Last Reviewed / Revised: 7/23/2026

PRIOR AUTHORIZATION CRITERIA

(May be considered medically necessary when criteria I through V are met)

- I. Documentation of one of the following FDA-approved diagnoses A through D AND must meet all criteria listed under the applicable diagnosis:

FDA-Approved Indication(s)

- A. Chronic lymphocytic leukemia (CLL).
- B. Small lymphocytic leukemia (SLL).
- C. Waldenström's macroglobulinemia (WM).
- D. Chronic graft versus host disease (cGVHD)
 - i. Documentation treatment with corticosteroids has been ineffective
 - ii. Imbruvica is used as monotherapy

Other Uses With Supportive Evidence

- E. B-Cell lymphomas
 - F. Central nervous system cancers
 - G. Hairy cell leukemia
 - H. Mantle cell lymphoma
 - I. Marginal zone lymphoma
 - J. Post-transplant lymphoproliferative disorder (PTLD)
- II. Minimum age requirement: 1 year and older for cGVHD; 18 years and older for all other indications.
- III. Treatment must be prescribed by or in consultation with an oncologist, hematologist, or bone marrow transplant specialist (cGHVD).
- IV. Request is for a medication with the appropriate FDA labeling, or its use is supported by current National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1 or 2Au.

- V. Refer to plan document for the list of preferred products. If requested agent is not listed as a preferred product, must have a documented failure, intolerance, or contraindication to the preferred product(s).

EXCLUSION CRITERIA

- N/A

OTHER CRITERIA

- N/A

QUANTITY / DAYS SUPPLY RESTRICTIONS

- CLL/SLL and WM:
 - Maximum dose: 420 mg orally once daily
- cGVHD
 - Maximum dose:
 - Age 12 years old and older: 420 mg orally once daily
 - Age 1 year old to less than 12 years old: 240 mg/m² orally once daily (maximum 420 mg)
- CLL, SLL, WM, or cGVHD:
 - Quantities limited to a maximum of 30-day supply
 - 140 mg capsules: Up to 90 capsules per 30 days
 - 70 mg capsules, or 140-, 280- 420 mg tablets: Up to 30 per 30 days
 - 70 mg/mL oral suspension: Up to 180 mL per 30 days

APPROVAL LENGTH

- **Authorization:** 1 year.
- **Re-Authorization:** An updated letter of medical necessity or progress notes showing current medical necessity criteria are met and does not show evidence of progressive disease.

APPENDIX

N/A

REFERENCES

1. Imbruvica. Prescribing information. Pharmacyclics LLC. Updated 2025. Accessed June 5, 2026. <https://www.imbruvica.com/files/prescribing-information.pdf>.
2. National Comprehensive Cancer Network. Clinical Practice Guidelines in Oncology. B-Cell Lymphomas. Version 4.2026. Updated May 20, 2026. Accessed July 23, 2026. https://www.nccn.org/professionals/physician_gls/pdf/b-cell.pdf.
3. National Comprehensive Cancer Network. Clinical Practice Guidelines in Oncology. Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma. Version 2.2026. Updated December 22, 2025. Accessed July 23, 2026. https://www.nccn.org/professionals/physician_gls/pdf/cll.pdf.
4. National Comprehensive Cancer Network. Clinical Practice Guidelines in Oncology. Waldenström's macroglobulinemia/Lymphoplasmacytic Lymphoma. Version 2.2026. Updated March 2, 2026. Accessed July 23, 2026. https://www.nccn.org/professionals/physician_gls/pdf/waldenstroms.pdf.
5. National Comprehensive Cancer Network. Clinical Practice Guidelines in Oncology. Hematopoietic Cell Transplantation. Version 2.2026. Updated April 3, 2026. Accessed July 23, 2026. www.nccn.org/professionals/physician_gls/pdf/hct.pdf
6. National Comprehensive Cancer Network. Clinical Practice Guidelines in Oncology. Central Nervous System Cancers. Version 2.2026. Updated June 10, 2026. Accessed July 23, 2026. www.nccn.org/professionals/physician_gls/pdf/cns.pdf
7. National Comprehensive Cancer Network. Clinical Practice Guidelines in Oncology. Hairy Cell Leukemia. Version 2.2026. Updated December 2, 2025. Accessed July 23, 2026. www.nccn.org/professionals/physician_gls/pdf/hairy_cell.pdf

DISCLAIMER: Medication Policies are developed to help ensure safe, effective and appropriate use of selected medications. They offer a guide to coverage and are not intended to dictate to providers how to practice medicine. Refer to Plan for individual adoption of specific Medication Policies. Providers are expected to exercise their medical judgement in providing the most appropriate care for their patients.