Generic Name: ibrutinib

Therapeutic Class or Brand Name: Imbruvica

Applicable Drugs (if Therapeutic Class): N/A

Preferred: N/A

Non-preferred: N/A

Date of Origin: 8/27/2019

Date Last Reviewed / Revised: 10/19/2024

PRIOR AUTHORIZATION CRITERIA

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

I. Documentation of one of the following diagnoses A through J 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) when treatment with corticosteroids has been ineffective AND ibrutinib (Imbruvica) is used as monotherapy.

Other Uses With Supportive Evidence

E. Diffuse large B-cell lymphoma, OR high-grade B-cell lymphoma, OR HIV-related B-cell lymphoma, OR post-transplant lymphoproliferative disorder (PTLD) and meets ALL of the following criteria:

i. Used as a single agent.

ii. Used as second-line or subsequent therapy.

iii. Documentation there is no intention to proceed to transplant.

F. Extranodal marginal zone lymphoma of non-gastric site (non-cutaneous), OR extranodal marginal zone lymphoma of the stomach, OR nodal marginal zone lymphoma OR splenic marginal zone lymphoma and meets ALL of the following criteria:

i. Used as second-line or subsequent therapy.

ii. Documentation that disease is relapsed, refractory, or progressive.

iii. Documentation that combination chemoimmunotherapy is not expected to be tolerated.

G. Mantle cell lymphoma and meets ONE of the following criteria:

i. Used as part of aggressive induction therapy (TRIANGLE regimen: Alternating RCHOP (rituximab, doxorubicin, vincristine, cyclophosphamide, prednisone) + ibrutinib/RDHA (rituximab, dexamethasone, cytarabine) + platinum (carboplatin, cisplatin, or oxaliplatin) OR

ii. Used for pre-treatment in combination with a rituximab-based regimen OR

iii. Used for maintenance therapy with rituximab following autologous stem cell rescue OR

iv. Used for maintenance therapy in combination with rituximab following aggressive induction therapy with alternating RCHOP + ibrutinib/RDHAP OR

v. Relapsed or refractory disease as second-line or subsequent therapy as a single agent or in combination with rituximab or venetoclax.

H. Lymphoma with extensive or limited brain metastases

i. Used as single agent.

I. Primary CNS lymphoma and meets ONE of the following criteria:

i. Used as single agent for induction therapy and patient is unsuitable for or intolerant to high-dose methotrexate OR

ii. Relapsed or refractory disease +/- radiation or +/- high-dose methotrexate.

J. Hairy cell leukemia

i. Used as single agent.

ii. Documentation of progression after therapy for relapsed/refractory disease.

II. Minimum age requirement: 1 year and older for cGVHD; 18 years and older for all other indications.

III. Attestation that the patient's cardiac history, cardiac function, and blood pressure were monitored at baseline and will be monitored during treatment.

IV. Treatment must be prescribed by or in consultation with an oncologist, hematologist, or bone marrow transplant specialist (cGHVD).

V. Request is for a medication with the appropriate FDA labeling, or its use is supported by current clinical practice guidelines.

VI. 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

- Not recommended in pregnancy. Warning of Embryo-fetal toxicity: Can cause fetal harm. Advise women of the potential risk to the fetus and to avoid pregnancy while taking the drug and for 1 month after cessation of therapy. Advise men to avoid fathering a child during the same time period.

Other Criteria

- N/A

Quantity / Days Supply Restrictions

- CLL, SLL, WM, cGVHD, or hairy cell leukemia:
  - 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.
- Marginal zone lymphomas, Mantle cell lymphomas, B-cell lymphomas, Lymphoma with brain metastasis, and PTLD :
  - 560 mg: 420 mg tablet & 140 mg tablet: Up to 30 tablets of each per 30 days.
- Primary CNS lymphoma:
  - 840 mg: 420 mg tablet: Up to 60 tablets 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 that the medication is effective.

Appendix

N/A

References

1. Imbruvica. Prescribing information. Pharmacyclics LLC. Updated May 2024. Accessed October 19, 2024. https://www.imbruvica.com/files/prescribing-information.pdf.
2. National Comprehensive Cancer Network (NCCN). B-Cell Lymphomas v.3.2024. Updated August 26, 2024. Accessed October 19, 2024. https://www.nccn.org/professionals/physician_gls/pdf/b-cell.pdf.

3. National Comprehensive Cancer Network (NCCN). Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma v3.2024. Updated October 1, 2024. Accessed October 19, 2024. https://www.nccn.org/professionals/physician_gls/pdf/cll.pdf.
4. National Comprehensive Cancer Network (NCCN). Waldenström's macroglobulinemia/Lymphoplasmacytic v.1.2025. Updated September 13, 2024. Accessed October 19, 2024. https://www.nccn.org/professionals/physician_gls/pdf/waldenstroms.pdf.
5. National Comprehensive Cancer Network (NCCN). Hematopoietic Cell Transplantation (HCT. Version 2.2024, August 30, 2024. Accessed October 19, 2024. www.nccn.org/professionals/physician_gls/pdf/hct.pdf
6. National Comprehensive Cancer Network (NCCN). Central Nervous System Cancers. Version 3.2024, September 30, 2024. Accessed October 19, 2024. www.nccn.org/professionals/physician_gls/pdf/cns.pdf
7. National Comprehensive Cancer Network (NCCN). Hairy Cell Leukemia. Version 1.2025, September 26, 2024. Accessed October 19. 2024 www.nccn.org/professionals/physician_gls/pdf/hairy_cell.pdf