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: 9/15/2022

PRIOR AUTHORIZATION CRITERIA

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

I. Documented diagnosis of one of the following conditions A through F and must meet criteria listed under the applicable diagnosis:
   A. Mantle cell lymphoma (MCL) when criteria 1 through 3 are met:
      1. At least one prior therapy for MCL had been ineffective. (Appendix 1)
      2. The patient has received no prior therapy with a tyrosine kinase inhibitor, including but not limited to acalabrutinib (Calquence®).
      3. Ibrutinib (Imbruvica®) is used as monotherapy.
   B. Chronic lymphocytic leukemia (CLL).
   C. Small lymphocytic leukemia (SLL).
   D. Waldenström's macroglobulinemia (WM).
   E. Marginal zone lymphoma (MZL) when at least one prior CD20-directed therapy (see Appendix 2) for MZL has been ineffective AND ibrutinib (Imbruvica) is used as monotherapy.
   F. Chronic graft versus host disease (cGVHD) when treatment with corticosteroids has been ineffective AND ibrutinib (Imbruvica) is used as monotherapy.

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.

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

- MCL or MZL:
  - 140 mg capsules: Up to 120 capsules per 30 days.
  - 70 mg capsules, or 140-, 280- 420 mg tablets: Up to 30 per 30 days.
  - 560 mg tabs: Up to 30 tablets per 30 days
- CLL, SLL, WM, or cGVHD
  - 140 mg capsules: Up to 120 capsules per 30 days.
  - 70 mg capsules, or 140-, 280- 420 mg tablets: Up to 30 per 30 days.
  - 420 mg tablets: Up to 30 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

Appendix 1: Mantle Cell Lymphoma first-line therapy options
• RDHA (rituximab, dexamethasone, cytarabine) + platinum (carboplatin or cisplatin) • Alternating RCHOP/RDHAP (rituximab, cyclophosphamide, doxorubicin, vincristine, prednisone)/(rituximab, dexamethasone, cytarabine, cisplatin) • NORDIC (rituximab + cyclophosphamide, vincristine, doxorubicin, prednisone alternating with rituximab + high-dose cytarabine). • HyperCVAD (cyclophosphamide, vincristine, doxorubicin and dexamethasone alternating with high-dose methotrexate and cytarabine) + rituximab. • Bendamustine + rituximab. • VR-CAP (bortezomib, rituximab, cyclophosphamide, doxorubicin, and prednisone). • RCHOP/CHOP

• Lenalidomide + rituximab

Appendix 2: CD20-directed therapies
• rituximab (Rituxan)(Ruxience)(Truxima) • obinutuzumab (Gazyva) • ofatumumab (Arzerra)(Kesimpta)

REFERENCES

1. Imbruvica. Prescribing information. Pharmacyclics LLC; 2022. Accessed September 15, 2022. https://www.imbruvica.com/files/prescribing-information.pdf.
2. NCCN Clinical Practice Guidelines in Oncology. B-Cell Lymphomas v.5.2021 [Updated September 22, 2021]. Accessed September 15, 2022. https://www.nccn.org/professionals/physician_gls/pdf/b-cell.pdf.
3. NCCN Clinical Practice Guidelines in Oncology. Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma v2.2022 [Updated January]. Accessed September 15, 2022. https://www.nccn.org/professionals/physician_gls/pdf/cll.pdf.
4. NCCN Clinical Practice Guidelines in Oncology. Waldenström's macroglobulinemia/Lymphoplasmacytic v.2.2022 [Updated December 7, 2021]. Accessed September 15, 2022. https://www.nccn.org/professionals/physician_gls/pdf/waldenstroms.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.