PREFERRED SPECIALTY MANAGEMENT POLICY

POLICY: Oncology – Imbruvica Preferred Specialty Management Policy
- Imbruvica® (ibrutinib 140 mg and 280 mg tablets, 140 mg capsules – Pharmacyclics/Janssen)

REVIEW DATE: 07/13/2022

OVERVIEW

Imbruvica, a Bruton kinase inhibitor, is indicated in adults for the following:[1]
- **Chronic lymphocytic leukemia** or **small lymphocytic lymphoma**, including patients with 17p deletion.
- **Graft-Versus-Host Disease, chronic** after failure of one or more lines of systemic therapy.
- **Mantle cell lymphoma,** after at least one prior therapy.
- **Marginal zone lymphoma**, after systemic therapy and have received at least one prior anti-CD20-based therapy.
- **Waldenström Macroglobulinemia**.

Mantle cell lymphoma and marginal zone lymphoma are approved under accelerated approval based on overall response rate. Continued approval for these indications may be contingent upon verification and description of clinical benefit in confirmatory trials.

POLICY STATEMENT

This Preferred Specialty Management program has been developed to encourage the use of the Preferred Product. For all medications (Preferred and Non-Preferred), the patient is required to meet the standard *Oncology – Imbruvica Prior Authorization Policy* criteria. The program also directs the patient to try the Preferred Product (Imbruvica 140 mg capsules) prior to approval of a Non-Preferred Product (Imbruvica 140 mg and 280 mg tablets). Requests for Non-Preferred Products will also be reviewed using the exception criteria (below). If the patient meets the standard *Oncology – Imbruvica Prior Authorization Policy* criteria but has not tried a Preferred Product, approval for a Preferred Product will be authorized. Imbruvica is also available as a 70 mg capsule, a 420 mg tablet, and a 560 mg tablet that are not targeted in this policy. All approvals are provided for 1 year in duration.

Automation: None.

Preferred Product: Imbruvica 140 mg capsules
Non-Preferred Products: Imbruvica 140 mg tablets and 280 mg tablets

RECOMMENDED EXCEPTION CRITERIA

Non-Preferred Product	Exception Criteria
Imbruvica 140 and 280 mg tablets	**1.** Approve for 1 year if the patient meets BOTH of the following (A and B): **A)** Patient meets the standard – *Oncology – Imbruvica Prior Authorization Policy* criteria; AND **B)** Patient has tried Imbruvica 140 mg capsules. **2.** For a patient who has met the *Oncology –Imbruvica Prior Authorization Policy* criteria, but has not met exception criteria (1B): approve Imbruvica 140 mg capsules.

REFERENCES

1. Imbruvica® tablets and capsules [prescribing information]. Sunnyvale, CA and Horsham, PA: Pharmacyclics and Janssen Biotech; May 2022.