PREFERRED SPECIALTY MANAGEMENT POLICY

POLICY: Oncology – Imbruvica Preferred Specialty Management

DATE REVIEWED: 06/03/2020

DRUGS AFFECTED:

• Imbruvica® (ibrutinib 140 mg and 280 mg tablets – Pharmacyclics/Janssen)

OVERVIEW

Imbruvica, a Bruton kinase inhibitor, is indicated for the treatment of mantle cell lymphoma in adults with who have received at least one prior therapy. Imbruvica is also indicated for the treatment of chronic lymphocytic leukemia (CLL) and small lymphocytic lymphoma (SLL) in adult. Regarding CLL and SLL, Imbruvica is also indicated for the treatment of 17p deletion CLL and SLL in adults. Imbruvica is also indicated for the treatment of adult patients with Waldenström's macroglobulinemia. Imbruvica is indicated in the treatment of marginal zone lymphoma in adults who require systemic therapy and have received at least one prior anti-CD20-based therapy. Imbruvica is also indicated for the treatment of chronic graft-versus-host disease in adults after failure of one or more lines of systemic therapy. The dose of mantle cell lymphoma and marginal zone lymphoma is 560 mg once daily (QD). For CLL/SLL, Waldenstrom's macroglobulinemia, and chronic graft versus host disease, the recommended dose is 420 mg QD. For more information on Imbruvica, refer to the ESI Standard *Oncology – Imbruvica Prior Authorization Policy*.

POLICY STATEMENT

This Preferred Specialty Management (PSM) program requires the patient to meet *ESI Standard PA Policy* criteria for Imbruvica and meet the *Oncology – Imbruvica PSM Policy* criteria in this policy. Patients are directed to try one Preferred Product (Imbruvica 140 mg capsules) prior to approval of a Non-Preferred Product (Imbruvica 140 mg and 280 mg tablets). Imbruvica is also available as a 70-mg capsule, a 420 mg tablet, and a 560 mg tablet but 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

Trade Name	Exception
Imbruvica	1. The patient must meet the following criteria (A and B):
140 and 280	A) The patient meets the ESI Standard – $Oncology$ – $Imbruvica\ Prior\ Authorization$
mg tablets	Policy criteria; AND
	B) The patient has tried Imbruvica 140 mg capsules.

REFERENCES

- 1. Imbruvica® tablets and capsules [prescribing information]. Sunnyvale, CA and Horsham, PA: Pharmacyclics and Janssen Biotech; April 2020.
- 2. Oncology Imbruvica Prior Authorization Policy. Express Scripts Holding Company. Updated 06/03/2020.