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: 06/12/2024

INSTRUCTIONS FOR USE

THE FOLLOWING COVERAGE POLICY APPLIES TO HEALTH BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. CERTAIN CIGNA COMPANIES AND/OR LINES OF BUSINESS ONLY PROVIDE UTILIZATION REVIEW SERVICES TO CLIENTS AND DO NOT MAKE COVERAGE DETERMINATIONS. REFERENCES TO STANDARD BENEFIT PLAN LANGUAGE AND COVERAGE DETERMINATIONS DO NOT APPLY TO THOSE CLIENTS. COVERAGE POLICIES ARE INTENDED TO PROVIDE GUIDANCE IN INTERPRETING CERTAIN STANDARD BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. PLEASE NOTE, THE TERMS OF A CUSTOMER'S PARTICULAR BENEFIT PLAN DOCUMENT [GROUP SERVICE AGREEMENT, EVIDENCE OF COVERAGE, CERTIFICATE OF COVERAGE, SUMMARY PLAN DESCRIPTION (SPD) OR SIMILAR PLAN DOCUMENT] MAY DIFFER SIGNIFICANTLY FROM THE STANDARD BENEFIT PLANS UPON WHICH THESE COVERAGE POLICIES ARE BASED. FOR EXAMPLE, A CUSTOMER'S BENEFIT PLAN DOCUMENT MAY CONTAIN A SPECIFIC EXCLUSION RELATED TO A TOPIC ADDRESSED IN A COVERAGE POLICY. IN THE EVENT OF A CONFLICT, A CUSTOMER'S BENEFIT PLAN DOCUMENT ALWAYS SUPERSEDES THE INFORMATION IN THE COVERAGE POLICIES. IN THE ABSENCE OF A CONTROLLING FEDERAL OR STATE COVERAGE MANDATE, BENEFITS ARE ULTIMATELY DETERMINED BY THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT. COVERAGE DETERMINATIONS IN EACH SPECIFIC INSTANCE REQUIRE CONSIDERATION OF 1) THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT IN EFFECT ON THE DATE OF SERVICE; 2) ANY APPLICABLE LAWS/REGULATIONS; 3) ANY RELEVANT COLLATERAL SOURCE MATERIALS INCLUDING COVERAGE POLICIES AND; 4) THE SPECIFIC FACTS OF THE PARTICULAR SITUATION. EACH COVERAGE REQUEST SHOULD BE REVIEWED ON ITS OWN MERITS. MEDICAL DIRECTORS ARE EXPECTED TO EXERCISE CLINICAL JUDGMENT AND HAVE DISCRETION IN MAKING INDIVIDUAL COVERAGE DETERMINATIONS. COVERAGE POLICIES RELATE EXCLUSIVELY TO THE ADMINISTRATION OF HEALTH BENEFIT PLANS. COVERAGE POLICIES ARE NOT RECOMMENDATIONS FOR TREATMENT AND SHOULD NEVER BE USED AS TREATMENT GUIDELINES. IN CERTAIN MARKETS, DELEGATED VENDOR GUIDELINES MAY BE USED TO SUPPORT MEDICAL NECESSITY AND OTHER COVERAGE DETERMINATIONS.

CIGNA NATIONAL FORMULARY COVERAGE:

OVERVIEW

Imbruvica, a Bruton kinase inhibitor, is indicated for the following:[1]
- **Chronic lymphocytic leukemia** or **small lymphocytic lymphoma**, including adults with 17p deletion.
- **Graft-Versus-Host Disease, chronic** in adult and pediatric patients ≥ 1 year and older after failure of one or more lines of systemic therapy.
- **Waldenström Macroglobulinemia**, in adults.

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, a 560 mg tablet, and oral solution that are not targeted in this policy. All approvals are provided for 1 year in duration.

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

Oncology – Imbruvica non-preferred product(s) is(are) covered as medically necessary when the following non-preferred product exception criteria is(are) met. Any other exception is considered not medically necessary.

NON-PREFERRED PRODUCT 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 2023.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	No criteria changes.	07/12/2023
Annual Revision	No criteria changes.	06/12/2024