PREFERRED SPECIALTY MANAGEMENT POLICY

POLICY: Rituximab Intravenous Products Preferred Specialty Management Policy

- Riabni™ (rituximab-arrx intravenous infusion – Amgen)
- Rituxan® (rituximab intravenous infusion – Genentech)
- Ruxience™ (rituximab-pvvr intravenous infusion – Pfizer)
- Truxima® (rituximab-abbs intravenous infusion – Celltrion/Teva)

REVIEW DATE: 05/04/2022

OVERVIEW

Rituximab is a chimeric murine/human monoclonal antibody directed specifically against the CD20 antigen found on the surface of normal and malignant B lymphocytes.[1-4] The antigen CD20 is expressed on > 90% of B-cell non-Hodgkin's lymphomas. B-cells are thought to play a role in the pathogenesis of rheumatoid arthritis and associated chronic synovitis.

Riabni, Ruxience, and Truxima are approved as biosimilar to Rituxan intravenous, indicating no clinically meaningful differences in safety and effectiveness and the same mechanism of action, route of administration, dosage form, and strength as Rituxan intravenous. However, minor differences in clinically inactive components are allowed. At this time, only biosimilarity has been demonstrated, not interchangeability.

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 *Rituximab Intravenous Products Prior Authorization Policy* criteria. The program also directs the patient to the Preferred Product. Requests for Non-Preferred Products will be reviewed using the exception criteria (below). All approvals are provided for a duration as directed in the standard *Rituximab Intravenous Products Prior Authorization Policy*.

Automation: None.

Preferred Product: Ruxience
Non-Preferred Products: Riabni, Rituxan Intravenous, Truxima

RECOMMENDED EXCEPTION CRITERIA

Non-Preferred Products	Exception Criteria
Riabni Rituxan Intravenous Truxima	**1.** Approve if the patient meets ALL of the following (A, B, and C): **A)** Patient meets the standard *Rituximab Intravenous Products Prior Authorization Policy* criteria; AND **B)** Patient meets BOTH of the following (i and ii): **i.** Patient has tried Ruxience, AND **ii.** Patient cannot continue to use the Preferred medication due to a formulation difference in the inactive ingredient(s) [e.g., differences in stabilizing agent, buffering agent, and/or surfactant] which, according to the prescriber, would result in a significant allergy or serious adverse reaction]; OR **C)** Patient has already been started on or has previously received the requested rituximab intravenous product. **2.** For a patient who has met the standard *Rituximab Intravenous Products Prior Authorization Policy* criteria (1A), but have not met exception criteria (1B): approve Ruxience.

REFERENCES

1. Rituxan injection [prescribing information]. South San Fransisco, CA: Genentech; January 2019.
2. Ruxience injection [prescribing information]. New York, NY: Pfizer; July 2019.
3. Truxima injection [prescribing information]. North Wales, PA: Teva/Celltrion; November 2018.
4. Riabni injection [prescribing information]. Thousand Oaks, CA: Amgen; December 2020.