MED RX POLICY

POLICY: Rituximab Products Med Rx Policy

- Riabni™ (rituximab-arrx intravenous infusion – Amgen)
- Rituxan® (rituximab intravenous infusion – Genentech)
- Rituxan Hycela™ (rituximab and hyaluronidase human subcutaneous injection – Biogen and Genentech/Roche)
- Ruxience™ (rituximab-pvvr intravenous infusion – Pfizer)
- Truxima® (rituximab-abbs intravenous infusion – Celltrion/Teva)

REVIEW DATE: 02/26/2025

OVERVIEW

Rituximab products are CD20-directed cytolytic antibodies.[1-5] The antigen CD20 is expressed on > 90% of B-cell non-Hodgkin's lymphomas (NHLs). B-cells are also thought to play a role in the pathogenesis of rheumatoid arthritis (RA) and associated chronic synovitis.

Riabni, Ruxience, and Truxima are approved as biosimilars 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 established, not interchangeability. Rituxan Hycela is a combination of rituximab and hyaluronidase human for subcutaneous administration. It contains the identical molecular antibody of rituximab available in Rituxan intravenous with hyaluronidase added to facilitate systemic delivery.

POLICY STATEMENT

This Med Rx program has been developed to encourage the use of Preferred Products. For all medications (Preferred and Non-Preferred), the patient is required to meet the respective standard *Utilization Management Medical Policy* criteria. This program also directs the patient to try at least one Preferred Product prior to the approval of a Non-Preferred Product. Requests for Non-Preferred Products will also be reviewed using the exception criteria (below). All approvals are provided for the duration noted in the respective standard *Utilization Management Medical Policy*.

Automation: None.

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

RECOMMENDED EXCEPTION CRITERIA

Non-Preferred Products	Exception Criteria
Rituxan Hycela	**1.** Approve if the patient meets BOTH of the following (A and B): **A)** Patient meets the standard *Oncology – Rituxan Hycela Utilization Management Medical Policy* criteria; AND **B)** Patient meets ONE of the following (i, ii, or iii): **i.** Patient has tried one of Riabni, Ruxience, or Truxima but, according to the prescriber, cannot continue to use this product; OR **ii.** Patient cannot use rituximab intravenous due to an inability to obtain or maintain intravenous access; OR **iii.** Patient has been already started on or has previously received Rituxan Hycela.
Rituxan	**1.** Approve if the patient meets BOTH of the following (A and B): **A)** Patient meets the standard *Rituximab Intravenous Products Utilization Management Medical Policy* criteria; AND **B)** Patient meets BOTH of the following (i and ii): **i.** Patient has tried one of Riabni, Ruxience, or Truxima; 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.

REFERENCES

1. Rituxan® intravenous infusion [prescribing information]. South San Fransisco, CA: Genentech; December 2021.
2. Ruxience™ intravenous infusion [prescribing information]. New York, NY: Pfizer; October 2023.
3. Truxima® intravenous infusion [prescribing information]. North Wales, PA: Teva/Celltrion; November 2023.
4. Rituxan Hycela™ injection for SC use [prescribing information]. South San Francisco, CA: Biogen and Genentech/Roche; June 2021.
5. Riabni™ intravenous infusion [prescribing information]. Thousand Oaks, CA: Amgen; June 2022.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	No criteria changes.	03/01/2023
Annual Revision	No criteria changes.	02/28/2024
Selected Revision	**Changes effective 01/01/2025** **Riabni:** Moved from non-preferred to one of the preferred products. Rituxan and Rituxan Hycela remain non-preferred products.	10/09/2024
Annual Revision	**Rituxan:** Removed option of approval allowing continuation of therapy.	02/26/2025