Med Rx Policy

Policy: Inflammatory Conditions – Infliximab Products Med Rx Policy
- Avsola™ (infliximab-axxq intravenous infusion – Amgen)
- Inflectra™ (infliximab-dyyb intravenous infusion – Hospira/Pfizer)
- Remicade® (infliximab intravenous infusion – Janssen, authorized generic)
- Renflexis® (infliximab-abda intravenous infusion – Samsung Bioepis/Merck)

Review Date: 05/10/2023

Overview

Infliximab products are available and are indicated for the treatment of a variety of inflammatory conditions.[1-4] Avsola, Inflectra, and Renflexis were approved as biosimilar to Remicade, indicating no clinically meaningful differences in safety and effectiveness and the same mechanism of action, route of administration, dosage form, and strength as Remicade.[2-4] However, minor differences in clinically inactive components are allowed. At this time, Avsola, Inflectra, and Renflexis have only demonstrated biosimilarity, not interchangeability. Remicade is also available as an authorized generic which is produced using the same cell line as brand name Remicade. For all indications, infliximab authorized generic is substitutable for brand name Remicade.

Policy Statement

This Med Rx program has been developed to encourage the use of Preferred Products. For all products (Preferred and Non-Preferred), the patient is required to meet the standard *Inflammatory Conditions – Infliximab Products 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 standard *Inflammatory Conditions – Infliximab Products Utilization Management Medical Policy*.

Automation: None.

Preferred Products: Avsola, Inflectra
Non-Preferred Products: infliximab (authorized generic), Remicade, Renflexis

Recommended Exception Criteria

Non-Preferred Products	Exception Criteria
infliximab (authorized generic) Remicade Renflexis	1. Approve if the patient meets both of the following (A and B): A) Patient meets the standard *Inflammatory Conditions – Infliximab Products Utilization Management Medical Policy* criteria; AND B) Patient meets ONE of the following conditions (i or ii): **i.** Patient meets both of the following (a and b): **a)** Patient has tried one of Inflectra or Avsola; AND **b)** 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 ii. Patient is currently receiving requested agent for a condition other than plaque psoriasis. Note: For a patient currently taking for plaque psoriasis, refer to criterion 1Bi. However, if the patient is currently taking for concomitant plaque psoriasis and psoriatic arthritis, 1Bii applies.

References

1. Remicade injection [prescribing information]. Horsham, PA: Janssen; June 2018.
2. Inflectra injection [prescribing information]. Lake Forest, IL: Hospira/Pfizer; April 2016.
3. Renflexis injection [prescribing information]. Whitehouse Station, NJ: Samsung Bioepis/Merck; April 2017.
4. Avsola injection [prescribing information]. Thousand Oaks, CA: Amgen; December 2019.

History

Type of Revision	Summary of Changes	Review Date
Early Annual Revision	Infliximab authorized generic was added to the policy as a Preferred Product.	05/04/2022
Selected Revision	Effective 01/01/2023: **Avsola** was moved from Non-Preferred to be a Preferred Product. **Remicade** and **infliximab (authorized generic)** were moved from Preferred to be Non-Preferred Products.	09/21/2022
Annual Revision	No criteria changes.	05/10/2023