

CARE VALUE POLICY

- POLICY:** Inflammatory Conditions – Adalimumab Products Care Value Policy for National Preferred, High Performance, and Basic Formularies
- Abrilada[™] (adalimumab-afzb subcutaneous injection – Pfizer)
 - adalimumab-aacf subcutaneous injection (Fresenius Kabi)
 - adalimumab-adaz subcutaneous injection (Sandoz/Novartis)
 - adalimumab-adbm subcutaneous injection (Boehringer Ingelheim)
 - adalimumab-fkjp subcutaneous injection (Mylan)
 - Amjevita[™] (adalimumab-atto subcutaneous injection – Amgen)
 - Cyltezo[®] (adalimumab-adbm subcutaneous injection – Boehringer Ingelheim)
 - Hadlima[™] (adalimumab-bwwd subcutaneous injection – Organon/Samsung Bioepis)
 - Hulio[®] (adalimumab-fkjp subcutaneous injection – Mylan)
 - Humira[®] (adalimumab subcutaneous injection – AbbVie, Cordavis)
 - Hyrimoz[®] (adalimumab-adaz subcutaneous injection – Sandoz/Novartis, Cordavis)
 - Idacio[®] (adalimumab-aacf subcutaneous injection – Fresenius Kabi)
 - Yuflyma[®] (adalimumab-aaty subcutaneous injection – Celltrion)
 - Yusimry[™] (adalimumab-aqvh subcutaneous injection – Coherus)

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OVERVIEW

Adalimumab products are indicated for the treatment of a variety of inflammatory conditions.¹⁻¹⁰ Multiple adalimumab products were approved as biosimilar to Humira, indicating no clinically meaningful differences in safety and effectiveness and the same mechanism of action, route of administration, dosage form, and strength as Humira.^{1-4,6-10} However, minor differences in clinically inactive components are allowed. There are unbranded versions of Cyltezo, Hulio, Hyrimoz, and Idacio which are identically formulated and packaged by the same manufacturer as the corresponding branded biosimilar.

POLICY STATEMENT

This Care Value 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 – Adalimumab Products Prior Authorization Policy* criteria. This program also directs the patient to try ALL of the Preferred Products 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 – Adalimumab Products Prior Authorization Policy*. If the patient meets the standard *Prior Authorization Policy* criteria but has not tried a Preferred Product, approval for the Preferred Products will be authorized.

Automation: None.

Preferred and Non-Preferred Products.

Preferred Products	• Cyltezo • Humira (NDCs starting with 00074) • Hyrimoz (NDCs starting with 61314)
Non-Preferred Products (directed to <u>ALL</u> Preferred Products) [documentation required]*	• Abrilada • adalimumab-aacf • adalimumab-adaz – <i>directed to Preferred NDCs of Hyrimoz</i> • adalimumab-adbm – <i>directed to Cyltezo</i> • adalimumab-fkjp • Amjevita • Hadlima • Hulio • Humira (NDCs starting with 83457) – <i>directed to Preferred NDCs of Humira</i> • Hyrimoz (NDCs starting with 83457) – <i>directed to Preferred NDCs of Hyrimoz</i> • Idacio • Yuflyma • Yusimry

RECOMMENDED EXCEPTION CRITERIA

Non-Preferred Products	Exception Criteria
Abrilada adalimumab-aacf adalimumab-fkjp Amjevita Hadlima Hulio Idacio Yuflyma Yusimry	1. Approve if the patient meets both of the following (A and B): A) Patient meets the standard <i>Inflammatory Conditions – Adalimumab Products Prior Authorization Policy</i> criteria; AND B) Patient meets ALL of the following (i, ii, and iii): i. Patient is currently taking the requested adalimumab product for ≥ 120 days; AND ii. Patient has tried ALL of Cyltezo, Humira, <u>and</u> Hyrimoz [documentation required]; AND iii. Patient cannot continue to use ALL Preferred medications (i.e., Cyltezo, Humira, <u>and</u> Hyrimoz) due to formulation differences 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 [documentation required]. <u>Note:</u> The Preferred Hyrimoz product includes NDCs starting with 61314. The Preferred Humira product includes NDCs starting with 00074. A trial of adalimumab-adaz counts towards a trial of Hyrimoz. A trial of adalimumab-adbm counts towards a trial of Cyltezo. 2. If the patient has met the standard <i>Inflammatory Conditions – Adalimumab Products Prior Authorization Policy</i> criteria (1A), but has <u>not</u> met exception criteria (1B): approve the Preferred Products.
adalimumab-adaz Hyrimoz (NDCs starting with 83457)	Adalimumab-adaz and Hyrimoz (NDCs starting with 83457) are not approved. Offer to review for Hyrimoz (NDCs starting with 61314) using the <i>Inflammatory Conditions – Adalimumab Products Prior Authorization Policy</i> criteria.

adalimumab-adbm	Adalimumab-adbm is not approved. Offer to review for Cyltezo using the <i>Inflammatory Conditions – Adalimumab Products Prior Authorization Policy</i> criteria.
Humira (NDCs starting with 83457)	Humira (NDCs starting with 83457) are not approved. Offer to review for Humira (NDCs starting with 00074) using the <i>Inflammatory Conditions – Adalimumab Products Prior Authorization Policy</i> criteria.

REFERENCES

1. Abrilada™ subcutaneous injection [prescribing information]. New York, NY: Pfizer; October 2023.
2. Amjevita™ subcutaneous injection [prescribing information]. Thousand Oaks, CA: Amgen; July 2023.
3. Cyltezo® subcutaneous injection [prescribing information]. Ridgefield, CT: Boehringer Ingelheim; June 2023.
4. Hadlima™ subcutaneous injection [prescribing information]. Jersey City, NJ: Organon/Samsung Bioepis; July 2023.
5. Humira® subcutaneous injection [prescribing information]. North Chicago, IL: AbbVie; November 2023.
6. Hulio® subcutaneous injection [prescribing information]. Morgantown, WV: Mylan; August 2023.
7. Hyrimoz® subcutaneous injection [prescribing information]. Princeton, NJ: Sandoz/Novartis; September 2023.
8. Idacio® subcutaneous injection [prescribing information]. Lake Zurich, IL: Fresenius Kabi; October 2023.
9. Yuflyma® subcutaneous injection [prescribing information]. Jersey City, NJ: Celltrion; September 2023.
10. Yusimry™ subcutaneous injection [prescribing information]. Redwood City, CA: Coherus; September 2023.