PREFERRED SPECIALTY MANAGEMENT POLICY

POLICY: Inflammatory Conditions – Adalimumab Products Preferred Specialty Management Policy for National Preferred Formularies – **Choice**

- 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)

REVIEW DATE: 11/22/2023; selected revision 01/24/2024, 02/28/2024

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

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 Preferred Specialty Management 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.

Preferred and Non-Preferred Products.

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

Inflammatory Conditions – Adalimumab 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 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 *Inflammatory Conditions – Adalimumab Products Prior Authorization Policy* 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/adalimumab-adbm, Humira, and Hyrimoz/adalimumab-adaz **[documentation required]**; AND **iii.** Patient cannot continue to use ALL Preferred medications (i.e., Cyltezo/adalimumab-adbm, Humira, and Hyrimoz/adalimumab-adaz) 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]**. Note: The Preferred Hyrimoz product includes NDCs starting with 61314. The Preferred Humira product includes NDCs starting with 00074. **2.** If the patient has met the standard *Inflammatory Conditions – Adalimumab Products Prior Authorization Policy* criteria (1A), but has not met exception criteria (1B): approve the Preferred Products.
Humira (NDCs starting with 83457)	Humira (NDCs starting with 83457) are not approved. Offer to review for Humira (NDCs starting with 00074) using the *Inflammatory Conditions – Adalimumab Products Prior Authorization Policy* criteria.
Hyrimoz (NDCs starting with 83457)	Hyrimoz (NDCs starting with 83457) are not approved. Offer to review for Hyrimoz (NDCs starting with 61314) or adalimumab-adaz using the *Inflammatory Conditions – Adalimumab Products Prior Authorization Policy* 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.

HISTORY

Type of Revision	Summary of Changes	Review Date
New Policy	Effective 01/01/2024.	11/22/2023
Selected Revision	**Effective 03/01/2024** Adalimumab-aacf was added as Non-Preferred.	01/24/2024
Selected Revision	**Effective 04/01/2024** It was clarified that the Preferred Humira Product is specific for NDCs starting with 00074. Additionally, Humira (NDCs starting with 83457) were added to Non-Preferred. Requests for Humira (NDCs starting with 83457) are directed to review for the Preferred formulation of Humira (NDCs starting with 00074).	02/28/2024