PREFERRED SPECIALTY MANAGEMENT POLICY

POLICY: Inflammatory Conditions – Adalimumab Products Preferred Specialty Management Policy for National Preferred, High Performance, and Basic Formularies – **Choice**

- Abrilada™ (adalimumab-afzb subcutaneous injection – Pfizer)
- adalimumab-aacf subcutaneous injection (Fresenius Kabi)
- adalimumab-aaty subcutaneous injection (Celltrion)
- adalimumab-adaz subcutaneous injection (Sandoz/Novartis)
- adalimumab-adbm subcutaneous injection (Boehringer Ingelheim)
- adalimumab-fkjp subcutaneous injection (Mylan)
- adalimumab-ryvk subcutaneous injection (Alvotech/Teva)
- 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)
- Simlandi® (adalimumab-ryvk subcutaneous injection – Alvotech/Teva)
- Yuflyma® (adalimumab-aaty subcutaneous injection – Celltrion)
- Yusimry™ (adalimumab-aqvh subcutaneous injection – Coherus)

REVIEW DATE: 10/30/2024; selected revision 11/20/2024, 12/04/2024, 01/29/2025, 03/12/2025, 04/02/2025, 06/04/2025

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 WHERE APPROPRIATE AND HAVE

DISCRETION IN MAKING INDIVIDUAL COVERAGE DETERMINATIONS. WHERE COVERAGE FOR CARE OR SERVICES DOES NOT DEPEND ON SPECIFIC CIRCUMSTANCES, REIMBURSEMENT WILL ONLY BE PROVIDED IF A REQUESTED SERVICE(S) IS SUBMITTED IN ACCORDANCE WITH THE RELEVANT CRITERIA OUTLINED IN THE APPLICABLE COVERAGE POLICY, INCLUDING COVERED DIAGNOSIS AND/OR PROCEDURE CODE(S). REIMBURSEMENT IS NOT ALLOWED FOR SERVICES WHEN BILLED FOR CONDITIONS OR DIAGNOSES THAT ARE NOT COVERED UNDER THIS COVERAGE POLICY (SEE "CODING INFORMATION" BELOW). WHEN BILLING, PROVIDERS MUST USE THE MOST APPROPRIATE CODES AS OF THE EFFECTIVE DATE OF THE SUBMISSION. CLAIMS SUBMITTED FOR SERVICES THAT ARE NOT ACCOMPANIED BY COVERED CODE(S) UNDER THE APPLICABLE COVERAGE POLICY WILL BE DENIED AS NOT COVERED. 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.[1-11] 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.[1-4,6-11] However, minor differences in clinically inactive components are allowed. There are unbranded versions of Cyltezo, Hulio, Hyrimoz, Idacio, Simlandi, and Yuflyma which are identically formulated and packaged by the same manufacturer as the corresponding branded biosimilar.

POLICY STATEMENT

This 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.

Documentation: When documentation is required, the prescriber must provide written documentation supporting the trials of these other Products, noted in the criteria as **[documentation required]**. Documentation may include, but is not limited to chart notes, prescription claims records, and/or prescription receipts.

Preferred and Non-Preferred Products.

Preferred Products	• Cyltezo/adalimumab-adbm • adalimumab-adaz • Simlandi/adalimumab-ryvk
Non-Preferred Products (directed to **ALL** Preferred Products) **[documentation required]**	• Abrilada • Amjevita • Hadlima • Hulio/adalimumab-fkjp • Humira • Hyrimoz– *directed to adalimumab-adaz*

	• Idacio/adalimumab-aacf • Yuflyma/adalimumab-aaty • Yusimry

***Inflammatory Conditions – Adalimumab Products Preferred Specialty Management Policy* 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 Amjevita Hadlima Hulio/ adalimumab-fkjp Humira Idacio/ adalimumab-aacf Yuflyma/ adalimumab-aaty 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 BOTH of the following (i and ii): **i.** Patient has tried ALL of Cyltezo/adalimumab-adbm, adalimumab-adaz, and Simlandi/adalimumab-ryvk **[documentation required]**; AND **ii.** Patient cannot continue to use ALL Preferred medications (i.e., Cyltezo/adalimumab-adbm, adalimumab-adaz, and Simlandi/adalimumab-ryvk) 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]**. **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. For selected indications, patient will also be referred to other Preferred Products. Refer to Appendix A.
Hyrimoz	Hyrimoz is not approved. Offer to review for adalimumab-adaz using the *Inflammatory Conditions – Adalimumab Products Prior Authorization Policy* criteria.

REFERENCES

1. Abrilada™ subcutaneous injection [prescribing information]. New York, NY: Pfizer; April 2024.
2. Amjevita™ subcutaneous injection [prescribing information]. Thousand Oaks, CA: Amgen; August 2024.
3. Cyltezo® subcutaneous injection [prescribing information]. Ridgefield, CT: Boehringer Ingelheim; April 2024.
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 2024.
6. Hulio® subcutaneous injection [prescribing information]. Morgantown, WV: Mylan; December 2023.
7. Hyrimoz® subcutaneous injection [prescribing information]. Princeton, NJ: Sandoz/Novartis; June 2024.
8. Idacio® subcutaneous injection [prescribing information]. Lake Zurich, IL: Fresenius Kabi; June 2024.
9. Yuflyma® subcutaneous injection [prescribing information]. Jersey City, NJ: Celltrion; August 2024.
10. Yusimry™ subcutaneous injection [prescribing information]. Redwood City, CA: Coherus; September 2023.
11. Simlandi® subcutaneous injection [prescribing information]. Leesburg, VA: Alvotech/Teva; August 2024.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	**Effective 01/01/2025.** Policy name was changed to *Inflammatory Conditions – Adalimumab Products Preferred Specialty Management Policy for National Preferred and Basic Formularies – Choice*; previously High Performance Formulary was also included. The existing Non-Preferred Products were given a designation of Step 3; the requirement that a patient is taking the requested Non-Preferred Product for at least 120 days was removed. For targeted indications, a patient will also be referred to other (non-adalimumab) Preferred Products as listed in the *Inflammatory Conditions Preferred Specialty Management Policy for National Preferred, High Performance, and Basic Formularies – Choice/Alternate*. **Humira:** Products with NDCs starting with 00074 were moved from Preferred to a newly created Step 2 Non-Preferred. A patient is directed to a trial of one Preferred Product with documentation requirements. Documentation is also required to support the requirement that formulation difference(s) in the inactive ingredient(s) which, according to the prescriber, would result in a significant allergy or serious adverse reaction. **Hyrimoz:** The NDCs starting with 83457 were moved to Non-Preferred (Step 3). All requests for Hyrimoz are directed to adalimumab-adaz.	10/30/2024
Selected Revision	**Effective 01/01/2025.** **Humira (NDCs starting with 00074):** An exception was added for a patient currently taking Humira to allow continuation of therapy. **Velsipity:** This drug was added as a Preferred Product for Ulcerative Colitis.	11/20/2024

Selected Revision	Cosentyx subcutaneous was added as a Preferred Non-Adalimumab Product for hidradentitis suppurativa.	12/04/2024
Selected Revision	Omvoh subcutaneous was added as a Preferred Non-Adalimumab Product for Crohn's disease.	01/29/2025
Selected Revision	**Effective 03/21/2025.** Selarsdi, ustekinumab-ttwe, and Yesintek subcutaneous were added as Preferred Non-Adalimumab Products for psoriatic arthritis, psoriasis, Crohn's disease, and ulcerative colitis.	03/12/2025
Selected Revision	**Effective 04/18/2025.** Tremfya subcutaneous was added as a Preferred Non-Adalimumab Product for Crohn's disease.	04/02/2025
Selected Revision	The policy name was changed to include the descriptor, "High Performance Formulary" **Humira:** Products with NDCs starting with 00074 was removed as a Step 2 Non-Preferred Product. As a result, the "Step 2" category was removed, and products are now categorized as Preferred and Non-Preferred. In addition, exception criteria for Humira products with NDCs starting with 83457 was removed. All Humira NDC's are designated as a Non-Preferred Product; a patient is directed to a trial of all Preferred Products with documentation requirements.	06/04/2025

APPENDIX A.
Other (Non-Adalimumab) Preferred Products by Indication.

Rheumatology					Dermatology		Gastroenterology	
RA	**JIA**	**AS**	**nr-axSpA**	**PsA**	**HS**	**Psoriasis**	**CD**	**UC**
• **Enbrel**	• **Enbrel**	• **Enbrel** • **Taltz**	• **Cimzia** • **Taltz**	• **Enbrel** • **Otezla** • **Skyrizi SC#** • **Ustekinumab SC Products –** Stelara SC, Selarsdi SC, Ustekinumab-ttwe SC, Yesintek SC • **Taltz** • **Tremfya SC**	• **Cosentyx SC**	• **Enbrel** • **Otezla** • **Skyrizi SC#** • **Sotyktu** • **Ustekinumab SC Products –** Stelara SC, Selarsdi SC, Ustekinumab-ttwe SC, Yesintek SC • **Taltz** • **Tremfya SC**	• **Skyrizi SC** (on-body injector) • **Tremfya SC** • **Ustekinumab SC Products –** Stelara SC, Selarsdi SC, Ustekinumab-ttwe SC, Yesintek SC • **Zymfentra** • **Omvoh SC**	• **Omvoh SC** • **Skyrizi SC** (on-body injector) • **Ustekinumab SC Products –** Stelara SC, Selarsdi SC, Ustekinumab-ttwe SC, Yesintek SC • **Tremfya SC** • **Velsipity** • **Zymfentra**

RA – Rheumatoid arthritis; JIA – Juvenile idiopathic arthritis; AS – Ankylosing spondylitis; nr-ax-SpA – Non-radiographic spondyloarthritis; PsA – Psoriatic arthritis; HS – Hidradenitis suppurativa; CD – Crohn's disease; UC – Ulcerative colitis; SC – Subcutaneous; # Pen and syringe.