



Drug Coverage Policy

Effective Date03/01/2026
Coverage Policy Number.....PSM013
Policy Title.....Adalimumab Products
Preferred Specialty Management Policy
– Standard, Performance, Value,
Advantage, and Total Savings

Inflammatory Conditions – Adalimumab Products Preferred Specialty Management Policy: Standard/Performance, Value/Advantage, and Total Savings Prescription Drug Lists

- 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-bwwd subcutaneous injection (Cordavis)
- adalimumab-fkjp subcutaneous injection (Mylan)
- adalimumab-ryvk subcutaneous injection (Quallent/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)

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.

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, Hadlima, Hulio, Hyrimoz, Idacio, Simlandi, and Yuflyma which are identically formulated and packaged by the same manufacturer as the corresponding branded biosimilar.

Coverage Policy

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). This program is designed to allow continuation of therapy for a patient currently taking Humira. 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, a request for the Preferred Products may be reviewed using the *Inflammatory Conditions – Adalimumab Products Prior Authorization Policy* criteria.

The following products are not covered on the pharmacy and medical benefits for Employer Plans: adalimumab-bwdd, adalimumab-ryvk (-ryvk NDCs starting with 51759), Amjevita (NDCs starting

with 84612), Humira (NDCs starting with 83457), Hyrimoz (NDCs starting with 83457) Refer to the customer's benefit plan document for details of covered product(s).

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. All documentation must include patient-specific identifying information.

Preferred and Non-Preferred Products.

<p>Step 1 Preferred Products</p>	<ul style="list-style-type: none"> • Cyltezo/adalimumab-adbm • Simlandi/adalimumab-ryvk (-ryvk NDCs starting with 82009)
<p>Step 2 Non-Preferred Products (directed to ONE Preferred Product) [documentation required]</p>	<ul style="list-style-type: none"> • Humira (NDCs starting with 00074)
<p>Step 3 Non-Preferred Products (directed to ALL Preferred Products) [documentation required]</p>	<ul style="list-style-type: none"> • Abrilada • Amjevita (NDCs starting with 72511) • Hadlima • Hulio/adalimumab-fkjp • Hyrimoz (NDCs starting with 61314)/adalimumab-adaz • Idacio/adalimumab-aacf • Yuflyma/adalimumab-aaty • Yusimry
<p>Non-Covered Products</p>	<ul style="list-style-type: none"> • adalimumab-bwwd • adalimumab-ryvk (-ryvk NDCs starting with 51759) • Amjevita (NDCs starting with 84612) • Humira (NDCs starting with 83457) • Hyrimoz (NDCs starting with 83457)

Adalimumab non-preferred products are considered medically necessary when the following non-preferred product exception criteria are met. Any other exception is considered not medically necessary.

NON-PREFERRED PRODUCT EXCEPTION CRITERIA

Non-Preferred Products	Exception Criteria
<p>Abrilada, Amjevita (NDCs starting with 72511), Hadlima,</p>	<p>1. Approve if the patient meets BOTH of the following (A <u>and</u> B):</p> <ul style="list-style-type: none"> A) Patient meets the standard <i>Inflammatory Conditions – Adalimumab Products Prior Authorization Policy</i> criteria; AND B) Patient meets BOTH of the following (i <u>and</u> ii): <ul style="list-style-type: none"> i. Patient has tried BOTH of Cyltezo/adalimumab-adbm <u>and</u> Simlandi/adalimumab-ryvk (NDCs

<p>Hulio/ adalimumab- fkjp, Hyrimoz (NDCs starting with 61314)/ adalimumab- adaz, Idacio/ adalimumab- aacf, Yuflyma/ adalimumab- aaty, Yusimry</p>	<p>starting with 82009) [documentation required]; AND</p> <p>ii. Patient cannot continue to use BOTH Preferred medications (i.e., Cyltezo/adalimumab-adbm <u>and</u> Simlandi/adalimumab-ryvk [NDCs starting with 82009]) 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: A trial of adalimumab-ryvk with NDCs starting with 51759 also counts.</p> <p>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): A request for the Preferred Products (Cyltezo, adalimumab-adbm, Simlandi, or adalimumab-ryvk [NDCs starting with 82009]) may be reviewed. For selected indications, patient will also be referred to other Preferred Products. Refer to Appendix A.</p>
<p>Humira (NDCs starting with 00074)</p>	<p>1. Approve if the patient meets BOTH of the following (A <u>and</u> B):</p> <p>A) Patient meets the standard <i>Inflammatory Conditions – Adalimumab Products Prior Authorization Policy</i> criteria; AND</p> <p>B) Patient meets ONE of the following (i <u>or</u> ii):</p> <p>i. Patient meets BOTH of the following (a <u>and</u> b):</p> <p>a) Patient has tried ONE of Cyltezo/adalimumab-adbm <u>or</u> Simlandi/adalimumab-ryvk (NDCs starting with 82009) [documentation required]; AND</p> <p>b) Patient cannot continue to use the Preferred medications (i.e., Cyltezo/adalimumab-adbm, <u>or</u> Simlandi/adalimumab-ryvk [NDCs starting with 82009]) 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]; OR</p> <p>Note: A trial of adalimumab-ryvk with NDCs starting with 51759 also counts.</p> <p>ii. Patient is currently taking Humira.</p> <p>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): A request for the Preferred Products (Cyltezo, adalimumab-adbm, Simlandi, or adalimumab-ryvk [NDCs starting with 82009]) may be reviewed. For selected indications, the patient will also be referred to other Preferred Products. Refer to Appendix A.</p>
<p>adalimumab- bwwd,</p>	<p>Non-Covered adalimumab products are not approved. A request for the Preferred Products (Cyltezo, adalimumab-adbm, Simlandi,</p>

<p>adalimumab-ryvk (NDCs starting with 51759), Amjevita (NDCs starting with 84612), Humira (NDCs starting with 83457), Hyrimoz (NDCs starting with 83457)</p>	<p>or adalimumab-ryvk [NDCs starting with 82009]) may be reviewed using the <i>Inflammatory Conditions – Adalimumab Products Prior Authorization Policy</i> criteria.</p>
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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.

Revision Details

Type of Revision	Summary of Changes	Date
New	<p>New policy Effective 01/01/2025 Criteria has been relocated from <i>Inflammatory Conditions – Adalimumab Products Preferred Specialty Management Policy – (PSM003)</i> into this newly created policy for Standard/Performance, Value/Advantage, Total Savings drug list plans. The existing Non-Preferred Products were given a designation of Step 3; the requirement that a patient is taking the requested Non-Preferred</p>	01/01/2025

	<p>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 respective <i>Inflammatory Conditions Preferred Specialty Management Policy for Employer Plans</i>.</p> <p>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. Patients who are currently taking Humira (NDCs starting with 00074) are allowed an exception to the preferred product requirement.</p> <p>Hyrimoz: All requests for Hyrimoz are directed to adalimumab-adaz.</p> <p>Humira (NDCs starting with 00074): An exception was added for a patient currently taking Humira to allow continuation of therapy.</p>	
Selected Revision	Cosentyx subcutaneous was added to the Appendix as a Preferred Non-Adalimumab Product for hidradentitis suppurativa.	02/01/2025
Selected Revision	Velsipity: This drug was added as a Preferred Non-Adalimumab Product for Ulcerative Colitis.	03/15/2025
Selected Revision	OmvoH subcutaneous: This drug was added as a Preferred Non-Adalimumab Product for Crohn's disease and Ulcerative Colitis.	04/01/2025
Selected Revision	Updated Appendix to add Selarsdi, ustekinumab-ttwe, and Yesintek subcutaneous as Preferred Non-Adalimumab Products for psoriatic arthritis, psoriasis, Crohn's disease, and ulcerative colitis	04/15/2025
Selected Revision	Tremfya Subcutaneous was added to Appendix A as a Preferred Non-Adalimumab Product for Crohn's disease.	05/15/2025
Selected Revision	Adalimumab-adaz was moved from a Preferred Product to a Non-Preferred product. A patient is directed to a trial of Preferred Products 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. Patients who are currently taking adalimumab-adaz are allowed an exception to the preferred product requirement.	07/15/2025
Selected Revision	Adalimumab-adaz: removed "Patient is currently taking adalimumab-adaz" as an option of approval to allow continuation of therapy. The same	09/01/2025

	exception criteria will now apply for adalimumab-adaz as for all of the other Step 3 Non-Preferred Products.	
Annual Revision	<p>Adalimumab-ryvk: It was specified that NDCs starting with 82009 are a Preferred product.</p> <p>Non-Adalimumab Preferred Products:</p> <ul style="list-style-type: none"> • For psoriatic arthritis and psoriasis, Otezla XR was added as a Preferred product. • For psoriatic arthritis, psoriasis, Crohn’s disease, and ulcerative colitis, Stelara subcutaneous was removed from the Preferred products. 	01/01/2026
Selected Revision	<p>Adalimumab-bwwd, adalimumab-ryvk (NDCs starting with 51759), Amjevita (NDCs starting with 84612), Humira (NDCs starting with 83457), Hyrimoz (NDCs starting with 83457): Added to the policy as Non-Covered products and directing to Preferred Products.</p> <p>Adalimumab-ryvk: In the note, it was specified that NDCs starting with 51759 also count toward the trial of the preferred -ryvk product.</p>	03/01/2026

The policy effective date is in force until updated or retired.

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/Otezla XR •Skyrizi SC# •Ustekinumab SC Products –Selarsdi SC, Ustekinumab-ttwe SC, Yesintek SC •Taltz •Tremfya SC	•Cosentyx SC	•Enbrel •Otezla/Otezla XR •Skyrizi SC •Sotyktu •Ustekinumab SC Products –Selarsdi SC, Ustekinumab-ttwe SC, Yesintek SC •Taltz •Tremfya SC	•Omvoh SC •Skyrizi SC (on-body injector) •Tremfya SC •Ustekinumab SC Products –Selarsdi SC, Ustekinumab-ttwe SC, Yesintek SC •Zymfentra	•Omvoh SC •Skyrizi SC (on-body injector) •Ustekinumab SC Products –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.

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