# DRUG QUANTITY MANAGEMENT POLICY – PER DAYS

**POLICY:** Inflammatory Conditions – Adalimumab Products Drug Quantity Management Policy – Per Days

- 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 (Teva/Alvotech)
- Amjevita™ (adalimumab-atto subcutaneous injection – Amgen)
- CDV Humira® (adalimumab subcutaneous injection – Cordavis)
- CDV Hyrimoz® (adalimumab-adaz subcutaneous injection – Cordavis)
- 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)
- Hyrimoz® (adalimumab-adaz subcutaneous injection – Sandoz/Novartis)
- 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:** 05/07/2025; selected revision 07/02/2025

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***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 tumor necrosis factor inhibitors (TNFis) approved for the following:[1]

- **Ankylosing spondylitis**, for reducing signs and symptoms in adults with active disease.
- **Crohn's disease**, for treatment of moderately to severely active disease in patients ≥ 6 years of age.
- **Hidradenitis suppurativa**, for treatment of moderate to severe disease in patients ≥ 12 years of age.
- **Juvenile idiopathic arthritis**, ± methotrexate for reducing signs and symptoms of moderately to severely active polyarticular disease in patients ≥ 2 years of age.
- **Plaque psoriasis**, for treatment of adults with moderate to severe chronic disease who are candidates for systemic therapy or phototherapy and when other systemic therapies are medically less appropriate.
- **Psoriatic arthritis**, ± non-biologic disease-modifying antirheumatic drugs (DMARDs), for reducing the signs and symptoms, inhibiting the progression of structural damage, and improving physical function in adults with active disease.
- **Rheumatoid arthritis**, ± methotrexate or other non-biologic DMARDS to reduce the signs and symptoms, induce major clinical response, inhibit the progression of structural damage, and improve physical function in adults with moderately to severely active disease.
- **Ulcerative colitis**, for treatment of moderately to severely active disease in patients ≥ 5 years of age. However, efficacy has not been established in patients with ulcerative colitis who have lost response or were intolerant to another TNFi.
- **Uveitis**, in patients ≥ 2 years of age with noninfectious intermediate, posterior, and panuveitis.

Of note, FDA-approved indications for the adalimumab biosimilars to Humira may differ from the indications listed above.[2-10]

### Dosing

**Table 1. FDA-Approved Dosing of Adalimumab.[1-10]**

| FDA-Approved Indication | Dosing |
|---|---|
| Ankylosing spondylitis | 40 mg SC once every other week |
| Crohn's disease | Adults and pediatric patients weighing ≥ 40 kg (88 lbs): Initial dose of 160 mg SC (either given in 1 day or split over 2 consecutive days), then 80 mg SC on Day 15, followed by 40 mg SC once every other week starting on Day 29. |
| | Pediatric patients weighing 17 kg (37 lbs) to < 40 kg (88 lbs): Initial dose of 80 mg SC on Day 1, then 40 mg SC on Day 15, followed 20 mg SC once every other week starting on Day 29. |
| Hidradenitis suppurativa | Adults and adolescents weighing ≥ 60 kg (132 lbs): Initial dose of 160 mg SC (either given in 1 day or split over 2 consecutive days), then 80 mg SC on Day 15, followed by 40 mg SC QW or 80 mg SC once every other week starting on Day 29. |
| | Adolescents weighing 30 kg to < 60 kg: 80 mg SC on Day 1, followed by 40 mg SC every other week starting on Day 8. |
| Juvenile idiopathic arthritis | Dose is based on patient weight:<br>• 10 kg (22 lbs) to < 15 kg (33 lbs): 10 mg SC once every other week<br>• 15 kg (33 lbs) to < 30 kg (66 lbs): 20 mg SC once every other week<br>• ≥ 30 kg (66 lbs): 40 mg SC once every other week |
| Plaque psoriasis | Initial dose of 80 mg SC, followed by 40 mg SC every other week starting 1 week after the initial dose. |
| Psoriatic arthritis | 40 mg SC once every other week |
| Rheumatoid arthritis | 40 mg SC once every other week<br>• Some patients not taking concomitant MTX may derive additional benefit from increasing the dosage to 40 mg SC QW or 80 mg SC once every other week. |
| Ulcerative colitis | Adults: Initial dose of 160 mg SC (either given in 1 day or split over 2 consecutive days), then 80 mg SC on Day 15, followed by 40 mg SC once every other week starting on Day 29. Discontinue in patients without evidence of clinical remission by 8 weeks (Day 57). |
| | Pediatric patients weighing ≥ 40 kg (88 lbs):<br>Initial dose of 160 mg SC (either given in 1 day or split over 2 consecutive days), then 80 mg SC on Day 8 and 80 mg SC on Day 15, followed by 80 mg SC every other week or 40 mg SC QW starting on Day 29. |
| | Pediatric patients weighing 20 kg (44 lbs) to < 40 kg (88 lbs): Initial dose of 80 mg SC on Day 1, then 40 mg SC on Day 8 and 40 mg SC on Day 15, followed by 40 mg SC every other week or 20 mg SC QW starting on Day 29. |
| Uveitis | Adults: Initial dose of 80 mg SC, followed by 40 mg SC every other week starting 1 week after the initial dose. |
| | Pediatric patients: Dose is based on patient weight:<br>• 10 kg (22 lbs) to < 15 kg (33 lbs): 10 mg SC once every other week<br>• 15 kg (33 lbs) to < 30 kg (66 lbs): 20 mg SC once every other week<br>≥ 30 kg (66 lbs): 40 mg SC once every other week |

SC – Subcutaneous; NA – Not applicable; CD – Crohn's disease; UC – Ulcerative colitis; HS – Hidradenitis suppurativa; QW – Once weekly; MTX – Methotrexate.

Adalimumab has also demonstrated efficacy for treatment of several off-label indications such as Behcet's disease, pyoderma gangrenosum, sarcoidosis, scleritis or sterile corneal ulceration, and spondyloarthritis (subtypes other than ankylosing spondylitis).[2] A loading dose may be required for these indications and a maintenance dose of 40 mg administered once every other week is generally effective for most patients.

## Availability

Refer to Table 2 for the available strengths and dosage forms of adalimumab products.[1-10]

**Table 2. FDA-Approved Adalimumab Products.[1-10]**

| Dosage Form/ Strength | | Humira | CDV Humira | Abrilada | Amjevita | Adalimumab – adbm | Hadlima | Adalimumab- | Adalimumab-adaz | Hyrimoz | CDV Hyrimoz | Adalimumab-aacf | Idacio | Adalimumab-ryvk | Simlandi | Adalimumab-aaty | Yuflyma | Yusimry |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Pens | 40 mg/0.4 mL | √ | √ | | √ | √ | √ | | √ | √ | √ | | | √ | √ | √ | √ | |
| | 40 mg/0.8 mL | √ | | √ | √ | √ | √ | √ | √ NA | √ NA | √ | √ | √ NA | | | | | √ |
| | 80 mg/0.8 mL | √ | √ | | √ | | | | √ | √ | √ | | | √ NA | √ | √ | √ | |
| PFS | 10 mg/0.1 mL | √ | √ | | | | | | √ | √ | √ NA | | | | | | | |
| | 10 mg/0.2 mL | √ NA | | √ NA | √ | √ | | | √ NA | √ NA | √ NA | | | | | | | |
| | 20 mg/0.2 mL | √ | √ | | √ | | | | √ | √ | √ | | | √ NA | √ | √ | √ | |
| | 20 mg/0.4 mL | √ NA | | √ | √ | √ | | √ | √ NA | √ NA | √ NA | | | | | | | |
| | 40 mg/0.4 mL | √ | √ | | √ | √ | √ | | √ | √ | √ | | | √ | √ | √ | √ | |
| | 40 mg/0.8 mL | √ | | √ | √ | √ | √ | √ | √ NA | √ NA | √ | √ | √ NA | | | | | √ NA |
| | 80 mg/0.8 mL | √ NA | | | √ NA | | | | √ NA | √ NA | √ NA | | | √ NA | √ | √ NA | √ NA | |
| Vial | 40 mg/0.8 mL[β] | √ NA | | √ NA | | | √ NA | | | | | √ NA | √ NA | | | | | |
| Starter Packs* | 4 x 40 mg/0.4 mL pens | √ NA | | | | √ | | | √ NA | √ NA | √ NA | | | | | √ NA | √ NA | |
| | 4 x 40 mg/0.8 mL pens | √ NA | | | | √ | | | | | | √ | √ NA | | | | | |
| | 6 x 40 mg/0.4 mL pens | √ NA | | | | √ | | | | | | | | | | √ NA | √ NA | |
| | 6 x 40 mg/0.8 mL pens | √ NA | | | | √ | | | | | | √ | √ NA | | | | | |
| | 3 x 80 mg/0.8 mL pens | √ | | | | | | | √ NA | √ | √ | | | √ NA | √ NA | √ | √ | |
| | 4 x 80 mg/0.8 mL pens | √ NA | | | | | | | | | | | | | | | | |
| | 1 x 80 mg/0.8 mL pen and 2 x 40 mg/0.4 mL pens | √ | | | | | | | √ NA | √ | √ | | | | | √ NA | √ NA | |
| | 3 x 80 mg/0.8 mL pens and 1 x 40 mg/0.4 mL | | | | | | | | √ NA | √ NA | √ NA | | | | | | | |
| | 4 x 40 mg/0.4 mL PFS | | | | | | | | | | | | | | | √ NA | √ NA | |
| | 6 x 40 mg/0.4 mL PFS | | | | | | | | | | | | | | | √ NA | √ NA | |
| | 3 x 80 mg/0.8 mL PFS | √ NA | | | | | | | √ NA | √ | √ NA | | | | | √ NA | √ NA | |
| | 1 x 80 mg/0.8 mL PFS and 1 x 40 mg/0.4 mL PFS | √ NA | | | | | | | √ NA | √ | √ NA | | | | | √ NA | √ NA | |

[Ω] These products are FDA-approved, but may or may not be currently available; [α] Adalimumab products may be FDA-approved for additional strengths/package sizes not noted here. This table reflects the availability of the products as of

the date on this policy; PFS – Prefilled syringe; [β] Institutional use only; [*] Starter packs may have different names depending on the individual product's FDA-approved indications.

## POLICY STATEMENT

This Drug Quantity Management program has been developed to promote the safe, effective, and economic use of adalimumab products and to manage potential premature dose escalation. If the Drug Quantity Management rule is not met for the requested medication at the point of service, coverage will be determined by the Criteria below. Approvals are provided for 1 year in duration, unless otherwise noted below. "One-time" approvals are provided for 30 days in duration, unless otherwise noted below. Of note, all adalimumab products of the same strength (i.e., pens, prefilled syringes, vials) accumulate toward the total quantity limit.

## Drug Quantity Limits

| Product | Strength and Form | Retail Maximum Quantity | Home Delivery Maximum Quantity |
|---|---|---|---|
| Humira® (adalimumab SC injection)<br><br>CDV Humira® (adalimumab SC injection) | 40 mg/0.4 mL pens | 2 pens per 28 days | 6 pens per 84 days |
| | 40 mg/0.8 mL pens | 2 pens per 28 days | 6 pens per 84 days |
| | 80 mg/0.8 mL pens | 2 pens per 28 days | 6 pens per 84 days |
| | 10 mg/0.1 mL prefilled syringes | 2 syringes per 28 days | 6 syringes per 84 days |
| | 20 mg/0.2 mL prefilled syringes | 2 syringes per 28 days | 6 syringes per 84 days |
| | 40 mg/0.4 mL prefilled syringes | 2 syringes per 28 days | 6 syringes per 84 days |
| | 40 mg/0.8 mL prefilled syringes | 2 syringes per 28 days | 6 syringes per 84 days |
| | **Starter Packs** | | |
| | CD, UC, or HS Starter Pack: 6 x 40 mg/0.8 mL pens (obsolete 7/31/23) | 6 pens per 365 days | |
| | CD, UC, or HS Starter Pack: 3 x 80 mg/0.8mL pens | 3 pens per 365 days | |
| | Pediatric CD Starter Pack: 1 x 80 mg/0.8 mL prefilled syringe and 1 x 40 mg/0.4 mL prefilled syringe (obsolete 10/20/23) | 2 syringes per 365 days | |
| | Pediatric CD Starter Pack: 3 x 80 mg/0.8 mL prefilled syringes (obsolete 10/31/23) | 3 syringes per 365 days | |
| | Pediatric UC Starter Pack: 4 x 80 mg/0.8 mL pens (obsolete 04/03/24) | 4 pens per 365 days | |
| | Psoriasis, Uveitis, or Adolescent HS Starter Pack: 1 x 80 mg/0.8 mL pen and 2 x 40 mg/0.4 mL pens | 3 pens per 365 days | |
| | Psoriasis, Uveitis, or Adolescent HS Starter Pack: 4 x 40 mg/0.8 mL pens (obsolete 5/31/23) | 4 pens per 365 days | |
| Abrilada™ | 40 mg/0.8 mL pens | 2 pens per 28 days | 6 pens per 84 days |

| | | | |
|---|---|---|---|
| (adalimumab-afzb SC injection) | 20 mg/0.4 mL prefilled syringes | 2 syringes per 28 days | 6 syringes per 84 days |
| | 40 mg/0.8 mL prefilled syringes | 2 syringes per 28 days | 6 syringes per 84 days |
| Amjevita™ (adalimumab-atto SC injection) | 40 mg/0.4 mL pens | 2 pens per 28 days | 6 pens per 84 days |
| | 40 mg/0.8 mL pens | 2 pens per 28 days | 6 pens per 84 days |
| | 80 mg/0.8 mL pens | 2 pens per 28 days | 6 pens per 84 days |
| | 10 mg/0.2 mL prefilled syringes | 2 syringes per 28 days | 6 syringes per 84 days |
| | 20 mg/0.2 mL prefilled syringes | 2 syringes per 28 days | 6 syringes per 84 days |
| | 20 mg/0.4 mL prefilled syringes | 2 syringes per 28 days | 6 syringes per 84 days |
| | 40 mg/0.4 mL prefilled syringes | 2 syringes per 28 days | 6 syringes per 84 days |
| | 40 mg/0.8 mL prefilled syringes | 2 syringes per 28 days | 6 syringes per 84 days |

## Drug Quantity Limits (continued)

| Product | Strength and Form | Retail Maximum Quantity | Home Delivery Maximum Quantity |
|---|---|---|---|
| Cyltezo® (adalimumab-adbm SC injection)<br><br>adalimumab-adbm SC injection | 40 mg/0.4 ml pens | 2 pens per 28 days | 6 pens per 84 days |
| | 40 mg/0.8 mL pens | 2 pens per 28 days | 6 pens per 84 days |
| | 10 mg/0.2 mL prefilled syringes | 2 syringes per 28 days | 6 syringes per 84 days |
| | 20 mg/0.4 mL prefilled syringes | 2 syringes per 28 days | 6 syringes per 84 days |
| | 40 mg/0.4 mL prefilled syringes | 2 syringes per 28 days | 6 syringes per 84 days |
| | 40 mg/0.8 mL prefilled syringes | 2 syringes per 28 days | 6 syringes per 84 days |
| | **Starter Packs** | | |
| | Psoriasis or Uveitis Starter Pack: 4 x 40 mg/0.4 mL pens | 4 pens per 365 days | |
| | Psoriasis or Uveitis Starter Pack: 4 x 40 mg/0.8 mL pens | 4 pens per 365 days | |
| | CD, UC, or HS Starter Pack: 6 x 40 mg/0.4 mL pens | 6 pens per 365 days | |
| | CD, UC, or HS Starter Pack: 6 x 40 mg/0.8 mL pens | 6 pens per 365 days | |
| Hadlima™ (adalimumab-bwwd SC injection) | 40 mg/0.4 mL pens | 2 pens per 28 days | 6 pens per 84 days |
| | 40 mg/0.8 mL pens | 2 pens per 28 days | 6 pens per 84 days |
| | 40 mg/0.4 mL prefilled syringes | 2 syringes per 28 days | 6 syringes per 84 days |
| | 40 mg/0.8 mL prefilled syringes | 2 syringes per 28 days | 6 syringes per 84 days |
| Hulio® (adalimumab-fkjp SC injection)<br><br>adalimumab-fkjp SC injection | 40 mg/0.8 mL pens | 2 pens per 28 days | 6 pens per 84 days |
| | 20 mg/0.4 mL prefilled syringe | 2 syringes per 28 days | 6 syringes per 84 days |
| | 40 mg/0.8 mL prefilled syringes | 2 syringes per 28 days | 6 syringes per 84 days |
| Hyrimoz® | 40 mg/0.4 mL pens | 2 pens per 28 days | 6 pens per 84 days |
| | 40 mg/0.8 mL pens | 2 pens per 28 days | 6 pens per 84 days |

| | | | |
|---|---|---|---|
| (adalimumab-adaz SC injection)<br><br>adalimumab-adaz SC injection<br><br>CDV Hyrimoz® (adalimumab-adaz SC injection) | 80 mg/0.8 mL pens | 2 pens per 28 days | 6 pens per 84 days |
| | 10 mg/0.1 mL prefilled syringes | 2 syringes per 28 days | 6 syringes per 84 days |
| | 20 mg/0.2 mL prefilled syringes | 2 syringes per 28 days | 6 syringes per 84 days |
| | 40 mg/0.4 mL prefilled syringes | 2 syringes per 28 days | 6 syringes per 84 days |
| | 40 mg/0.8 mL prefilled syringes | 2 syringes per 28 days | 6 syringes per 84 days |
| | **Starter Packs** | | |
| | CD, UC, or HS Starter Pack: 3 x 80 mg/0.8mL pens | 3 pens per 365 days | |
| | Psoriasis Starter Pack: 1 x 80 mg/0.8 mL pen and 2 x 40 mg/0.4 mL pens | 3 pens per 365 days | |
| | Pediatric CD Starter Pack: 3 x 80 mg/0.8 mL prefilled syringes | 3 syringes per 365 days | |
| | Pediatric CD Starter Pack: 1 x 80 mg/0.8 mL prefilled syringe and 1 x 40 mg/0.4 mL prefilled syringe | 2 syringes per 365 days | |
| Idacio® (adalimumab-aacf SC injection)<br><br>adalimumab-aacf SC injection | 40 mg/0.8 mL pens | 2 pens per 28 days | 6 pens per 84 days |
| | 40 mg/0.8 mL prefilled syringes | 2 syringes per 28 days | 6 syringes per 84 days |
| | **Starter Packs** | | |
| | CD or UC Starter Pack: 6 x 40 mg/0.8 mL pens | 6 pens per 365 days | |
| | Psoriasis Starter Pack: 4 x 40 mg/0.8 mL pens | 4 pens per 365 days | |

## Drug Quantity Limits (continued)

| Product | Strength and Form | Retail Maximum Quantity | Home Delivery Maximum Quantity |
|---|---|---|---|
| Simlandi® (adalimumab-ryvk SC injection)<br><br>adalimumab-ryvk SC injection | 40 mg/0.4 mL pens | 2 pens per 28 days | 6 pens per 84 days |
| | 80 mg/0.8 mL pens | 2 pens per 28 days | 6 pens per 84 days |
| | 20 mg/0.2 mL prefilled syringe | 2 syringes per 28 days | 6 syringes per 84 days |
| | 40 mg/0.4 mL prefilled syringe | 2 syringes per 28 days | 6 syringes per 84 days |
| | 80 mg/0.8 mL prefilled syringe | 2 syringes per 28 days | 6 syringes per 84 days |
| Yuflyma® (adalimumab-aaty SC injection)<br><br>adalimumab-aaty SC injection | 40 mg/0.4 mL pens | 2 pens per 28 days | 6 pens per 84 days |
| | 80 mg/0.8 mL pens | 2 pens per 28 days | 6 syringes per 84 days |
| | 20 mg/0.2 mL prefilled syringes | 2 syringes per 28 days | 6 syringes per 84 days |
| | 40 mg/0.4 mL prefilled syringes | 2 syringes per 28 days | 6 syringes per 84 days |
| | **Starter Packs** | | |
| | CD, UC, or HS Starter Pack: 3 x 80 mg/0.8 mL pens | 3 syringes per 365 days | |
| Yusimry™ (adalimumab-aqvh SC injection) | 40 mg/0.8 mL pens | 2 pens per 28 days | 6 pens per 84 days |

SC – Subcutaneous; CD – Crohn's disease; UC – Ulcerative colitis; HS – Hidradenitis suppurativa.

**EXCEPTIONS TO THE QUANTITY LIMITS LISTED ABOVE ARE COVERED AS MEDICALLY NECESSARY WHEN THE FOLLOWING CRITERIA ARE MET. ANY OTHER EXCEPTION IS CONSIDERED NOT MEDICALLY NECESSARY.**

**CRITERIA**

Adalimumab 10 mg prefilled syringes

No overrides recommended.

Note: There are 20 mg, 40 mg, and 80 mg pens/syringes available if the patient requires a higher dose.

Adalimumab 20 mg prefilled syringes

1. Approve 4 syringes per 28 days at retail or 12 syringes per 84 days at home delivery, if the patient meets ALL of the following (A, B, and C):
   **A)** Adalimumab is being used to treat ulcerative colitis; AND
   **B)** Patient is 5 to 17 years of age; AND
   **C)** Patient weighs between 20 kg (44 lbs) and < 40 kg (88 lbs).

Adalimumab 40 mg pens and prefilled syringes (NOT starter packages)

1. If the patient has been receiving adalimumab 40 mg every other week for 12 weeks or longer and the dose of adalimumab is now being increased to 40 mg once weekly or 80 mg once every other week, approve 4 pens/syringes per 28 days at retail or 12 pens/syringes per 84 days at home delivery.

2. If the patient has been receiving 40 mg once weekly or 80 mg once every other week dosing, approve 4 pens/syringes per 28 days at retail or 12 pens/syringes per 84 days at home delivery.

3. If the patient is initiating treatment or requires additional induction dosing, as verified by the absence of claims for adalimumab in the past 130 days, approve a one-time override for 8 additional pens/syringes at retail or home delivery. Note: This override also applies if the patient has recently received initiation/induction dosing and now requires an override to finish induction dosing or begin maintenance dosing. At retail, the approval quantity should be the number of adalimumab 40 mg pens/syringes the patient has received in the past 28 days plus 8 pens/syringes. At home delivery, the approval quantity should be the number of adalimumab 40 mg pens/syringes the patient has received in the past 84 days plus 8 pens/syringes.

**4.** Approve 4 pens/syringes per 28 days retail or 12 pens/syringes per 84 days at home delivery, if the patient meets ALL of the following (A, B, and C):
**A)** Adalimumab is being used to treat hidradenitis suppurativa; AND
**B)** Patient is ≥ 12 years of age; AND
**C)** Patient weighs ≥ 60 kg (132 lbs).

**5.** Approve 4 pens/syringes per 28 days at retail or 12 pens/syringes per 84 days at home delivery, if the patient meets ALL of the following (A, B, and C):
**A)** Adalimumab is being used to treat ulcerative colitis; AND
**B)** Patient is 5 to 17 years of age; AND
**C)** Patient weighs ≥ 40 kg (88 lbs).

Adalimumab 80 mg pens (NOT starter packages)

**1.** Approve a one-time override for 3 additional pens at retail or home delivery, if the patient meets BOTH of the following (A and B):
**A)** The patient is initiating treatment or requires additional induction dosing for ulcerative colitis, as verified by the absence of claims for adalimumab in the past 130 days; AND
**B)** Patient is ≥ 18 years of age.
Note: This override also applies if the patient has recently received initiation/induction dosing and now requires an override to finish induction dosing or begin maintenance dosing. At retail, the approval quantity should be the number of adalimumab 80 mg pens/syringes the patient has received in the past 28 days plus 3 pens. At home delivery, the approval quantity should be the number of adalimumab 80 mg pens/syringes the patient has received in the past 84 days plus 3 pens.

**2.** Approve a one-time override for 4 additional pens at retail or 8 additional pens at home delivery, if the patient meets ALL of the following (A, B, and C):
**A)** The patient is initiating treatment or requires additional induction dosing for ulcerative colitis, as verified by the absence of claims for adalimumab in the past 130 days; AND
**B)** Patient is 5 to 17 years of age; AND
**C)** Patient weighs ≥ 40 kg (88 lbs).
Note: This override also applies if the patient has recently received initiation/induction dosing and now requires an override to finish induction dosing or begin maintenance dosing. At retail, the approval quantity should be the number of adalimumab 80 mg pens/syringes the patient has received in the past 28 days plus 4 pens. At home delivery, the approval quantity should be the number of adalimumab 80 mg pens/syringes the patient has received in the past 84 days plus 8 pens.

**3.** Approve a one-time override for 3 additional pens at retail or 7 additional pens at home delivery, if the patient meets BOTH of the following (A and B):
**A)** The patient is initiating treatment or requires additional induction dosing for hidradenitis suppurativa, as verified by the absence of claims for adalimumab in the past 130 days; AND
**B)** Patient meets ONE of the following (i or ii):

**i.** Patient is ≥ 18 years of age; OR
**ii.** Patient is ≥ 12 to 17 years of age and weighs ≥ 60 kg (132 lbs).

Note: This override also applies if the patient has recently received initiation/induction dosing and now requires an override to finish induction dosing or begin maintenance dosing. At retail, the approval quantity should be the number of adalimumab 80 mg pens/syringes the patient has received in the past 28 days plus 3 pens. At home delivery, the approval quantity should be the number of adalimumab 80 mg pens/syringes the patient has received in the past 84 days plus 7 pens.

**4.** Approve a one-time override for 3 additional pens at retail or home delivery, if the patient meets BOTH of the following (A and B):
**A)** The patient is initiating treatment or requires additional induction dosing for Crohn's disease, as verified by the absence of claims for adalimumab in the past 130 days; AND
**B)** Patient meets ONE of the following (i or ii):
**i.** Patient is ≥ 18 years of age; OR
**ii.** Patient is 6 to 17 years of age and weighs ≥ 40 kg (88 lbs).

Note: This override also applies if the patient has recently received initiation/induction dosing and now requires an override to finish induction dosing or begin maintenance dosing. At retail, the approval quantity should be the number of adalimumab 80 mg pens/syringes the patient has received in the past 28 days plus 3 pens. At home delivery, the approval quantity should be the number of adalimumab 80 mg pens/syringes the patient has received in the past 84 days plus 3 pens.

Starter Pack of 4 x 40 mg pens

**1.** If the patient requires additional induction dosing, as verified by the absence of claims for adalimumab in the past 130 days, approve a one-time override for 4 additional pens (1 Starter Pack) at retail or home delivery.
Note: The approval quantity should be the number of adalimumab 40 mg pens (Starter Pack) the patient has received in the past 365 days plus 4 pens.

Starter Pack of 6 x 40 mg pens

**1.** If the patient requires additional induction dosing, as verified by the absence of claims for adalimumab in the past 130 days, approve a one-time override for 6 additional pens (1 Starter Pack) at retail or home delivery.
Note: The approval quantity should be the number of adalimumab 40 mg pens (Starter Pack) the patient has received in the past 365 days plus 6 pens.

Starter Pack of 3 x 80 mg pens

**1.** If the patient requires additional induction dosing, as verified by the absence of claims for adalimumab in the past 130 days, approve a one-time override for 3 additional pens (1 Starter Pack) at retail or home delivery.
Note: The approval quantity should be the number of adalimumab 80 mg pens (Starter Pack) the patient has received in the past 365 days plus 3 pens.

Starter Pack of 4 x 80 mg pens

**1.** If the patient requires additional induction dosing, as verified by the absence of claims for adalimumab in the past 130 days, approve a one-time override for 4 additional pens (1 Starter Pack) at retail or home delivery.
Note: The approval quantity should be the number of adalimumab 80 mg pens (Starter pack) the patient has received in the past 365 days plus 4 pens.

Starter Pack of 1 x 80 mg prefilled pen and 2 x 40 mg prefilled pens

**1.** If the patient requires additional induction dosing, as verified by the absence of claims for adalimumab in the past 130 days, approve a one-time override for 3 additional pens (1 x 80 mg pen and 2 x 40 mg pens [1 Starter Pack]) at retail or home delivery.
Note: The approval quantity should be the number of adalimumab 40 mg and 80 mg pens (Starter Pack) the patient has received in the past 365 days plus 3 pens.

Starter Pack of 3 x 80 mg pens and 1 x 40 mg pens

**1.** If the patient requires additional induction dosing, as verified by the absence of claims for adalimumab in the past 130 days, approve a one-time override for 4 additional pens (3 x 80 mg pens and 1 x 40 mg pen [1 Starter Pack]) at retail or home delivery.
Note: The approval quantity should be the number of adalimumab 40 mg and 80 mg pens (Starter Pack) the patient has received in the past 365 days plus 4 pens.

Starter Pack of 3 x 80 mg prefilled syringes

**1.** If the patient requires additional induction dosing, as verified by the absence of claims for adalimumab in the past 130 days, approve a one-time override for 3 additional syringes (1 Starter Pack) at retail or home delivery.
Note: The approval quantity should be the number of adalimumab 80 mg syringes (Starter Pack) the patient has received in the past 365 days plus 3 syringes.

Starter Pack of 1 x 80 mg prefilled syringe and 1 x 40 mg prefilled syringe

**1.** If the patient requires additional induction dosing, as verified by the absence of claims for adalimumab in the past 130 days, approve a one-time override for 2 additional syringes (1 x 80 mg and 1 x 40 mg syringe [1 Starter Pack]) at retail or home delivery.
Note: The approval quantity should be the number of adalimumab 40 mg and 80 mg syringes (Starter Pack) the patient has received in the past 365 days plus 2 syringes.

## REFERENCES


1. Humira® subcutaneous injection [prescribing information]. North Chicago, IL: AbbVie; February 2024.
2. Amjevita™ subcutaneous injection [prescribing information]. Thousand Oaks, CA: Amgen; April 2025.
3. Abrilada™ subcutaneous injection [prescribing information]. New York, NY: Pfizer; January 2025.

4. Cyltezo® subcutaneous injection [prescribing information]. Ridgefield, CT: Boehringer Ingelheim; April 2024.
5. Hadlima™ subcutaneous injection [prescribing information]. Jersey City, NJ: Organon/Samsung Bioepis; June 2024.
6. Hulio® subcutaneous injection [prescribing information]. Morgantown, WV: Mylan; February 2025.
7. Hyrimoz® subcutaneous injection [prescribing information]. Princeton, NJ: Sandoz; June 2024.
8. Idacio® subcutaneous injection [prescribing information]. Lake Zurich, IL: Fresenius Kabi; October 2024.
9. Yuflyma® subcutaneous injection [prescribing information]. Jersey City, NJ: Celltrion; January 2024.
10. Yusimry™ subcutaneous injection [prescribing information]. Redwood City, CA: Coherus; September 2023.
11. Simlandi® subcutaneous injection [prescribing information]. Leesburg, VA: Alvotech; February 2025.

## History

| Type of Revision | Summary of Changes | Review Date |
|---|---|---|
| Early Annual Revision | **Pediatric Crohn's Disease Starter Pack (3 x 40 mg/0.8 mL prefilled syringes):** Product was removed from policy (obsolete for more than 3 years).<br><br>**Pediatric Crohn's Disease Starter Pack (6 x 40 mg/0.8 mL prefilled syringes):** Product was removed from policy (obsolete for more than 3 years).<br><br>**Abrilada 40 mg pens and 10 mg, 20 mg, and 40 mg prefilled syringes:** New quantity limits were added to the policy. The same overrides apply to Abrilada products as have previously applied to the Humira products.<br><br>**Cyltezo 40 mg pens; 10 mg, 20 mg, 40 mg prefilled syringes; and Starter Packs of 4 x 40 mg pens and 6 x 40 mg pens:** New quantity limits were added to the policy. The same overrides apply to Cyltezo products as have previously applied to the Humira products.<br><br>**Hadlima 40 mg pens and 40 mg prefilled syringes:** New quantity limits were added to the policy. The same overrides apply to Hadlima products as have previously applied to the Humira products.<br><br>**Hulio and adalimumab-fkjp SC injection 40 mg pens and 20 mg and 40 mg prefilled syringes:** New quantity limits were added to the policy. The same overrides apply to Hulio/adalimumab-fkjp products as have previously applied to the Humira products.<br><br>**Hyrimoz and adalimumab-adaz SC injection 40 mg and 80 mg pens; 10 mg, 20 mg, 40 mg, and 80 mg prefilled syringes and Starter Packs of 3 x 80 mg pens, 3 x 80 mg prefilled syringes, 4 x 40 mg pens, 3 x 80 mg pens with 1 x 40 mg pen, 1 x 80 mg pen with 2 x 40 mg pens, and 1 x 80 mg prefilled syringe with 1 x 40 mg prefilled syringe :** New quantity limits were added to the policy. The same overrides apply to Hyrimoz products as have previously applied to the Humira products.<br><br>**Idacio 40 mg pens; 40 mg prefilled syringes; and Starter Packs of 6 x 40 mg pens and 4 x 40 mg pens:** New quantity limits were | 07/05/2023 |

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|---|---|---|
| | added to the policy. The same overrides apply to Idacio products as have previously applied to the Humira products.<br><br>**Yuflyma 40 mg pens:** New quantity limits were added to the policy. The same overrides apply to Yuflyma products as have previously applied to the Humira products.<br><br>**Yusimry 40 mg pens:** New quantity limits were added to the policy. The same overrides apply to Yusimry products as have previously applied to the Humira products.<br><br>**Adalimumab 40 mg pens and prefilled syringes (NOT starter packages):** Override criteria were updated to approve an additional quantity if the patient has been receiving adalimumab 40 mg every other week for 12 weeks or longer and the dose is now being increased. Previously, this criteria did not include a time frame and approved an additional quantity if the patient had been receiving adalimumab 40 mg every other week for any period of time. Additionally, override criteria were updated to approve an additional quantity if the patient has been receiving 40 mg once weekly or 80 mg once every other week. Previously, this criteria approved an additional quantity if the patient had been started and stabilized on 40 mg once weekly or 80 mg once every other week. | |

## History (continued)

| Type of Revision | Summary of Changes | Review Date |
|---|---|---|
| Early Annual Revision | **Adalimumab-adbm SC injection:** Adalimumab-adbm added to the policy. The existing quantity limits and overrides that apply to Cyltezo apply to adalimumab-adbm.<br><br>**Amjevita 40 mg/0.4 mL pens, 80 mg/0.8 mL pens, 20 mg/0.2 mL prefilled syringes, 40 mg/0.4 mL prefilled syringes:** New dosage forms of Amjevita added to the policy. The same quantity limits and overrides apply to Amjevita products as have previously applied to the Humira products.<br><br>**Yuflyma 80 mg/0.8 mL pens, 40 mg/0.4 mL prefilled syringes, Crohn's Disease/Ulcerative Colitis/Hidradenitis Suppurativa Starter Pack (3 x 80 mg/0.8 mL pens):** New dosage forms of Yuflyma added to the policy. The same quantity limits and overrides apply to Yusimry products as have previously applied to the Humira products. | 01/03/2024 |
| Update | **03/29/2024:** No criteria changes. Yuflyma 20 mg/0.2 mL prefilled syringes were added to the policy. Same quantity limits and overrides apply to Yuflyma as have previously applied to the Humira products. | NA |
| Selected Revision | **Simlandi 40 mg/0.4 mL autoinjectors:** Simlandi 40 mg/0.4 mL auto-injectors added to the policy. The same quantity limits and overrides apply to Simlandi products as have previously applied to the Humira products. | 04/19/2024 |
| Selected Revision | **Cyltezo and adalimumab-adbm SC injection 40 mg/0.4 mL pens, 40 mg/0.4 mL prefilled syringes, and Starter Packs of 4 x 40 mg/0.4 mL pens and 6 x 40 mg/0.4 mL pens:** New quantity limits were added to the policy. The same quantity limits and overrides apply to Cyltezo and adlimumab-adbm products as have previously applied to the Humira products. | 05/22/2024 |

## History (continued)

| Type of Revision | Summary of Changes | Review Date |
|---|---|---|
| Annual Revision | The policy statement was updated to clarify that "one-time" approvals are provided for 30 days in duration, unless otherwise noted in the policy.<br><br>The policy statement was clarified to note that all adalimumab products of the same strength (i.e., pens, prefilled syringes, vials) accumulate toward the total quantity limit. Previously, the statement noted that all package sizes of adalimumab accumulate toward the limit as they all contain the same pen or syringe products.<br><br>**Abrilada 10 mg/0.2 mL prefilled syringes:** Product was removed from the policy (obsolete).<br><br>**Hyrimoz Crohn's Disease, Ulcerative Colitis, or Hidradenitis Supperativa Starter Pack (3 x 80 mg/0.8mL pens and 1 x 40 mg/0.4 mL pens):** Product was removed from the policy (obsolete).<br><br>**Hyrimoz Starter Packs of 40 mg/0.4 mL pens:** Product was removed from the policy (obsolete).<br><br>**Simlandi 20 mg/0.2 mL, 40 mg/0.4 mL, and 80 mg/0.8 mL prefilled syringes:** New dosage forms of Simlandi were added to the policy. The same quantity limits and overrides apply to Simlandi products as have previously applied to the Humira products.<br><br>**Adalimumab-aacf SC injection:** Adalimumab-aacf added to the policy. The existing quantity limits and overrides that apply to Idacio apply to adalimumab-aacf.<br><br>**Adalimumab-aaty SC injection:** Adalimumab-aaty added to the policy. The existing quantity limits and overrides that apply to Yuflyma apply to adalimumab-aaty.<br><br>**Adalimumab-ryvk SC injection:** Adalimumab-ryvk added to the policy. The existing quantity limits and overrides that apply to Simlandi apply to adalimumab-ryvk.<br><br>**CDV Humira (adalimumab SC injection):** CDV Humira added to the policy. The existing quantity limits and overrides that apply to Humira apply to CDV Humira.<br><br>**CDV Hyrimoz (adalimumab-adaz SC injection):** CDV Hyrimoz added to the policy. The existing quantity limits and overrides that apply to Hyrimoz apply to CDV Hyrimoz.<br><br>Throughout the override criteria, approvals for the "requested quantity, not to exceed" were clarified to approve the specific amount already listed in criteria.<br><br>Throughout the override criteria, the Notes were updated to clarify how to determine the total approval quantities. | 02/05/2025 |

## HISTORY (CONTINUED)

| Type of Revision | Summary of Changes | Review Date |
|---|---|---|
| Early Annual Revision | **Simlandi 80 mg/0.8 mL pens:** New dosage form of Simlandi was added to the policy. The same quantity limits and overrides apply to Simlandi products as have previously applied to other adalimumab products.<br><br>**Adalimumab-adaz 10 mg/0.1 mL prefilled syringes:** New dosage form of adalimumab-adaz was added to the policy. The same quantity limits and overrides apply to adalimumab-adaz products as have previously applied to other adalimumab products.<br><br>**Adalimumab-aaty Crohn's Disease, Ulcerative Colitis, Hidradenitis Suppurativa Starter Pack (3 x 80 mg/0.8 mL pens):** New dosage form of adalimumab-aaty was added to the policy. The same quantity limits and overrides apply to adalimumab-adaz products as have previously applied to other adalimumab products.<br><br>**Hyrimoz/CDV Hyrimoz/adalimumab-adaz 10 mg/0.2 mL, 20 mg/0.4 mL, and 80 mg/0.8 mL prefilled syringes:** The quantity limits for these products were removed from the policy as they are not available.<br><br>**Adalimumab 80 mg pens (NOT Starter Packages):**<br>• Existing override criteria for initiating treatment or additional induction dosing for hidradenitis suppurativa was updated to approve a one-time override for 3 additional pens at retail or 7 additional pens at home delivery. Previously, these criteria approved a one-time override for 4 additional pens at retail or 8 additional pens at home delivery.<br>• New override criteria were added to approve a one-time override for 3 additional pens at retail or home delivery if the patient is initiating treatment or requires additional induction dosing for Crohn's disease, as verified by the absence of claims for adalimumab in the past 130 days AND if the patient is ≥ 18 years of age or is 6 to 17 years of age and weighs ≥ 40 kg. | 05/07/2025 |
| Update | 06/03/2025: No criteria changes.<br><br>**Adalimumab 40 mg pens and prefilled syringes (NOT starter packages) and adalimumab 80 mg pens (NOT starter packages):** Notes were clarified to state that overrides for a patient who is initiating treatment or requires additional induction dosing also apply if the patient has recently received initiation/induction dosing and now requires an override to finish induction dosing or begin maintenance dosing. | NA |
| Selected Revision | **Adalimumab 80 mg pens (NOT Starter Packages):** New override criteria were added to approve a one-time override for 3 additional pens at retail or home delivery if the patient is initiating treatment or requires additional induction dosing for ulcerative colitis, as verified by the absence of claims for adalimumab in the past 130 days AND the patient is ≥ 18 years of age. | 07/02/2025 |

NA – Not applicable.

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