



DRUG QUANTITY MANAGEMENT POLICY – PER DAYS

- POLICY:** Inflammatory Conditions – Adalimumab Products Drug Quantity Management Policy – Per Days
- Abrilada™ (adalimumab-afzb subcutaneous injection – Pfizer)
 - 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)
 - Hyrimoz® (adalimumab-adaz subcutaneous injection – Sandoz/Novartis)
 - Idacio® (adalimumab-aacf subcutaneous injection – Fresenius Kabi)
 - Yuflyma® (adalimumab-aaty subcutaneous injection – Celltrion)
 - Yusimry™ (adalimumab-aqvh subcutaneous injection – Coherus)

REVIEW DATE: 01/03/2024

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 tumor necrosis factor inhibitors (TNFi) approved for the following:¹⁻¹⁰

- **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**, \pm 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**, \pm conventional synthetic disease-modifying antirheumatic drugs (DMARDs), for reducing the signs and symptoms of active arthritis, inhibiting the progression of structural damage, and improving physical function.
- **Rheumatoid arthritis**, \pm methotrexate or other conventional synthetic DMARDS to reduce the signs and symptoms, induce major clinical response, inhibit the progression of structural damage, and improve physical function in adult patients 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	<u>Adults and pediatric patients weighing ≥ 40 kg (88 lbs):</u> 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.
	<u>Pediatric patients weighing 17 kg (37 lbs) to < 40 kg (88 lbs):</u> 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	<u>Adults and adolescents weighing ≥ 60 kg (132 lbs):</u> 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.
	<u>Adolescents weighing 30 kg to < 60 kg:</u> 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: <ul style="list-style-type: none"> • 10 kg (22 lbs) to < 15 kg (33 lbs): 10 mg SC once every other week • 15 kg (33 lbs) to < 30 kg (66 lbs): 20 mg SC once every other week • ≥ 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 <ul style="list-style-type: none"> • 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	<u>Adults</u> : 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).
	<u>Pediatric patients weighing ≥ 40 kg (88 lbs)</u> : 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.
	<u>Pediatric patients weighing 20 kg (44 lbs) to < 40 kg (88 lbs)</u> : 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	<u>Adults</u> : Initial dose of 80 mg SC, followed by 40 mg SC every other week starting 1 week after the initial dose.
	<u>Pediatric patients</u> : Dose is based on patient weight: <ul style="list-style-type: none"> • 10 kg (22 lbs) to < 15 kg (33 lbs): 10 mg SC once every other week • 15 kg (33 lbs) to < 30 kg (66 lbs): 20 mg SC once every other week • ≥ 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. Adalimumab Products.¹⁻¹⁰

Dosage Form/ Strength		Humira	Abrilada	Amjevita	Adalimumab – adbm (Cyltezo)	Hadlima	Adalimumab- fkjp (Hulio)	Adalimumab- adaz (Hyrimoz)	Idacio	Yuflyma	Yusimry
Pen	40 mg/ 0.4 mL	√		√		√		√		√	
	40 mg/ 0.8 mL	√	√	√	√	√	√	√	√		√
	80 mg/ 0.8 mL	√		√				√		√	
PFS	10 mg/ 0.1 mL	√						√			
	10 mg/ 0.2 mL	√	√	√	√			√			
	20 mg/ 0.2 mL	√		√				√		√	
	20 mg/ 0.4 mL	√	√	√	√		√	√			
	40 mg/ 0.4 mL	√		√		√		√		√	
	40 mg/ 0.8 mL	√	√	√	√	√	√	√	√		
	80 mg/ 0.8 mL	√		√				√		√	
Via	40 mg/0.8 mL ^B	√	√			√					
Starter Packs*	4 x 40 mg/0.4 mL pens	√						√		√	
	4 x 40 mg/0.8 mL pens	√			√				√		
	6 x 40 mg/0.4 mL pens	√								√	
	6 x 40 mg/0.8 mL pens	√			√				√		
	3 x 80 mg/0.8mL pens	√						√		√	
	4 x 80 mg/0.8 mL pens	√									
	1 x 80 mg/0.8 mL pen and 2 x 40 mg/0.4 mL pens	√						√		√	
	3 x 80 mg/0.8 mL pens and 1 x 40 mg/0.4 mL							√			
	3 x 40 mg/0.8 mL PFS	√									
	4 x 40 mg/0.4 mL PFS									√	
	6 x 40 mg/0.4 mL PFS									√	
	6 x 40 mg/0.8 mL PFS	√									
	3 x 80 mg/0.8 mL PFS	√						√		√	
	1 x 80 mg/0.8 mL PFS and 1 x 40 mg/0.4 mL PFS	√						√		√	

^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. All approvals are provided for 1 year in duration, unless otherwise noted below. Of note, all package sizes of adalimumab accumulate toward the limit as they all contain the same pen or syringe formulation.

Drug Quantity Limits

Product	Strength and Form	Retail Maximum Quantity	Home Delivery Maximum Quantity	
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	6 pens per 365 days	6 pens per 365 days	
	CD, UC, or HS Starter Pack: 3 x 80 mg/0.8mL pens	3 pens per 365 days	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	2 syringes per 365 days	2 syringes per 365 days	
	Pediatric CD Starter Pack: 3 x 80 mg/0.8 mL prefilled syringes	3 syringes per 365 days	3 syringes per 365 days	
	Pediatric UC Starter Pack: 4 x 80 mg/0.8 mL pens	4 pens per 365 days	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	3 pens per 365 days	

	Psoriasis, Uveitis, or Adolescent HS Starter Pack: 4 x 40 mg/0.8 mL pens	4 pens per 365 days	4 pens per 365 days
Abrilada™ (adalimumab-afzb SC injection)	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/0.8 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) and Adalimumab-adbm SC injection	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/0.8 mL prefilled syringes	2 syringes per 28 days	6 syringes per 84 days	
	Starter Packs			
	Psoriasis or Uveitis Starter Pack: 4 x 40 mg/0.8 mL pens	4 pens per 365 days	4 pens per 365 days	
	CD, UC, or HS Starter Pack: 6 x 40 mg/0.8 mL pens	6 pens per 365 days	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) and 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® (adalimumab-adaz 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	

and Adalimumab-adaz SC injection	10 mg/0.1 mL prefilled syringes	2 syringes per 28 days	6 syringes 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
	80 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	3 pens per 365 days
	CD, UC, or HS Starter Pack: 3 x 80 mg/0.8mL pens and 1 x 40 mg/0.4 mL pens	4 pens per 365 days	4 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	3 pens per 365 days
	Pediatric CD Starter Pack: 3 x 80 mg/0.8 mL prefilled syringes	3 syringes per 365 days	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	2 syringes per 365 days
4 x 40 mg/0.4 mL pens	4 pens per 365 days	4 pens per 365 days	
Idacio® (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	6 pens per 365 days
	Psoriasis Starter Pack: 4 x 40 mg/0.8 mL pens	4 pens per 365 days	4 pens per 365 days

Drug Quantity Limits (continued)

Product	Strength and Form	Retail Maximum Quantity	Home Delivery Maximum Quantity
Yuflyma® (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
	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	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

CD – Crohn’s disease; UC – Ulcerative colitis; HS – Hidradenitis suppurativa.

Inflammatory Conditions – Adalimumab Products Drug Quantity Management Policy – Per Days product(s) is(are) covered as medically necessary when the following criteria is(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 the requested quantity, not to exceed 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;
 - 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 the requested quantity, not to exceed 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 the requested quantity, not to exceed 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 the requested quantity, not to exceed 8 pens/syringes at retail or home delivery.
- 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 \geq 12 years of age; AND
 - C)** Patient weighs \geq 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 \geq 40 kg (88 lbs).

Adalimumab 80 mg pens (NOT starter packages)

- 1.** Approve a one-time override for 4 pens for a 28-day supply at retail or 8 pens as an 84-day supply 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 absence of claims for adalimumab in the past 130 days; AND
 - B)** Patient is 5 to 17 years of age; AND
 - C)** Patient weighs \geq 40 kg (88 lbs).

- 2.** Approve a one-time override for the requested quantity, not to exceed 4 pens as a 42-day supply at retail or 8 pens as an 84-day supply 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 absence of claims for adalimumab in the past 130 days; AND
 - B)** Patient meets one of the following (i or ii):
 - i.** Patient is \geq 18 years of age; OR
 - ii.** Patient is \geq 12 to 17 years of age and weighs \geq 60 kg (132 lbs).

Note: The home delivery override includes a quantity sufficient for the 4-week initiation dosing and maintenance dosing for the following 8 weeks, rounded up to the nearest package size.

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 pens (1 Starter Pack) at retail or home delivery.

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 pens (1 Starter Pack) at retail or home delivery.

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 pens (1 Starter Pack) at retail or home delivery.

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 pens (1 Starter Pack) at retail or home delivery.

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

pens (1 x 80 mg pen and 2 x 40 mg pens [1 Starter Pack]) at retail or home delivery.

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 pens (3 x 80 mg pens and 1 x 40 mg pen [1 Starter Pack]) at retail or home delivery.

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 syringes (1 Starter Pack) at retail or home delivery.

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 syringes (1 x 80 mg and 1 x 40 mg syringe [1 Starter Pack]) at retail or home delivery.

REFERENCES

1. Humira® subcutaneous injection [prescribing information]. North Chicago, IL: AbbVie; February 2021.
2. Amjevita™ subcutaneous injection [prescribing information]. Thousand Oaks, CA: Amgen; August 2023.
3. Abrilada™ subcutaneous injection [prescribing information]. New York, NY: Pfizer; October 2023.
4. Cyltezo® subcutaneous injection [prescribing information]. Ridgefield, CT: Boehringer Ingelheim; July 2023.
5. Hadlima™ subcutaneous injection [prescribing information]. Jersey City, NJ: Organon/Samsung Bioepis; July 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; December 2023.
10. Yusimry™ subcutaneous injection [prescribing information]. Redwood City, CA: Coherus; September 2023.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	<p>Policy was updated to reflect the existing quantity limits when a product is obtained via home delivery.</p> <p>Humira 80 mg pens (NOT starter packages): Override criteria were updated to approve the requested quantity, not to exceed 4 pens as a 42-day supply at retail or 8 pens as an 84-day supply at home delivery, if the patient is initiating treatment or requires additional induction dosing for hidradenitis suppurativa and is either ≥ 18 years of age or is ≥ 12 to 17 years of age and weighs ≥ 60 kg</p>	01/04/2023

	(132 lbs). Previously, this override approved for a patient who was \geq 12 years of age and weighs \geq 60 kg (132 lbs).	
Selected Revision	Amjevita 20 mg prefilled syringes and 40 mg prefilled syringes and pens: New quantity limits were added to the policy. The same overrides apply to Amjevita products as have previously applied to the Humira products.	02/22/2023
Update	06/08/2023: No criteria changes. Amjevita 10 mg/0.2 mL prefilled syringes added to the policy. Same quantity limits and overrides apply to Amjevita as have previously applied to the Humira products.	NA

History (continued)

Type of Revision	Summary of Changes	Review Date
Early Annual Revision	<p>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).</p> <p>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).</p> <p>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.</p> <p>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.</p> <p>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.</p> <p>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.</p> <p>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.</p> <p>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 added to the policy. The same overrides apply to Idacio products as have previously applied to the Humira products.</p> <p>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.</p>	07/05/2023

	<p>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.</p> <p>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.</p>	
--	---	--

Type of Revision	Summary of Changes	Review Date
Early Annual Revision	<p>Adalimumab-adbm SC injection: Adalimumab-adbm added to the policy. The existing quantity limits and overrides that apply to Cyltezo apply to adalimumab-adbm.</p> <p>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.</p> <p>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.</p>	01/03/2024

"Cigna Companies" refers to operating subsidiaries of The Cigna Group. All products and services are provided exclusively by or through such operating subsidiaries, including Cigna Health and Life Insurance Company, Connecticut General Life Insurance Company, Evernorth Behavioral Health, Inc., Cigna Health Management, Inc., and HMO or service company subsidiaries of The Cigna Group. © 2024 The Cigna Group.