Drug Coverage Policy

Effective Date……08/15/2026
Coverage Policy Number…… DQM005
Policy Title……Adalimumab Products Drug Quantity Management Policy – Per Days

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)
- adalimumab-adbm subcutaneous injection (Boehringer Ingelheim)
- adalimumab-fkjp subcutaneous injection (Biocon)
- adalimumab-ryvk subcutaneous injection (Teva/Alvotech)
- 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)
- Idacio® (adalimumab-aacf subcutaneous injection – Fresenius Kabi) [discontinued]
- 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 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: • 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 • 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): 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: • 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. FDA-Approved Adalimumab Products.[1-10]

Dosage Form/ Strength		Humira	CDV Humira	Abrilada	Amjevita	Adalimumab – adbm	Hadlima	Adalimumab-fkjp	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	√	√		√				√	√	√			√	√	√	√	
PFS	10 mg/0.1 mL	√	√						√	√	√ NA							
	10 mg/0.2 mL	√ NA		√ NA	√	√				√ NA	√ NA							
	20 mg/0.2 mL	√	√		√				√	√	√			√ NA	√	√	√	
	20 mg/0.4 mL	√ 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	
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	
	4 x 40 mg/0.8 mL pens					√						√	√ NA					
	6 x 40 mg/0.4 mL pens					√										√ 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	
	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	
	1 x 80 mg/0.8 mL PFS and 1 x 40 mg/0.4 mL PFS	√ 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.

Coverage Policy

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. Meeting Drug Quantity Management Program Criteria does not satisfy any other prior authorization or medical necessity criteria requirements.

Drug Quantity Limits

Product	Strength and Form	Retail Maximum Quantity	Home Delivery Maximum Quantity
Humira® (adalimumab SC injection)	40 mg/0.4 mL pens	4 pens per 28 days	12 pens per 84 days
	40 mg/0.8 mL pens	4 pens per 28 days	12 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	4 syringes per 28 days	12 syringes per 84 days
	40 mg/0.8 mL prefilled syringes	4 syringes per 28 days	12 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™ (adalimumab-afzb SC injection)	40 mg/0.8 mL pens	4 pens per 28 days	12 pens 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	4 syringes per 28 days	12 syringes per 84 days
Amjevita™ (adalimumab-atto SC injection)	40 mg/0.4 mL pens	4 pens per 28 days	12 pens per 84 days
	40 mg/0.8 mL pens	4 pens per 28 days	12 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	4 syringes per 28 days	12 syringes per 84 days
	40 mg/0.8 mL prefilled syringes	4 syringes per 28 days	12 syringes per 84 days

Product	**Strength and Form**	**Retail Maximum Quantity**	**Home Delivery Maximum Quantity**
Cyltezo® (adalimumab-adbm SC injection) adalimumab-adbm SC injection	40 mg/0.4 ml pens	4 pens per 28 days	12 pens per 84 days
	40 mg/0.8 mL pens	4 pens per 28 days	12 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	4 syringes per 28 days	12 syringes per 84 days
	40 mg/0.8 mL prefilled syringes	4 syringes per 28 days	12 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	4 pens per 28 days	12 pens per 84 days
	40 mg/0.8 mL pens	4 pens per 28 days	12 pens per 84 days
	40 mg/0.4 mL prefilled syringes	4 syringes per 28 days	12 syringes per 84 days
	40 mg/0.8 mL prefilled syringes	4 syringes per 28 days	12 syringes per 84 days
Hulio®	40 mg/0.8 mL pens	4 pens per 28 days	12 pens per 84 days

(adalimumab-fkjp SC injection) adalimumab-fkjp SC injection	20 mg/0.4 mL prefilled syringe	2 syringes per 28 days	6 syringes per 84 days
	40 mg/0.8 mL prefilled syringes	4 syringes per 28 days	12 syringes per 84 days
Hyrimoz® (adalimumab-adaz SC injection) adalimumab-adaz SC injection	40 mg/0.4 mL pens	4 pens per 28 days	12 pens per 84 days
	40 mg/0.8 mL pens (obsolete 6/2025)	4 pens per 28 days	12 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	4 syringes per 28 days	12 syringes per 84 days
	40 mg/0.8 mL prefilled syringes (obsolete 6/2025)	4 syringes per 28 days	12 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) [discontinued 4/01/2025] adalimumab-aacf SC injection	40 mg/0.8 mL pens	4 pens per 28 days	12 pens per 84 days
	40 mg/0.8 mL prefilled syringes	4 syringes per 28 days	12 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	

Product	**Strength and Form**	**Retail Maximum Quantity**	**Home Delivery Maximum Quantity**
Simlandi® (adalimumab-ryvk SC injection) adalimumab-ryvk SC injection	40 mg/0.4 mL pens	4 pens per 28 days	12 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	4 syringes per 28 days	12 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) adalimumab-aaty SC injection	40 mg/0.4 mL pens	4 pens per 28 days	12 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	4 syringes per 28 days	12 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	4 pens per 28 days	12 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.

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 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.

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; July 2025.
2. Amjevita™ subcutaneous injection [prescribing information]. Thousand Oaks, CA: Amgen; August 2024.
3. Abrilada™ subcutaneous injection [prescribing information]. New York, NY: Pfizer; January 2025.
4. Cyltezo® subcutaneous injection [prescribing information]. Ridgefield, CT: Boehringer Ingelheim; August 2025.

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; July 2025.
8. Idacio® subcutaneous injection [prescribing information]. Lake Zurich, IL: Fresenius Kabi; October 2024.
9. Yuflyma® subcutaneous injection [prescribing information]. Jersey City, NJ: Celltrion; March 2025.
10. Yusimry™ subcutaneous injection [prescribing information]. Redwood City, CA: Coherus; May 2025.
11. Simlandi® subcutaneous injection [prescribing information]. Leesburg, VA: Alvotech; February 2025.

Revision Details

Summary of Changes	Review Date	Effective Date
New policy	07/10/2025	08/15/2025
Adalimumab 40 mg pens and syringes (NOT Starter Packages): Quantity limits were increased to 4 pens/syringes per 28 days at retail or 12 pens/syringes per 84 days at home delivery (previous limits were 2 pens/syringes per 28 days at retail or 6 pens/syringes per 84 days at home delivery). All override criteria that approved 4 pens/syringes per 28 days at retail or 12 pens/syringes per 84 days at home delivery were removed (no longer needed).	10/02/2025	11/01/2025
No criteria changes.	07/30/2026	08/15/2026

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

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