DRUG QUANTITY MANAGEMENT POLICY – PER DAYS

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

- Amjevita™ (adalimumab-atto subcutaneous injection – Amgen)
- Humira® (adalimumab subcutaneous injection – AbbVie)

REVIEW DATE: 01/04/2023; selected revision 02/22/2023

OVERVIEW

Adalimumab products are tumor necrosis factor inhibitors (TNFis) approved for the following uses:[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 (brand Humira only).
- **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**, ± 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**, ± 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 (Amjevita is only indicated in adults).
- **Uveitis**, in patients ≥ 2 years of age with noninfectious intermediate, posterior, and panuveitis (brand Humira only).

Dosing

Table 1. FDA-approved Dosing of Adalimumab.[1]

FDA-Approved Indication	Dosing	Quantity Needed for 28-Day Induction Dosing
Ankylosing spondylitis	40 mg SC once every other week	NA
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.	• CD, UC, or HS Starter Pack: 3 x 80 mg/0.8mL pens; OR • Pediatric CD Starter Pack: 3 x 80 mg/0.8 mL prefilled syringes; OR • CD, UC, or HS Starter Pack: 6 x 40 mg/0.8 mL pens; OR • 6 x 40 mg pens/prefilled syringes.
	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.	• Pediatric CD Starter Pack: 1 x 80 mg/0.8 mL prefilled syringe and 1 x 40 mg/0.4 mL prefilled syringe

Table 1 (continued). FDA-approved Dosing of Adalimumab.[1]

FDA-Approved Indication	Dosing	Quantity Needed for 28-Day Induction Dosing
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.	• CD, UC, or HS Starter Pack: 3 x 80 mg/0.8mL pens; OR • CD, UC, or HS Starter Pack: 6 x 40 mg/0.8 mL pens; OR • 6 x 40 mg pens/prefilled syringes • 3 x 80 mg pens
	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.	• Psoriasis, Uveitis, or Adolescent HS: 4 x 40 mg/0.8 mL pens; OR • Psoriasis, Uveitis, or Adolescent HS: 1 x 80 mg/0.8 mL pen and 2 x 40 mg/0.4 mL pens; OR • 4 x 40 mg pens/prefilled syringes
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	NA
Plaque psoriasis	Initial dose of 80 mg SC, followed by 40 mg SC every other week starting 1 week after the initial dose.	• Psoriasis, Uveitis, or Adolescent HS: 4 x 40 mg/0.8 mL pens; OR • Psoriasis, Uveitis, or Adolescent HS: 1 x 80 mg/0.8 mL pen and 2 x 40 mg/0.4 mL pens; OR • 4 x 40 mg pens/prefilled syringes
Psoriatic arthritis	40 mg SC once every other week	NA
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.	NA
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).	• CD, UC, or HS Starter Pack: 3 x 80 mg/0.8mL pens; OR • CD, UC, or HS Starter Pack: 6 x 40 mg/0.8 mL pens; OR • 6 x 40 mg pens/prefilled syringes
	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 UC Starter Pack: 4 x 80 mg/0.8 mL pens; OR • 4 x 80 mg pens; OR • 8 x 40 mg pens/prefilled syringes
	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.	4 x 40 mg pens/prefilled syringes
Uveitis	Adults: Initial dose of 80 mg SC, followed by 40 mg SC every other week starting 1 week after the initial dose.	• Psoriasis, Uveitis, or Adolescent HS: 4 x 40 mg/0.8 mL pens; OR • 4 x 40 mg pens/prefilled syringes
	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	NA

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.[1] Of note, there are several strengths and package sizes that are FDA-approved, but are not currently available.

Table 2. Availability of Adalimumab.[1]

Dosage form	Strengths	Package Sizes
Humira Pen	40 mg/0.4 mL 40 mg/0.8 mL 80 mg/0.8 mL	2-pack Cartons • 40 mg/0.4 mL pens • 40 mg/0.8 mL pens • 80 mg/0.8 mL pens Starter Packs • CD, UC, or HS: 3 x 80 mg/0.8mL pens • CD, UC, or HS: 6 x 40 mg/0.8 mL pens • Pediatric UC: 4 x 80 mg/0.8 mL pens • Psoriasis, Uveitis, or Adolescent HS: 4 x 40 mg/0.8 mL pens • Psoriasis, Uveitis, or Adolescent HS: 1 x 80 mg/0.8 mL pen and 2 x 40 mg/0.4 mL pens Not Available • CD, UC, or HS Starter Pack: 6 x 40 mg/0.4 mL pens • Psoriasis, Uveitis, or Adolescent HS Starter Pack: 4 x 40 mg/0.4 mL pens
Humira Prefilled Syringe	10 mg/0.1 mL 20 mg/0.2 mL 40 mg/0.4 mL 40 mg/0.8 mL Not Available 10 mg/0.2 mL 20 mg/0.4 mL 80 mg/0.8 mL	2-pack Cartons • 10 mg/0.1 mL prefilled syringes • 20 mg/0.2 mL prefilled syringes • 40 mg/0.4 mL prefilled syringes • 40 mg/0.8 mL prefilled syringes Starter Packs • Pediatric CD: 3 x 80 mg/0.8 mL prefilled syringes • Pediatric CD: 1 x 80 mg/0.8 mL prefilled syringe and 1 x 40 mg/0.4 mL prefilled syringe Not Available • 20 mg/0.4 mL prefilled syringe 2-pack carton • 10 mg/0.2 mL prefilled syringe 2-pack carton • Pediatric CD Starter Pack: 6 x 40 mg/0.8 mL prefilled syringes • Pediatric CD Starter Pack: 3 x 40 mg/0.8 mL prefilled syringes
Humira Vial	40 mg/0.8 mL	40 mg/0.8 mL vial for institutional use - Not available
Amjevita Prefilled Syringe	20 mg/0.4 mL 40 mg/0.8 mL	Single-syringe Cartons
Amjevita Pen	40 mg/0.8 mL pens	Single-pen Cartons

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

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.

Automation: None.

Drug Quantity Limits

Product	Strength and Form	Retail Maximum Quantity	Home Delivery Maximum Quantity
Humira® (adalimumab SC injection)	**2-Packs**		
	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 CD Starter Pack: 3 x 40 mg/0.8 mL prefilled syringes (Not Available)	3 syringes per 365 days	3 syringes per 365 days
	Pediatric CD Starter Pack: 6 x 40 mg/0.8 mL prefilled syringes (Not Available)	6 syringes per 365 days	6 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
Amjevita™ (adalimumab-atto 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 syringe	2 syringes per 28 days	6 syringes per 84 days
	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.

CRITERIA

Adalimumab 10 mg prefilled syringes

No overrides recommended.

Note: There are 20 mg, 40 mg, and 80 mg pens/prefilled 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 started and stabilized on 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.

2. If the patient has been receiving adalimumab 40 mg every other week 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/prefilled 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.
   Note: Examples of induction dosing include the following: Plaque psoriasis, uveitis (adults), or hidradenitis suppurativa (pediatric) induction dosing is 80 mg on Day 1, followed in one week (Day 8) by 40 mg every other week (Total: four 40 mg pens or prefilled syringes for a 28-day supply). Crohn's disease (adults and pediatric patients weighing 40 kg [88 lbs] or greater) or ulcerative colitis (adults) induction dosing is 160 mg on Day 1 (four 40 mg injections in 1 day OR two 40 mg injections per day for 2 consecutive days), followed by 80 mg 2 weeks later (Day 15), then a 40 mg every other week maintenance dose starting on day 29 (Total: six 40 mg pens or prefilled syringes for a 28-day supply). Hidradenitis suppurativa (adults) induction dosing is 160 mg on Day 1 (four 40 mg injections in one day OR two 40 mg injections per day for two consecutive days), followed by 80 mg 2 weeks later (Day 15), then either a 40 mg every week or 80 mg every other week maintenance dose beginning on Day 29 (Total: six 40 mg pens or prefilled syringes for a 28-day supply). Ulcerative colitis (pediatric patients weighing ≥ 44 kg [88 lbs]) induction dosing is 160 mg on Day 1 (four 40 mg injections in 1 day OR two 40 mg injections per day for 2 consecutive days), followed by 80 mg 1 week later (Day 8) and 80 mg on Day 15, then either a 40 mg every week or 80 mg every other week maintenance dose beginning on Day 29 (Total: eight 40 mg pens or prefilled syringes for a 28-day supply). Ulcerative colitis (pediatric patients weighing 20 kg [44 lbs] to < 40 kg [88 lbs]) induction dosing is 80 mg on Day 1, followed by 40 mg 1 week later (Day 8) and 40 mg on Day 15, then either a 40 mg every other week or 20 mg every week maintenance dose beginning on Day 29 (Total: four 40 mg pens or prefilled syringes for a 28-day supply). Examples of other indications that may require loading doses are pyoderma gangrenosum and sarcoidosis.

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 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 ≥ 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.** Patient is ≥ 18 years of age; OR
  - **ii.** Patient is ≥ 12 to 17 years of age and weighs ≥ 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.

Adalimumab Crohn's Disease/Ulcerative Colitis/Hidradenitis Suppurativa Starter Package
(Each package contains 6 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 6 pens (1 Starter Pack) at retail or home delivery.

Adalimumab Crohn's Disease/Ulcerative Colitis/Hidradenitis Suppurativa Starter Package
(Each package contains 3 x 80 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 prefilled pens (1 Starter Pack) at retail or home delivery.

Adalimumab Pediatric Crohn's Disease Starter Package (Not Available)
(Each package contains 3 x 40 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.

Adalimumab Pediatric Crohn's Disease Starter Package (Not Available)
(Each package contains 6 x 40 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 6 syringes (1 Starter Pack) at retail or home delivery.

Adalimumab Pediatric Crohn's Disease Starter Package
(Each package contains 3 x 80 mg 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.

Adalimumab Pediatric Crohn's Disease Starter Package
(Each package contains 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.

Adalimumab Pediatric Ulcerative Colitis Starter Package
(Each package contains 4 x 80 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 4 pens (1 Starter Pack) at retail or home delivery.

Adalimumab Psoriasis/Uveitis/Adolescent Hidradenitis Suppurativa Starter Package
(Each package contains 4 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 4 pens (1 Starter Pack) at retail or home delivery.

Adalimumab Psoriasis/Uveitis/Adolescent Hidradenitis Suppurativa Starter Package
(Each package contains 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 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; July 2022.