

DRUG QUANTITY MANAGEMENT POLICY – PER DAYS

- POLICY:** Inflammatory Conditions – Etanercept Products Drug Quantity Management Policy – Per Days
- Enbrel® (etanercept subcutaneous injection – Immunex/Amgen)

REVIEW DATE: 12/16/2022

OVERVIEW

Etanercept products are tumor necrosis factor inhibitors (TNFis) approved for the following uses:¹

- **Ankylosing spondylitis**, for reducing signs and symptoms in patients with active disease.
- **Juvenile idiopathic arthritis**, for reducing the signs and symptoms of moderate or severe active polyarticular disease in patients aged ≥ 2 years.
- **Plaque psoriasis**, for treatment patients 4 years of age or older with chronic moderate to severe plaque psoriasis who are candidates for systemic therapy or phototherapy.
- **Psoriatic arthritis**, \pm methotrexate for reducing the signs and symptoms, inhibiting the progression of structural damage of active arthritis, and improving physical function in patients with psoriatic arthritis.
- **Rheumatoid arthritis**, \pm methotrexate for reducing the signs and symptoms, inducing major clinical response, inhibiting the progression of structural damage, and improving physical function in patients with moderate or severe active disease.

Dosing

Etanercept is administered by subcutaneous (SC) injection.¹

- **Adult rheumatoid arthritis, ankylosing spondylitis, or psoriatic arthritis:** 50 mg SC once weekly (QW).
 - Doses higher than 50 mg per week are not recommended.
- **Adult plaque psoriasis:**
 - Starting dose: 50 mg SC twice weekly for 3 months.
 - Maintenance dose: 50 mg SC QW.
- **Pediatric juvenile idiopathic arthritis or plaque psoriasis:**
 - Weight ≥ 63 kg: 50 mg SC QW.
 - Weight < 63 kg: 0.8 mg/kg SC QW.
 - To achieve pediatric doses other than 25 mg or 50 mg, use etanercept solution in a single-dose vial or reconstituted lyophilized powder in a multi-dose vial.
 - Doses greater than 50 mg per week have not been studied in pediatric patients.

Availability

Etanercept for subcutaneous injection is available in the following forms:

- 25 mg/0.5 mL prefilled syringes
- 25 mg/0.5 mL single-dose vials
- 25 mg multi-dose vials (powder for reconstitution)
- 50 mg/mL prefilled syringes in cartons of 4 syringes
- 50 mg/mL prefilled SureClick autoinjector in cartons of 4 autoinjectors
- 50 mg/mL mini prefilled cartridges for use with the AutoTouch reusable autoinjector

POLICY STATEMENT

This Drug Quantity Management program has been developed to promote the safe, effective, and economic use of etanercept, and to manage potential premature dose escalation. If the Drug Quantity Management

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rule is not met at the point of service, coverage will be determined by the Criteria below. All approvals are provided for the duration noted below.

Automation: None.

Drug Quantity Limits

Product	Strength and Form	Retail Maximum Quantity per 28 Days	Home Delivery Maximum Quantity per 84 Days
Enbrel® (etanercept subcutaneous injection)	25 mg/0.5 mL mg prefilled syringes	8 prefilled syringes (4 mL)	24 prefilled syringes (12 mL)
	25 mg/0.5 mL single-use vials	8 vials (4 mL)	24 vials (12 mL)
	25 mg multi-dose vials	8 vials	24 vials
	50 mg/mL prefilled syringes	4 prefilled syringes (4 mL)	12 prefilled syringes (12 mL)
	50 mg/mL prefilled autoinjectors	4 prefilled autoinjectors (4 mL)	12 prefilled autinjectors (12 mL)
	50 mg/mL mini cartridges	4 mini cartridges (4 mL)	12 mini cartridges (12 mL)

CRITERIA

Enbrel 25 mg prefilled syringes, single-dose vials, multi-dose vials

1. If the patient is initiating treatment or requires additional induction dosing for plaque psoriasis, as verified by the absence of claims for Enbrel in the past 130 days, approve 16 prefilled syringes/vials per 28 days for 3 months at retail or home delivery.

Enbrel 50 mg/mL prefilled syringes, prefilled autoinjectors, mini cartridges

1. If the patient is initiating treatment or requires additional induction dosing for plaque psoriasis, as verified by the absence of claims for Enbrel in the past 130 days, approve 8 prefilled syringes/autoinjectors/mini cartridges per 28 days for 3 months at retail or home delivery.

REFERENCES

1. Enbrel® subcutaneous injection [prescribing information]. Thousand Oaks, CA: Immunex/Amgen; August 2022.