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: 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

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 ≥ 2 years of age.
- **Plaque psoriasis**, for treatment patients ≥ 4 years of age with chronic moderate to severe plaque psoriasis who are candidates for systemic therapy or phototherapy.
- **Psoriatic arthritis**, ± methotrexate for reducing the signs and symptoms, inhibiting the progression of structural damage of active arthritis, and improving physical function.
- **Juvenile psoriatic arthritis**, for the treatment of active disease in patients ≥ 2 years of age.
- **Rheumatoid arthritis**, ± 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, juvenile psoriatic 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:[1]

- 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 products, and to manage potential premature dose escalation. If the Drug Quantity Management 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.

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 autoinjectors (12 mL)
	50 mg/mL mini cartridges	4 mini cartridges (4 mL)	12 mini cartridges (12 mL)

Inflammatory Conditions – Etanercept 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

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

1. If the patient is initiating treatment for plaque psoriasis 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 a total of 84 days at retail or a one-time override for 48 prefilled syringes/vials at home delivery.

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

1. If the patient is initiating treatment for plaque psoriasis 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 a total of 84 days at retail or a one-time override of 24 prefilled syringes/autoinjectors/mini cartridges at home delivery.

REFERENCES

1. Enbrel® subcutaneous injection [prescribing information]. Thousand Oaks, CA: Immunex/Amgen; October 2023.

History

Type of Revision	Summary of Changes	Review Date
Early Annual Revision	No criteria changes. Policy was updated to reflect the existing quantity limits when a product is obtained via home delivery.	12/16/2022
Annual Revision	**Enbrel 25 mg prefilled syringes, single-dose vials, multi-dose vials:** Clarified wording of criteria to indicate the patient is initiating treatment "for plaque psoriasis". Clarified 3 months to be "84 days" and clarified that the override at home delivery is a one-time override for 48 prefilled syringes/vials. **Enbrel 50 mg/mL prefilled syringes, prefilled autoinjectors, mini cartridges:** Clarified wording of criteria to indicate the patient is initiating treatment "for plaque psoriasis". Clarified 3 months to be "84 days" and clarified that the override at home delivery is a one-time override for 24 prefilled syringes/vials.	01/03/2024