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. 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.

NPF Coverage Policy

**Enbrel 25 mg pre-filled syringes or vials**

Maximum quantity per 28 days = 8 syringes/vials

**Enbrel 50 mg pre-filled syringes/ autoinjectors/mini cartridge**

Maximum quantity per 28 days = 4 syringes/autoinjectors/mini cartridges

A quantity of four 50 mg syringes/autoinjectors/mini cartridges or eight 25 mg vials/syringes will be covered. This is enough drug for a 28-day supply at 50 mg once weekly or 25 mg twice weekly dosing for most approved indications. The objective of this program is to manage potential premature dose escalation of Enbrel in the treatment of RA, JIA, PsA, PsO and ankylosing spondylitis while providing a sufficient quantity for indications covered.

**Criteria**

Cigna covers quantities as medically necessary when the following criteria are met:

All approvals are provided for 3 years in duration unless otherwise noted below.
1. Individual has rheumatoid arthritis (RA) or plaque psoriasis (PsO) and has been previously stabilized on 50 mg twice weekly dosing, a quantity of up to (8) x 50 mg syringes/autoinjectors/mini cartridges OR (16) x 25 mg vials/syringes for a 28-day supply, OR

2. Individual is initiating therapy for the treatment of PsO, a quantity of up to (8) x 50 mg syringes/autoinjectors/mini cartridges OR (16) x 25 mg vials/syringes for a 28-day supply for 3 months

Conditions Not Covered

Any other exception is considered not medically necessary.

Background

Overview
Enbrel is indicated for the treatment of rheumatoid arthritis (RA), polyarticular juvenile idiopathic arthritis (JIA) in individuals ages 2 and older, psoriatic arthritis (PsA), ankylosing spondylitis, and plaque psoriasis (PsO) in individuals 4 years or older.

Dosing
- The recommended dose of Enbrel for adult individuals with RA, PsA, and ankylosing spondylitis is 50 mg per week by subcutaneous (SC) injection either as 50 mg once weekly or 25 mg twice weekly given 3 or 4 days apart.
  - The recommended dose in the treatment of JIA or pediatric plaque psoriasis is 0.8 mg/kg/week up to a maximum of 50 mg/week.
  - In RA, PsA, and ankylosing spondylitis doses > 50 mg/week are not recommended due to a higher incidence of adverse effects with no better response rates.
- The recommended dose for the treatment of adult plaque psoriasis is 50 mg twice weekly 3 or 4 days apart for 3 months followed by reduction to a maintenance dose of 50 mg per week.
- The recommended dosing for pediatric individuals with PsO or JIA is in the table below.

<table>
<thead>
<tr>
<th>Pediatric Individuals</th>
<th>Recommended Dose</th>
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<tbody>
<tr>
<td>63 kg (138 pounds) or more</td>
<td>50 mg weekly</td>
</tr>
<tr>
<td>Less than 63 kg (138 pounds)</td>
<td>0.8 mg/kg weekly</td>
</tr>
</tbody>
</table>

To achieve pediatric doses other than 25 mg or 50 mg, use reconstituted Enbrel lyophilized powder. Doses of Enbrel higher than those described in the table above have not been studied in pediatric individuals.

Formulations
Enbrel for SC injection is supplied as 50 mg pre-filled syringes/autoinjectors, mini cartridges, 25 mg pre-filled syringes, and 25 mg/mL (once reconstituted) multiple-use vials. A 50 mg dose can be given as one SC injection using either a 50 mg pre-filled syringe or a prefilled autoinjector or as two 25 mg injections using 25 mg pre-filled syringes or 25 mg multiple-use vials.¹

References


Last Revision Details

Annual Revision | Reviewed by Clinical Specialists. No changes to criteria. | 07/24/2020

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