



Medical Necessity Criteria for Targeted Immunomodulatory Biologics

Drug Class - Targeted Immunomodulatory Biologics. This drug class includes Humira (adalimumab), Amevive (alefacept), Raptiva (efalizumab), Enbrel (etanercept), Kineret (anakinra), Cimzia (certolizumab), and Simponi (golimumab). All of these medications are given by subcutaneous injection (under the skin) with the exception of Amevive, which is given intramuscularly.

NOTE: Remicade (infliximab), Orencia (abatacept), and Rituxan (rituximab), which are intravenously-administered medications used to treat many of the same conditions, are covered by TRICARE under the medical rather than the pharmacy benefit.

Background - After evaluating the relative clinical and cost effectiveness of the targeted immunomodulatory biologics, the DoD P&T Committee recommended that the following medications be designated as non-formulary. This recommendation has been approved by the Director, TMA.

- Enbrel (etanercept)
- Kineret (anakinra)
- Cimzia (certolizumab)
- Simponi (golimumab)

Effective Date: December 30, 2009

Uniform Formulary Status, Cost Shares, and Therapeutic Alternatives for Targeted Immunomodulatory Biologics 1,2,5,6

Uniform Formulary Status	Medication	MTF (Days supply varies by drug) ³	MOP (Days supply varies by drug) ³	Retail (Up to a 30-day supply) ³
Non-Formulary (Tier 3)	Enbrel ⁵ , Kineret ⁵ , Cimzia ⁵ , Simponi ⁵	Not available ²	Non-Formulary cost share applies	Non-Formulary cost share applies
Formulary (Tier 2)	Humira, Amevive ⁴	\$0	Formulary (Brand) cost share applies	Formulary (Brand) cost share applies
Generic (Tier 1)	-	\$0	Generic cost share applies	Generic cost share applies
<ol style="list-style-type: none"> 1. Active duty cost share always \$0 in all points of service for all three tiers; TRICARE does not cover nonformulary medications for active duty service members unless they are determined to be medically necessary. 2. MTFs will be able to fill non-formulary requests for non-formulary medications only if both of the following conditions are met: 1) a MTF provider writes the prescription, and 2) medical necessity is 				

established for the non-formulary medication. MTFs may (but are not required to) fill a prescription for a non-formulary medication written by a non-MTF provider to whom the patient was referred, as long as medical necessity has been established.

- Quantity and/or days supply limits apply to Enbrel, Humira, Kineret, Cimzia and Simponi. No more than a 4-week supply will be dispensed at any one time at retail network pharmacies (no multiple fills for multiple cost shares); no more than a 6- to 8-week supply will be dispensed at any one time at the TMOP. Usual program limits apply to Raptiva and Amevive. Please see the [Formulary Search Tool](#) for specific limits.
- Amevive, which is given via intramuscular injection, is not available at the TMOP.
- Medications in this class are given for a number of different rheumatological, dermatological, and gastrointestinal conditions. Not all drugs are FDA-approved (or effective) for all conditions. Three of the medications in this class have only one FDA-approved indication (Kineret for rheumatoid arthritis and Raptiva and Amevive for plaque psoriasis).
- The medications in this class with multiple FDA-approved indications are Enbrel, Humira, Cimzia and Simponi. Enbrel and Humira are FDA-approved for rheumatoid arthritis, moderate to severe chronic plaque psoriasis, psoriatic arthritis, and ankylosing spondylitis. Enbrel has an FDA-approved indication for juvenile rheumatoid arthritis, which Humira lacks. Humira has an FDA-approved indication for Crohn's disease, which Enbrel lacks. Because of the similarity of Enbrel and Humira with regard to mechanism of action and overlap among FDA-approved indications, Humira is considered to be the most reasonable formulary alternative to Enbrel for those conditions in which both are FDA-approved. Humira is also considered to be the most reasonable formulary alternative for Kineret, since it is the only UF medication in this class also indicated for RA. Cimzia is FDA-approved for treating rheumatoid arthritis and Crohn's disease. Simponi is FDA-approved for treating rheumatoid arthritis when used in combination with methotrexate, ankylosing spondylitis, and psoriatic arthritis.

SPECIAL NOTE

Prior authorization (PA) requirements apply to all drugs in this class. The medical necessity form may NOT be used to meet PA requirements. Please see the TRICARE Pharmacy Prior Authorization page for more information.

Medical Necessity Criteria

The non-formulary cost share for Enbrel, Kineret, Cimzia, or Simponi may be reduced to the formulary cost share if the patient meets any of the following criteria.

1. Use of Humira is contraindicated.
2. The patient has experienced or is likely to experience significant adverse effects from Humira.
3. Use of Humira has resulted or is likely to result in therapeutic failure.
4. The patient previously responded to a non-formulary agent and changing to Humira would incur unacceptable risk.

*Criteria approved through the Uniform Formulary decision-making process
(November 2007; June 2008; August 2009).*

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Skyline 5, Suite 810, 5111 Leesburg Pike,
Falls Church, VA 22041-3206

