



## MEDICAL POLICY STATEMENT

Original Effective Date	Next Annual Review Date	Last Review / Revision Date
02/22/2011	02/22/2017	03/09/2016
Policy Name		Policy Number
Psoriasis: Biological Therapies		SRx-0043
Policy Type		
<input checked="" type="checkbox"/> Medical	<input type="checkbox"/> Administrative	<input type="checkbox"/> Payment

Medical Policy Statements prepared by CSMG Co. and its affiliates (including CareSource) are derived from literature based on and supported by clinical guidelines, nationally recognized utilization and technology assessment guidelines, other medical management industry standards, and published MCO clinical policy guidelines. Medically necessary services include, but are not limited to, those health care services or supplies that are proper and necessary for the diagnosis or treatment of disease, illness, or injury and without which the patient can be expected to suffer prolonged, increased or new morbidity, impairment of function, dysfunction of a body organ or part, or significant pain and discomfort. These services meet the standards of good medical practice in the local area, are the lowest cost alternative, and are not provided mainly for the convenience of the member or provider. Medically necessary services also include those services defined in any Evidence of Coverage documents, Medical Policy Statements, Provider Manuals, Member Handbooks, and/or other policies and procedures.

Medical Policy Statements prepared by CSMG Co. and its affiliates (including CareSource) do not ensure an authorization or payment of services. Please refer to the plan contract (often referred to as the Evidence of Coverage) for the service(s) referenced in the Medical Policy Statement. If there is a conflict between the Medical Policy Statement and the plan contract (i.e., Evidence of Coverage), then the plan contract (i.e., Evidence of Coverage) will be the controlling document used to make the determination.

### A. SUBJECT

Psoriasis: Biological Therapies

- Tumor Necrosis Factor Inhibitor
  - **adalimumab (Humira)**
  - **etanercept (Enbrel)**
  - **infliximab (Remicade)**
- Phosphodiesterase-4 Enzyme Inhibitors
  - **apremilast (Otezla)**
- IL-12 and IL-23 Inhibitors
  - **ustekinumab (Stelara)**
- IL-17A inhibitor
  - **secukinumab (Cosentyx)**

### B. BACKGROUND

Tumor necrosis factor-alpha (TNF) is a messenger protein, or cytokine, produced by monocytes and macrophages that mediates inflammation and induces the destruction of some tumor cells in the body. Five TNF inhibitors have been approved for the treatment of selected rheumatic and inflammatory bowel diseases.

Phosphodiesterase 4 (PDE4) is the predominant enzyme that degrades the second messenger cAMP in many immune cells, including eosinophils, neutrophils, macrophages, T cells, and monocytes. Evidence suggests that cAMP causes a down regulatory signal in immune cells, thus suppressing the production of proinflammatory mediators, including tumor necrosis factor (TNF)- $\alpha$ , interleukin (IL)-17, and interferon (IFN)- $\gamma$ . It is also believed that cAMP promotes the production of anti-inflammatory mediators such as IL-10.



Human IgG1k is a monoclonal antibody that binds with specificity to the p40 protein subunit used by both the IL-12 and IL-23 cytokines. IL-12 and IL-23 are naturally occurring cytokines that are involved in inflammatory and immune responses, such as natural killer cell activation and CD4+ T-cell differentiation and activation.

IL-17A is a naturally occurring cytokine that is involved in normal inflammatory and immune responses. When the monoclonal antibody binds to the IL-17A cytokine and inhibits its interaction with the IL-17A receptor, the release of proinflammatory cytokines and chemokines are then inhibited.

The intent of this pre-authorization (PA) program is to encourage the appropriate selection of preferred therapeutic agents for patients with such disorders as supported by product labeling, clinical studies and clinical guidelines.

### C. DEFINITIONS

N/A

### D. POLICY

CareSource will approve the use of the following medications and consider them use as **medically necessary** when the following criteria have been met:

I. **Infliximab (Remicade)** is considered **medically necessary** when criteria is met for the following indication:

A. **Plaque Psoriasis (Ps)** when **ALL** of the following are met:

1. Individual is 18 years of age or older
2. Prescribed by a dermatologist or rheumatologist
3. Documented negative TB test (ie, tuberculosis skin test (PPD), an interferon-release assay (IGRA), or a chest x-ray) within 6 months prior to initiating a biologic therapy OR yearly for members with risk factors that are requesting continuation of therapy
4. No concomitant systemic therapy or phototherapy
5. Chronic moderate to severe plaque Ps with **ALL** of the following:
  - 5.1 Plaque Ps involving 10% or more of the body surface area (BSA)
  - 5.2 Systemic therapy or phototherapy evaluation, as indicated by **one (1) or more of** the following:
    - a. Candidate for systemic therapy or phototherapy
    - b. Previous treatment with systemic therapy or phototherapy for 12 weeks
  - 5.3 Individual has failed to respond to **one (1) or more** of the following:
    - a. Immunosuppressive treatments (eg, cyclosporine, methotrexate) for a 12-week trial
    - b. Photochemotherapy (ie, psoralen plus ultraviolet A therapy) for 12 weeks
    - c. Phototherapy (ie, ultraviolet light therapy) for 12 weeks
    - d. Topical agents (eg, anthralin, calcipotriene, coal tars, corticosteroids, tazarotene) for a 4-week trial
  - 5.4 There is clinical documentation that treatment with another Tumor Necrosis Factor Inhibitor was not effective after at least a 12-week treatment course

II. **Adalimumab (Humira) or etanercept (Enbrel)** is considered **medically necessary** when criteria is met for the following indication:

A. **Plaque Psoriasis (Ps)** when **ALL** of the following are met:

1. Individual is 18 years of age or older
  2. Prescribed by a dermatologist or rheumatologist
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3. Documented negative TB test (ie, tuberculosis skin test (PPD), an interferon-release assay (IGRA), or a chest x-ray) within 6 months prior to initiating a biologic therapy OR yearly for members with risk factors that are requesting continuation of therapy
4. No concomitant systemic therapy or phototherapy
5. Chronic moderate to severe plaque Ps with **ALL** of the following:
  - 5.1 Plaque Ps involving 10% or more of the body surface area (BSA)
  - 5.2 Systemic therapy or phototherapy evaluation, as indicated by **one (1) or more of** the following:
    - a. Candidate for systemic therapy or phototherapy
    - b. Previous treatment with systemic therapy or phototherapy for 12 weeks
  - 5.3 Individual has failed to respond to **one (1) or more** of the following:
    - a. Immunosuppressive treatments (eg, cyclosporine, methotrexate) after a 12-week trial
    - b. Photochemotherapy (ie, psoralen plus ultraviolet A therapy) for 12 weeks
    - c. Phototherapy (ie, ultraviolet light therapy) for 12 weeks
    - d. Topical agents (eg, anthralin, calcipotriene, coal tars, corticosteroids, tazarotene) after a 4-week trial

III. **Ustekinumab (Stelara) or secukinumab (Cosentyx)** is considered **medically necessary** when criteria is met for the following indication:

- A. **Plaque Psoriasis (Ps)** when **ALL** of the following are met:
1. Age 18 years or older
  2. Prescribed by a dermatologist or rheumatologist
  3. Documented negative TB test (ie, tuberculosis skin test (PPD), an interferon-release assay (IGRA), or a chest x-ray) within 6 months prior to initiating a biologic therapy OR yearly for members with risk factors that are requesting continuation of therapy
  4. Duration of psoriasis of 6 or more months
  5. No concomitant systemic therapy or phototherapy
  6. Chronic moderate to severe plaque Ps with **ALL** of the following:
    - 6.1 Plaque Ps involving 10% or more of the body surface area (BSA)
    - 6.2 Systemic therapy or phototherapy evaluation, as indicated by **one (1) or more of** the following:
      - a. Candidate for systemic therapy or phototherapy
      - b. Previous treatment with systemic therapy or phototherapy for 12 weeks
    - 6.3 Individual has failed to respond to **one (1) or more** of the following:
      - a. Immunosuppressive treatments (eg, cyclosporine, methotrexate) after a 12-week trial
      - b. Photochemotherapy (ie, psoralen plus ultraviolet A therapy) for 12 weeks
      - c. Phototherapy (ie, ultraviolet light therapy) for 12 weeks
      - d. Topical agents (eg, anthralin, calcipotriene, coal tars, corticosteroids, tazarotene) after a 4-week trial
    - 6.4 There is clinical documentation that treatment with another Tumor Necrosis Factor Inhibitor was not effective after at least a 12-week treatment course

IV. **Apremilast (Otezla)** is considered **medically necessary** when criteria is met for the following indication:

- A. **Plaque Psoriasis (Ps)** when **ALL** of the following are met:
1. Prescribed by a dermatologist
  2. Individual is 18 years of age or older
  3. Chronic (greater than or equal to 1 year) plaque Ps with **ALL** of the following:
    - 3.1 Plaque Ps involving greater than ten (10) percent body surface area (BSA)
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- 3.2 Systemic therapy or phototherapy evaluation, as indicated by **one (1) or more** of the following:
  - a. Candidate for systemic therapy or phototherapy
  - b. Previous treatment with systemic therapy or phototherapy for 12 weeks
- 3.3 Individual has failed to respond to **one (1) or more** of the following:
  - a. Immunosuppressive treatments (eg, cyclosporine, methotrexate) after a 12-week trial
  - b. Photochemotherapy (ie, psoralen plus ultraviolet A therapy) for 12 weeks
  - c. Phototherapy (ie, ultraviolet light therapy) for 12 weeks
  - d. Topical agents (eg, anthralin, calcipotriene, coal tars, corticosteroids, tazarotene) after a 4-week trial
4. Weigh the benefits and risks of treatment with Otezla in patients with history of depression and/or suicidal thoughts or behaviors, due to the increase in these events with Otezla.

**ALL** other uses of adalimumab, infliximab, apremilast, ustekinumab, and secukinumab are considered experimental/investigational and therefore, will follow CareSource's off-label policy.

**Note:** Patient is required to have completed the trial listed in the above criteria unless the patient is unable to tolerate or has a contraindication. Documentation such as chart notes or pharmacy claims may be requested.

**Note:** Documented diagnosis must be confirmed by portions of the individual's medical record which will confirm the presence of disease and will need to be supplied with prior authorization request. These medical records may include, but not limited to test reports, chart notes from provider's office or hospital admission notes.

**Refer to the product package insert for dosing, administration and safety guidelines.**

#### **CONDITIONS OF COVERAGE**

<b>HCPCS</b>	J0135 adalimumab ( <b>Humira</b> ) J1745 infliximab ( <b>Remicade</b> ) J3357 ustekinumab ( <b>Stelara</b> ) J8499 apremilast ( <b>Otezla</b> ) J1438 etanercept ( <b>Enbrel</b> ) J3590 secukinumab ( <b>Cosentyx</b> )
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#### **CPT**

#### **Step Therapy**

Under some plans, including plans that use an open or closed formulary, some of the medications in this policy may be subject to step-therapy. Refer to the CareSource formulary tool or PDL for further guidance.

#### **PLACE OF SERVICE**

Office, Outpatient, Home

\*\*Preferred place of service is in the home.

These medications can be self-administered and can be billed through the pharmacy benefit.

**Note:** CareSource supports administering injectable medications in various settings, as long as those services are furnished in the most appropriate and cost-effective setting that are supportive of the patient's medical condition and unique needs and condition. The decision on the most appropriate setting for administration is based on the member's current medical condition and any



required monitoring or additional services that may coincide with the delivery of the specific medication.

#### **AUTHORIZATION PERIOD**

Approved initial authorizations are valid for 12 months. Continued treatment may be considered when the member has shown /clinical response to treatment. **ALL** authorizations are subject to continued eligibility.

#### **E. RELATED POLICIES/RULES**

- SRx-0041 Inflammatory Bowel Disease: Biologic Therapies
- SRx-0042 Autoimmune Disease: Biologic Therapies

#### **F. REVIEW/REVISION HISTORY**

Date Issued: 06/22/2011  
Date Reviewed: 06/22/2011, 12/22/2012, 12/22/2013, 10/22/2014, 02/22/2015,  
04/21/2015, 06/01/15, 08/11/2015, 03/09/2016  
Date Revised: 12/22/2012  
12/22/2013 – Added detail to criteria, increased % body involvement,  
changed agents to fail  
10/22/2104 – Add indication Psoriatic Arthritis & Crohn’s Disease  
02/22/2015 – Combine TNF and Stelara policies; revised diagnoses for  
Certolizumab, Infliximab & Adalimumab, added Apremilast and changed  
duration of initial authorization for all  
4/21/2015 – Add Ilaris & criteria, Entyvio & criteria, Xeljanz & criteria, trial  
length added for UC and Crohn’s  
08/11/2015 - Removed all criteria and information around all disease  
states other than Psoriasis, TB criteria added detail,  
Added related policies/rules  
03/09/2016 – Add criteria to Stelara and Otezla

#### **G. REFERENCES**

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13. Otezla [prescribing information]. Summit, NJ; Celgene Corporation: Revised December 2015.
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This guideline contains custom content that has been modified from the standard care guidelines and has not been reviewed or approved by MCG Health, LLC.

**The Medical Policy Statement detailed above has received due consideration as defined in the Medical Policy Statement Policy and is approved.**

Independent Medical Review - 2011

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