MEDICAL POLICY STATEMENT		
Original Effective Date	**Next Annual Review Date**	**Last Review / Revision Date**
02/22/2011	**02/22/2016**	**8/11/2015**
Policy Name		**Policy Number**
Psoriasis: Biological Therapies		**SRx-0043**

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.

For Medicare plans please reference the below link to search for Applicable National Coverage Descriptions (NCD) and Local Coverage Descriptions (LCD):

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)-α, interleukin (IL)-17, and interferon (IFN)-γ. It is also believed that cAMP promotes the production of anti-inflammatory mediators such as IL-10.

Human IgG1κ 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 of 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 ten percent 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

3. Documented negative TB test (ie, tuberculosis skin test (PPD), an interferon-release assay (IGRA), or a chest x-ray) within 6 months of 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 greater than ten percent 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) & 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. Documented negative TB test (ie, tuberculosis skin test (PPD), an interferon-release assay (IGRA), or a chest x-ray) within 6 months of initiating a biologic therapy OR yearly for members with risk factors that are requesting continuation of therapy
      2. Age 18 years or older
      3. Duration of psoriasis of 6 or more months
      4. Prescribed by a dermatologist or rheumatologist
      5. No concomitant systemic therapy or phototherapy
      6. Chronic moderate to severe plaque Ps with **ALL** of the following:
         6.1 Plaque Ps involving ten (10) percent body surface area (BSA) or more
         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

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 moderate to severe plaque Ps with **ALL** of the following:
         3.1 Plaque Ps involving greater than ten (10) percent body surface area (BSA)
         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

ALL other uses of adalimumab, infliximab, apremilast, ustekinumab, 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.

For Medicare Plan members, reference the below link to search for Applicable National Coverage Descriptions (NCD) and Local Coverage Descriptions (LCD):

If there is no NCD or LCD present, reference the CareSource Policy for coverage.

CONDITIONS OF COVERAGE

HCPCS J0135 adalimumab **(Humira)**
J1745 infliximab **(Remicade)**
J3357 ustekinumab **(Stelara)**
J8499 apremilast **(Oztela)**
J1438 etanercept **(Enbrel)**
J3590 with NDC secukinumab **(Cosentyx)**

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.**
This medication can be self-administered and can be billed through the pharmacy benefit.
Note: CareSource supports administering inject able medications in various setting, 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 biological response to treatment. A reauthorization will be placed if there is evidence of patient taking the medication within the last 60 days. **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
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

G. REFERENCES

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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