



Ustekinumab

DESCRIPTION

Ustekinumab is a human IgG1κ monoclonal antibody produced by recombinant DNA technology. It binds specifically to the p40 protein subunit which is shared by the cytokines interleukin (IL)-12 and IL-23. IL-12 and IL-23 are involved in inflammatory and immune responses. Ustekinumab has been shown to disrupt IL-12 and IL-23 mediated signaling and cytokine cascades.

An example of a preparation of ustekinumab is Stelara™.

REFER TO DECISION SUPPORT TREE

POLICY

- Ustekinumab for the treatment of psoriasis is considered **medically necessary** if the medical appropriateness criteria are met. **(See Medical Appropriateness below.)**
- Ustekinumab for the treatment of other conditions/diseases is considered **investigational**.

MEDICAL APPROPRIATENESS

- Ustekinumab for the treatment of psoriasis is considered **medically appropriate** if **ALL** of the following criteria are met:
 - Individual is 18 years of age or older
 - Level of disease is moderate to severe chronic plaque psoriasis
 - Individual has failed phototherapy
 - Other systemic therapy is less appropriate

APPLICABLE TENNESSEE STATE MANDATE REQUIREMENTS

Tennessee State law requires coverage of off-label indications of Food and Drug Administration (FDA) approved drugs when the off-label use is relative to life-threatening illnesses, such as cancer, AIDS, and coronary heart disease and recognized in one of the standard reference compendia (As defined in the statute: The United States Pharmacopoeia Drug Information, The American Medical Association Drug Evaluations, & The American Hospital Formulary Service Drug Information) or in the medical literature. This law is applicable to all fully insured members. The law is not applicable to self-funded accounts, but coverage for off-label uses may be provided based on the contractual agreement.

ADDITIONAL INFORMATION

For appropriate dosage information, contraindications, precautions, warnings, and monitoring information, please refer to one of the standard reference compendia (e.g., The American Hospital Formulary Service Drug Information).

No controlled studies were found in the published literature that validate the use of ustekinumab in the treatment of or prevention of other conditions/diseases.

SOURCES



BlueCross BlueShield
of Tennessee

Policy

Medical Policy Manual

Draft: Do Not Implement

MICROMEDEX Healthcare Series. Drugdex Drug Evaluations. (2009). *Ustekinumab*. Retrieved October 26, 2009 from MICROMEDEX Healthcare Series.

U. S. Food and Drug Administration. (2009, September). Center for Drug Evaluation and Research. *Flolan*[®] (*epoprostenol*). Retrieved September 29, 2009 from http://www.accessdata.fda.gov/drugsatfda_docs/label/2009/125261lbl.pdf.

ID_BT



**BlueCross BlueShield
of Tennessee**

Pharmaceutical Decision Support Tree

Generic or Chemical Name (Trade Name[®])

1. Is the requested medication being used to treat psoriasis?

If yes, go to question #2

If no, this does not meet medical necessity and/or medical appropriateness criteria

2. Does the individual show evidence of **ALL** of the following?

- Individual is 18 years of age or older
- Level of disease is moderate to severe chronic plaque psoriasis
- Individual has failed phototherapy
- Other systemic therapy is less appropriate

If yes, this satisfies medical necessity and medical appropriateness criteria

If no, this does not meet medical necessity and/or medical appropriateness criteria