

Medical Policy Manual **Approved: Do Not Implement Until 12/12/09**

Golimumab

DESCRIPTION

Golimumab is a human IgG1_k monoclonal antibody specific for tumor necrosis factor alpha (TNF α), a cytokine protein. It is considered an immune modulator and TNF-blocker. Golimumab binds to bioactive forms of human TNF α and inhibits the biological activity of TNF α by preventing TNF α from binding to its receptors. Elevated TNF α levels are found in the blood, synovium, and joints of individuals with several chronic inflammatory conditions.

An example of a preparation of golimumab is Simponi™.

REFER TO DECISION SUPPORT TREE

POLICY

- Golimumab for the treatment of the following is considered **medically necessary** if the medical appropriateness criteria are met. **(See Medical Appropriateness below.)**
 - Rheumatoid arthritis
 - Psoriatic arthritis
 - Ankylosing spondylitis
- Golimumab for the treatment of other conditions/diseases is considered **investigational**.

MEDICAL APPROPRIATENESS

- Golimumab for the treatment of **ANY ONE** of the following is considered **medically appropriate** if **ALL** of the following criteria are met:
 - Rheumatoid arthritis if **ALL** of the following:
 - Disease is moderately- to severely-active
 - Individual is 18 years of age or older
 - Treatment is in combination with methotrexate, if tolerated, or as monotherapy
 - Psoriatic arthritis if **ALL** of the following:
 - Disease is active
 - Individual is 18 years of age or older
 - Ankylosing spondylitis if **ALL** of the following:
 - Disease is active
 - Individual is 18 years of age or older

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



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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).

Moderately-active to severely-active rheumatoid arthritis is determined using an accepted composite scoring system such as the Disease Activity Score in 28 joints (DAS28) or the Simplified Disease Activity Index (SDAI).

No controlled studies were found in the published literature that validate the use of golimumab for the treatment of any other conditions diseases.

SOURCES

Aletaha, D., & Smolen, J. (2005). The Simplified Disease Activity Index (SDAI) and the Clinical Disease Activity Index (CDAI): A review of their usefulness and validity in rheumatoid arthritis. *Clinical and Experimental Rheumatology*, 23 (39), S100 - S108.

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EFFECTIVE DATE 12/12/2009

ID_BT



Pharmaceutical Decision Support Tree

Golimumab (Simponi®)

1. Is the individual 18 years of age or older?

If yes, go to question #2

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

2. Does the individual have a diagnosis of rheumatoid arthritis?

If yes, go to question # 3

If no, go to question # 5

3. Is the disease moderately- to severely-active?

If yes, go to question # 4

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

4. Is the requested agent to be administered with methotrexate, if tolerated, or as monotherapy?

If yes, this satisfies medical necessity and medical appropriateness criteria

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

5. Does the individual have a diagnosis of active psoriatic arthritis?

If yes, this satisfies medical necessity and medical appropriateness criteria

If no, go to question #6

6. Does the individual have a diagnosis of active ankylosing spondylitis?

If yes, this satisfies medical necessity and medical appropriateness criteria

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