



CIGNA MEDICAL COVERAGE POLICY

The following Coverage Policy applies to all health benefit plans administered by CIGNA Companies including plans formerly administered by Great-West Healthcare, which is now a part of CIGNA.

Subject **Golimumab (Simponi™)**

Effective Date 7/15/2011
Next Review Date 7/15/2012
Coverage Policy Number 9014

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Hyperlink to Related Coverage Policies

Actemra®
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 Humira®
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 Orencia®
 Remicade®
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INSTRUCTIONS FOR USE

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Coverage Policy

CIGNA covers golimumab (Simponi™) as medically necessary for the treatment of ANY of the conditions listed when the associated criteria are met:

- rheumatoid arthritis (RA), when used in combination with methotrexate, **AND** when **EITHER** of the following is met:
 - history of beneficial clinical response to golimumab
 - failure, intolerance, or contraindication to at least **ONE** disease-modifying anti-rheumatic drug (DMARDs) (Methotrexate, Azathioprine, gold, Hydroxychloroquine, Leflunomide, Penicillamine, Sulfasalazine) **AND** to **TWO self administered preferred** tumor necrosis factor (TNF) antagonists [adalimumab (Humira®) and etanercept (Enbrel®)]
- psoriatic arthritis (PsA) when **EITHER** of the following criteria is met:
 - history of beneficial clinical response to golimumab
 - failure, contraindication, or intolerance to **BOTH** methotrexate therapy **AND** to **ONE** preferred tumor necrosis factor (TNF) antagonist [adalimumab (Humira), etanercept (Enbrel)]

- ankylosing spondylitis (AS) when **EITHER** of the following criteria is met:
 - history of beneficial clinical response to golimumab
 - failure, contraindication, or intolerance to **ONE** nonsteroidal anti-inflammatory drug (NSAIDs) **AND** to **ONE** preferred tumor necrosis factor (TNF) antagonist [adalimumab (Humira), etanercept (Enbrel)]

The dosage, frequency, site of administration, and duration of therapy are reasonable, clinically appropriate, and supported by evidence-based literature and adjusted based upon severity, alternative available treatments, and previous response to golimumab (Simponi™) therapy.

FDA Approved Indications

Rheumatoid Arthritis (RA)

Simponi, in combination with methotrexate, is indicated for the treatment of adult patients with moderately to severely active rheumatoid arthritis.

Psoriatic Arthritis (PsA)

Simponi, alone or in combination with methotrexate, is indicated for the treatment of adult patients with active psoriatic arthritis.

Ankylosing Spondylitis (AS)

Simponi is indicated for the treatment of adult patients with active ankylosing spondylitis.

FDA Recommended Dosing

The Simponi dose regimen is 50 mg administered by subcutaneous (SC) injection once a month. For patients with rheumatoid arthritis (RA), Simponi should be given in combination with methotrexate. For patients with psoriatic arthritis (PsA) or ankylosing spondylitis (AS), Simponi may be given with or without methotrexate or other non-biologic DMARDs. For patients with RA, PsA, or AS, corticosteroids, non-biologic DMARDs, and/or NSAIDs may be continued during treatment with Simponi.

Black Box Warnings

Patients treated with Simponi are at increased risk for developing serious infections that may lead to hospitalization or death. Most patients who developed these infections were taking concomitant immunosuppressants such as methotrexate or corticosteroids. Simponi should be discontinued if a patient develops a serious infection. Reported infections include:

- **active tuberculosis, including reactivation of latent tuberculosis. Patients with tuberculosis have frequently presented with disseminated or extrapulmonary disease. Patients should be tested for latent tuberculosis before Simponi use and during therapy. Treatment for latent infection should be initiated prior to Simponi use.**
- **invasive fungal infections, including histoplasmosis, coccidioidomycosis, and pneumocystosis. Patients with histoplasmosis or other invasive fungal infections may present with disseminated, rather than localized, disease. Antigen and antibody testing for histoplasmosis may be negative in some patients with active infection. Empiric anti-fungal therapy should be considered in patients at risk for invasive fungal infections who develop severe systemic illness.**
- **bacterial, viral, and other infections due to opportunistic pathogens.**

The risks and benefits of treatment with Simponi should be carefully considered prior to initiating therapy in patients with chronic or recurrent infection. Patients should be closely monitored for the development of signs and symptoms of infection during and after treatment with Simponi, including the possible development of tuberculosis in patients who tested negative for latent tuberculosis infection prior to initiating therapy.

Drug Availability

Simponi is available as a single dose in a prefilled glass syringe containing 50 mg per 0.5 mL of solution.

General Background

Pharmacology

Golimumab is a tumor necrosis factor (TNF) antagonist approved by the FDA in April 2009 for the treatment of active chronic inflammatory disease including RA, PsA and AS. Golimumab is a recombinant, human IgG1 monoclonal antibody which binds to both soluble and transmembrane TNF alpha. The bioavailability of subcutaneous golimumab is approximately 53%. Peak serum concentration is achieved at 2 to 6 days after subcutaneous administration. Golimumab has a terminal half-life of approximately 2 weeks and reaches steady state by week 12 when given subcutaneously once every 4 weeks.

Guidelines

American College of Rheumatology (ACR)

The American College of Rheumatology (ACR) 2010 recommendations include the use of nonbiologic and biologic therapies in patients with RA when starting or resuming these therapies. The 2010 ACR recommendations address five key areas including: the indications for use, monitoring for side-effects, screening for tuberculosis which is a risk factor associated with biologic DMARDs, and off-label uses. The duration of RA disease duration, disease severity, and prognostic features were also considered when developing these recommendations. According to ACR guideline, it is important that RA patients be seen regularly to assess disease activity, evaluate disease severity, and determine whether alternative therapies are warranted. Because there was no evidence to support a specific recommendation on the frequency of provider visits, a specific and potentially arbitrary time frame is not recommended at this point. However, based on these recommendations, commonly used but not exclusive tools to assess the RA disease activity include: Disease Activity Score (DAS) in 28 joints, Simplified Disease Activity Index (SDAI), Clinical Disease Activity Index (CDAI), Rheumatoid Arthritis Disease Activity Index, Patient Activity Scale (PAS), and Routine Assessment Patient Index Data. In addition it is recommended to use the combinations of commonly used but not exclusive prognostic factors to evaluate the patients with RA, including: Health Assessment Questionnaire (HAQ) score, Evidence of radiographic erosions, Elevated erythrocyte sedimentation rate, Elevated C-reactive protein level, and elevated levels of rheumatoid factor (RF) and/or anti-cyclic citrullinated peptide (anti-CCP) antibodies. Due to the absence of a single "gold standard" measure, multiple measures or pooled indices are used to determine a diagnosis, estimate prognosis, and to assess and monitor disease activity and response to treatment. Other commonly used measures in the clinical settings include: Visual Analogue scale (VAS), Likert scales of global response to pain by the patient/doctor, and Global Arthritis Score (GAS).

Many autoimmune rheumatic diseases have severe multisystem manifestations, including internal organ involvement and premature death. Unfortunately, for many of these conditions, standard (FDA approved) therapies do not exist, or are only effective in a subset of patients. The rarity of some of these conditions presents a barrier to performing large scale studies required for regulatory approval. However, valuable information is obtained in the published clinical reports of biologic DMARD therapies for many less common but disabling autoimmune conditions. When successful treatment options have been clearly documented in peer-reviewed journals, patients should receive the opportunity to benefit from these effective therapies.

While the American College of Rheumatology (ACR) offers a model for recommended off-label coverage criteria for use of TNF's. Other uses where TNF products have shown efficacy of use have not been shown with this product. Therefore, any other use for this product that is not listed in the criteria coverage stem is considered experimental, investigational, and unproven.

American Academy of Dermatology (AAD)

The American Academy of Dermatology (AAD) published a consensus statement (Callen, et al., 2003) on psoriasis therapies. The document is intended to be used as a guide to the evaluation and treatments of psoriasis until evidence based guidelines are developed. Within this document, the authors state that BSA should not generally be used to determine which therapy to select; moderate and severe disease overlap and individuals with limited disease can be considered moderate for the purposes of selecting a therapy. Topical therapies are recommended for limited plaque disease. For moderate to severe disease, the AAD recommends phototherapy, targeted phototherapy, narrowband UVB, photochemotherapy with psoralen and UVA light (PUVA), topicals and systemic treatments.

Adverse Reactions

The most commonly reported adverse events with golimumab were upper respiratory tract infection and nasopharyngitis. Concomitant administration of methotrexate and golimumab results in higher serum levels of golimumab. Avoid concomitant administration with anakinra, abatacept, or live vaccines.

Coding/Billing Information

Note: This section is not in use.

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