

## Simponi®

To Initiate a Coverage Review, call 1 800 753-2851

### Covered Medication

Golimumab (Simponi® Injection)

### What it does and how it is used

- Simponi® is a biological agent that is used to treat rheumatoid arthritis (RA), psoriatic arthritis (PsA), and ankylosing spondylitis (AS).
- Simponi® is a monoclonal antibody that binds specifically to soluble and transmembrane bioactive forms of tumor necrosis factor (TNF). TNF is a naturally occurring cytokine that is involved in normal inflammatory and immune responses.
- At this time, there are no published radiologic data regarding the efficacy of Simponi®. Currently, there are four other TNF-α inhibitors approved for the treatment of rheumatoid arthritis, psoriatic arthritis, and/or ankylosing spondylitis: adalimumab (Humira®), infliximab (Remicade®), etanercept (Enbrel®), and certolizumab (Cimzia®). These other four drugs have been shown to have radiologic activity in published studies.
- **Rheumatoid arthritis (RA)** is a progressive chronic inflammatory disease that primarily affects large and small joints. The disease is characterized by joint deformities of the hands, wrists, neck, jaw, elbows, feet, and ankles. In addition to pain, patients can experience neuropathy (numbness or loss of feeling in hands or feet). Other conditions associated with RA include cardiac abnormalities, pulmonary fibrosis, and corneal defects. RA is associated with a significant amount of morbidity, which can lead to a higher risk of mortality.
- RA treatment is aggressive soon after diagnosis with the goal of treatment being to eliminate synovitis (joint swelling) and joint destruction. Joint erosion is due to the presence of inflammatory mediators, which cause joint and cartilage destruction. These damaging substances include prostaglandins, cytokines, and tumor necrosis factor.
- Initial treatment in the mild stages can include NSAIDs and then usually a conventional disease-modifying antirheumatic drug (DMARD). DMARDs decrease pain, slow disease progression, and retard development of joint erosions.
- Methotrexate is the most commonly used DMARD. It may be used alone or with a biologic agent (e.g., Enbrel®, Remicade®, Kineret® or Humira®). Simponi® is indicated for the treatment of *moderately to severely active* RA in adults in combination with methotrexate. Initial treatment with Simponi® plus methotrexate has been shown to be more effective in treating RA than either agent alone.
- **Psoriatic arthritis (PsA)** is a chronic inflammatory joint disease that is associated with psoriasis. In approximately 70% of patients, psoriasis alone precedes the onset of PsA by an average of ten years. However, the onset of the skin condition and arthropathy can occur simultaneously in 11% to 15% of patients.
- Simponi® is also indicated for reducing signs and symptoms in patients with active **ankylosing spondylitis (AS)**: a chronic, slowly progressive disease characterized by mild or moderate inflammation of the sacroiliac, intervertebral, and costovertebral joints within the spine alternating with periods of almost no symptoms. *Ankylos* in Greek means bent or crooked and *spondylos* means vertebrae. AS primarily affects the spine or back causing pain and stiffness and in severe cases can result in fusing of the spine leading to a forward-stooped position. AS can damage other joints in the hips, shoulders, ribs, and heels along with other parts in the body such as the heart, lungs, and eyes.
- Though some NSAIDs have the labeled indication for AS, they only provide modest anti-inflammatory analgesic effects for symptoms. The Ankylosing Spondylitis Assessment Score (ASAS) measures disease status and change in status within 6 domains of AS, including pain, patient global assessment, function, inflammation, spinal mobility, and C reactive protein level. A treatment response is defined as ≥20% improvement in 5 of 6 domains without deterioration in the 6th domain.
- Significantly more patients in the Simponi® ± DMARD group achieved ASAS 20, compared to placebo ± DMARD (59% Simponi® 50 mg ± DMARD vs 22% placebo ± DMARD) by week 14. 48% of patients in the Simponi® ± DMARD group experienced ASAS 20 as early as week 4. The effect on ASAS 20 was maintained through week 24.
- The FDA agreed upon these criteria for assessing efficacy of drugs for AS. NSAIDs were not previously reviewed using the ASAS criteria.
- In situations where patients have not responded to traditional therapies such as NSAIDs, glucocorticoids, salicylates, analgesics, or methotrexate, Simponi® may be used alone or in combination with these therapies for the treatment of ankylosing spondylitis. Traditional DMARDs used for RA are ineffective for this condition.

### Rationale for coverage authorization

To reduce exposure to cost associated with Simponi® for the treatment of conditions for which its effectiveness is not known (such as ulcerative colitis). Simponi® has been shown to be effective for the treatment of rheumatoid or psoriatic arthritis, and ankylosing spondylitis.

### Benefit design

- Coverage for Simponi® is determined through prior authorization for every claim.

### Coverage authorization criteria

Coverage is determined in accord with the following criteria:

- Patients must have had an inadequate response to or have been intolerant to treatment with at least one TNF- $\alpha$  inhibitor (that is, Remicade<sup>®</sup>, Enbrel<sup>®</sup>, Humira<sup>®</sup>, Cimzia<sup>®</sup>).
  1. Coverage is provided for the treatment of moderate to severe rheumatoid arthritis in combination with methotrexate.
  2. Coverage is provided for the treatment of psoriatic arthritis alone or in combination with methotrexate.
  3. Coverage is provided for the treatment of ankylosing spondylitis
    - In situations where the patient has experienced inadequate symptom relief from other treatments such as NSAIDs or COX-2 inhibitors, or methotrexate unless the patient is unable to receive treatment with these drugs.

Coverage is not provided for use of Simponi<sup>®</sup> in combination with another biologic agent.

Coverage is not provided unless the patient has been evaluated for the presence of latent TB infection.

Duration of coverage:

Coverage is provided for 12 months.

### References

- American College of Rheumatology. Guidelines for the management of rheumatoid arthritis, 2002 Update. Available at: <http://www.rheumatology.org/publications/guidelines/raguidelines02.asp>. Accessed March 25, 2008.
- Braun J, Davis J, et al. for the ASAS working group. First update of the international ASAS consensus statement for the use of anti-TNF agents in patients with ankylosing spondylitis., [Ann Rheum Dis](#). 2006 Mar;65(3):316-320.
- Simponi<sup>®</sup> (golimumab injection) Prescribing information. Horsham, PA: Centocor Ortho Biotech Inc., April 2009.
- Spondylitis Association of America. Guidelines for the use of anti-TNF therapy in patients with ankylosing spondylitis: breakdown of criteria. September 2008. Available at [http://www.spondylitis.org/physician\\_resources/guidelines.aspx](http://www.spondylitis.org/physician_resources/guidelines.aspx) Accessed August 10, 2009.