BlueCross BlueShield of Kansas City

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Simponi® (golimumab)

Policy Number: 5.01.535
Origination: 12/2009
Last Review: 03/2014
Next Review: 12/2014

Policy

BCBSKC will provide coverage for Simponi® (golimumab) when it is determined to be medically necessary because the criteria shown below are met.

When Policy Topic is covered

Golimumab may be considered **medically necessary for the following conditions** after at least a 12-week treatment course with either etanercept (Enbrel) **and** adalimumab (Humira) has not been effective.

• Moderately to severely active **rheumatoid arthritis** in adults, in combination with methotrexate, and

• Active **psoriatic arthritis** in adults, alone or in combination with methotrexate, and

• Active **ankylosing spondylitis** in adults

Golimumab may be considered **medically necessary for the following conditions** after at least a 12-week treatment course with either adalimumab (Humira) or infliximab (Remicade) has not been effective.

- Moderate to severe **ulcerative colitis** in adults

When Policy Topic is not covered

Other uses of golimumab are considered **investigational.**

Considerations

Golimumab (Simponi) requires prior authorization through pharmacy services.

Golimumab 50mg is administered by subcutaneous injection once a month, and can be self-administered. The self-administered product will pay through pharmacy. Golimumab is also available as a 2mg/kg intravenous infusion and is administered at weeks 0 and 4, then every 8 weeks thereafter. The IV infusion will process through the medical benefit.

This Blue Cross and Blue Shield of Kansas City policy statement was developed using available resources such as, but not limited to: Hayes Medical Technology Directory, Food and Drug

Administration (FDA) approvals, Facts and Comparisons, National specialty guidelines, Local medical policies of other health plans, Medicare (CMS), Local providers.

Description of Procedure or Service

Golimumab (Simponi®) binds to and inhibits the activity of tumor necrosis factor (TNF), a chemical in the body that causes inflammation. It is used to treat diseases that may be caused or worsened by an overactive immune system, such as rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis or ulcerative colitis.

Tumor necrosis factor (TNF) is a cytokine produced by macrophages and T cells. Its name is based on the original observations 25 years ago that TNF killed tumor cells in vitro. Further research has revealed that TNF has a broad spectrum of biologic activities; in particular, it is a key mediator of inflammation and is produced in response to infection and immunologic injury.

There are a number of TNF alpha blocking agents; etanercept (ENBREL®, Amgen); adalimumab (HUMIRA, Abbott)®; certolizumab (CIMZIA®, UCB), golimumab (SIMPONI®, Centocor) administered via subcutaneous injection and infliximab (REMICADE® Centocor) administered via an intravenous (IV) infusion in the physician's office, outpatient setting, or infusion center. This policy focuses on golimumab that is typically adjudicated under the pharmacy benefit.

Rationale

In a placebo-controlled trial that evaluated the effectiveness of golimumab in patients with rheumatoid arthritis, 444 patients were randomized to receive golimumab 50 mg or 100 mg subcutaneously given every 4 weeks along with weekly methotrexate, golimumab 100 mg given 4 weeks alone, or placebo given every 4 weeks with methotrexate. [2] At the end of 24 weeks (6 months), 55% and 56 % of patients receiving golimumab 50 mg or 100 mg (respectively) plus methotrexate experienced a 20% improvement in symptoms compared with 33% of patients receiving placebo plus methotrexate. Patients receiving golimumab 100 mg alone did not differ significantly from patients receiving methotrexate alone.

Golimumab has been shown to have the best efficacy when administered with methotrexate for the treatment of moderate to severe rheumatoid arthritis. There is reliable evidence that golimumab improves symptoms in patients with psoriatic arthritis. [5] In a trial of 405 patients, 45% to 51% of patients taking golimumab (with or without methotrexate) achieved a 20% reduction in the symptoms of arthritis compared to only 9% of patients taking a placebo.

There is reliable evidence that golimumab improves symptoms in patients with ankylosing spondylitis. [6] In a trial of 356 patients, about 60% of patients taking golimumab achieved a 20% reduction in the symptoms of ankylosing spondylitis compared to only 22% of patients taking a placebo.

The safety and efficacy of golimumab were evaluated in two multi-center randomized,double-blind placebo-controlled clinical trials in patients over the age of 18. Trial UC-1 was an induction trial conducted in patients with moderately to severly active UC. In trial UC-1, a greater proportion of patients achieved clinical response, clinical remission and had improvement of endoscopic appearance of the mucosa at Week 6 compared with the placebo group. In Trial UC-2, a greater proportion of patients maintained clinical response through Week 54 compared with the placebo group.

Safety
Commonly seen side effects of golimumab include upper respiratory tract infections and nasopharyngitis. [1]
Rare, but serious side effects include serious infections (fungal infections, tuberculosis), reactivation of hepatitis B, some forms of cancer (such as lymphoma), heart failure, and disorders of the brain and central nervous system. [1]

Dosing
RA, PsA and AS – 50 mg administered by subcutaneous injection once a month or 2mg/kg IV infusion at weeks 0 and 4, then every 8 weeks thereafter.
UC – 200 mg initially administered by subcutaneous injection at Week 0, followed by 100 mg at Week 2 and then 100 mg every 4 weeks. [1]
Higher doses do not appear to result in improved efficacy. [1-6]

References:

1. Simponi® [package insert]. Horsham, PA: Centocor Ortho Biotech Inc.; April 2009
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3. Smolen J, Kay J, Doyle M.K., et al. Golimumab, A New Human Anti-TNF-Alpha Monoclonal Antibody, Subcutaneously Administered Every 4 Weeks In Patients With Active Rheumatoid Arthritis Who Were Previously Treated With Anti-TNF-Alpha Agent(S): Results Of The Randomized, Double-Blind, Placebo-C. Ann Rheum Dis 2008;67(Suppl II):50.
4. Emery P, Fleischmann R.M, Moreland L.W, et al. Golimumab (GLM), A New Human Anti-Tnf-Alpha Monoclonal Antibody, Administered Subcutaneously (SC) Every 4 Weeks In Methotrexate-Naïve Patients With Active Rheumatoid Arthritis (Ra): A Randomized, Double-Blind, Placebo-Controlled, Go-Before Study. Ann Rheum Dis 2008;67(Suppl II):179
5. Kavanaugh A, McInnes I, Mease P, et al. Golimumab, a new human tumor necrosis factor alpha antibody, administered every four weeks as a subcutaneous injection in psoriatic arthritis: Twenty-four-week efficacy and safety results of a randomized, placebo-controlled study. Arthritis Rheum. 2009 Apr;60(4):976-86.
6. Inman RD, Davis JC Jr, Heijde D, et al. Efficacy and safety of golimumab in patients with ankylosing spondylitis: results of a randomized, double-blind, placebo-controlled, phase III trial. Arthritis Rheum. 2008 Nov;58(11):3402-12

Billing Coding/Physician Documentation Information

J1602 Injection, golimumab, 1 mg, for intravenous use

Additional Policy Key Words

5.01.535

Related Topics

N/A

Policy Implementation/Update Information

12/2009 New policy titled Simponi® (golimumab)
12/2010 Reviewed – no changes made
12/2011 Reviewed – no changes made
05/2013 Policy updated with new indication
03/2014 Policy updated for double step
