

Corporate Medical Policy

Golimumab (Simponi Aria®)

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Origination:	8/2013
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Next CAP Review:	2/2021
Last Review:	11/2020

Description of Procedure or Service

Golimumab (Simponi® and Simponi Aria®), a human monoclonal antibody, inhibits the biological activity of tumor necrosis factor alpha (TNF-alpha). Elevated TNF-alpha levels have been implicated in the pathophysiology of several chronic inflammatory diseases, including rheumatoid arthritis (RA), psoriatic arthritis (PsA), and ankylosing spondylitis (AS). Tumor necrosis factor-alpha is an important mediator of the articular inflammation that is characteristic of these diseases. Golimumab neutralizes the biologic activity of tumor necrosis factor (TNF)-alpha by binding to and blocking its interaction with cell surface TNF receptors. Elevated TNF-alpha concentrations in the blood, synovium, and joints have been implicated in the pathophysiology of several chronic inflammatory diseases such as rheumatoid arthritis. TNF-alpha is a naturally occurring cytokine that is involved in normal inflammatory and immune responses.

Golimumab (Simponi) for subcutaneous use was approved by the U.S. Food and Drug Administration (FDA) on April 24, 2009 for adults with moderately-to-severely active rheumatoid arthritis, active psoriatic arthritis, and active ankylosing spondylitis. Simponi Aria is given by intravenous infusion and is intended for use in combination with methotrexate (MTX) in adult patients with moderately to severely active rheumatoid arthritis. Simponi Aria is also approved to treat active psoriatic arthritis in patients 2 years of age and older, active polyarticular juvenile idiopathic arthritis in patients 2 years of age and older, and active ankylosing spondylitis in adult patients.

Rheumatoid arthritis (RA) is a chronic, inflammatory, autoimmune disorder characterized by inflammation of synovial joints resulting in progressive erosion of cartilage and bone. The main objectives of treatment of RA are three-fold: to interfere with the disease process (i.e., inflammation and destruction of the joints), preserve physical function, and prevent long-term disability. The American College of Rheumatology (ACR)'s guidelines for the treatment of RA (1996) recommend that newly diagnosed patients with RA begin treatment with disease modifying anti-rheumatic drugs (DMARDs) within 3 months of diagnosis. Methotrexate remains the most commonly prescribed DMARD and is the standard by which recent new and emerging therapies are measured.

Related Policies:

Abatacept (Orencia)
Infliximab (Remicade)
Nononcologic Uses of Rituximab
Tocilizumab (Actemra)

*****Note: This Medical Policy is complex and technical. For questions concerning the technical language and/or specific clinical indications for its use, please consult your physician.**

Golimumab (Simponi Aria®)

Policy

BCBSNC will provide coverage for golimumab (Simponi Aria) for the treatment of rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis, and polyarticular juvenile idiopathic arthritis when it is determined to be medically necessary because the medical criteria and guidelines shown below are met.

Benefits Application

This medical policy relates only to the services or supplies described herein. Please refer to the Member's Benefit Booklet for availability of benefits. Member's benefits may vary according to benefit design; therefore member benefit language should be reviewed before applying the terms of this medical policy.

Coverage for Golimumab (Simponi Aria) requires prior review.

When Golimumab (Simponi Aria) is covered

Golimumab (Simponi Aria®) may be medically necessary for treatment of the following:

1. Moderately to severely active rheumatoid arthritis in adult patients when:
 - a. There has been a therapeutic failure/inadequate response with methotrexate alone,
OR
 - b. Methotrexate is contraindicated, AND
 - c. The member is not using Simponi in combination with another biologic agent (e.g., Enbrel, Humira, Kineret, Cimzia, Remicade, Orencia, Rituxan, Kevzara, Cosentyx, Actemra, or Xeljanz)
2. Active psoriatic arthritis in patients 2 years of age and older
3. Active ankylosing spondylitis in adult patients
4. Active polyarticular juvenile idiopathic arthritis in patients 2 years of age and older

When Golimumab (Simponi Aria) is not covered

Golimumab (Simponi Aria®) is considered not medically necessary when the criteria stated above are not met.

Golimumab (Simponi Aria®) is considered not medically necessary for patients with an active infection, invasive fungal infections, Hepatitis B, malignancies, congestive heart failure, demyelinating disorders, or lupus-like syndromes.

Golimumab (Simponi Aria®) is considered not medically necessary when used in combination with Abatacept, Adalimumab, Anakinra, Certolizumab, Etanercept, Infliximab, Rituximab, Sarilumab, Secukinumab, Tocilizumab, Tofacitinib, and live vaccines.

Policy Guidelines

According to the Food and Drug Administration (FDA) approved labeling for golimumab (Simponi Aria), the dose for intravenous infusion in adult patients is 2 mg/kg over 30 minutes at weeks 0 and 4, then every 8 weeks thereafter. For pediatric patients with polyarticular juvenile idiopathic arthritis and psoriatic arthritis, the dose is 80 mg/m² given as an intravenous infusion over 30 minutes at weeks 0 and 4, then every 8 weeks thereafter. For patients with rheumatoid arthritis, golimumab (Simponi Aria) should be given in combination with methotrexate.

Patients treated with Simponi Aria are at increased risk for developing serious infections involving various organ systems and sites that may lead to hospitalization or death. Opportunistic infections due to bacterial, mycobacterial, invasive fungal, viral, or parasitic organisms including aspergillosis,

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blastomycosis, candidiasis, coccidioidomycosis, histoplasmosis, legionellosis, listeriosis, pneumocystosis, and tuberculosis have been reported with TNF-blockers. Patients have frequently presented with disseminated rather than localized disease. The concomitant use of a TNF-blocker and abatacept or anakinra was associated with a higher risk of serious infections; therefore, the concomitant use of Simponi Aria and these biologic products is not recommended.

Treatment with Simponi Aria should not be initiated in patients with an active infection, including clinically important localized infections. Patients greater than 65 years of age, patients with co-morbid conditions and/or patients taking concomitant immunosuppressants such as corticosteroids or methotrexate may be at greater risk of infection. Consider the risks and benefits of treatment prior to initiating Simponi Aria in patients:

- with chronic or recurrent infection;
- who have been exposed to tuberculosis;
- with a history of an opportunistic infection;
- who have resided or traveled in areas of endemic tuberculosis or endemic mycoses, such as histoplasmosis, coccidioidomycosis, or blastomycosis; or
- with underlying conditions that may predispose them to infection.

Golimumab Site of Care Eligibility

1. Golimumab administration may be given in an inpatient setting if the inpatient setting is medically necessary. An inpatient admission for the sole purpose of Golimumab infusion is not medically necessary, OR
2. Golimumab administration in a hospital outpatient setting is considered medically necessary if the following criteria are met:
 - a. History of mild adverse events that have not been successfully managed through mild pre-medication (diphenhydramine, acetaminophen, steroids, fluids, etc.), OR
 - b. Inability to physically and cognitively adhere to the treatment schedule and regimen complexity, OR
 - c. First infusion, OR
 - d. Less than 3 months since first Golimumab infusion, OR
 - e. First infusion after six months of no Golimumab infusions, OR
 - f. Requirement of a change in Golimumab product.
3. Members who do not meet the criteria above are appropriate for Golimumab administration in a **home-based infusion** or physician office setting with or without supervision by a certified healthcare professional. Inpatient and hospital outpatient infusion, in the absence of the criteria in #1 or #2 above is considered not medically necessary.

DEFINITIONS

Biologic DMARDs: A class of drugs thought to work by targeting components of the immune system by blocking specific immune cytokines, blocking other cytokines, binding with cytokines suppressing IL-12 and IL-23, or by directly suppressing lymphocytes; includes the anti-CD20 monoclonal antibodies (e.g. rituximab), interleukin-1 receptor antagonists (IL-1Ra) (e.g. anakinra), interleukin-6 (IL-6) receptor antagonists (e.g. tocilizumab), interleukin-(IL)-12 and IL-23 antagonists (e.g. ustekinumab), selective co-stimulation modulators (e.g. abatacept), and the tumor necrosis factor (TNF) antagonists (inhibitors).

Nonbiologic DMARDs: A class of drugs, also referred to as synthetic DMARDs, thought to work by altering the immune system function to halt the underlying processes that cause certain forms of inflammatory conditions, although their exact mechanisms of action are unknown. Drugs in this class include azathioprine, hydroxychloroquine, leflunomide, methotrexate (MTX), minocycline, organic gold compounds, penicillamine, and sulfasalazine.

Tumor Necrosis Factor (TNF) antagonists: A class of biologic DMARDs designed to neutralize inflammatory cytokines that target specific pathways of the immune system and either enhance or

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inhibit immune response. Drugs in this class include adalimumab (Humira®, Abbott Laboratories, North Chicago, IL), certolizumab pegol (Cimzia®, UCB, Inc., Smyrna, GA), etanercept (Enbrel®, Immunex Corporation, Thousand Oaks, CA), golimumab (Simponi®, Centocor Ortho Biotech Inc., Horsham, PA), and infliximab (Remicade®, Centocor Ortho Biotech Inc., Horsham, PA).

Billing/Coding/Physician Documentation Information

This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at www.bcsnc.com. They are listed in the Category Search on the Medical Policy search page.

Applicable service codes: J1602

BCBSNC may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

Scientific Background and Reference Sources

Simponi (golimumab). Product Information. Centocor Ortho Biotech, Inc. 2010.

Saag KG, Teng GG, Patkar NM, et al. American College of Rheumatology 2008. Recommendations for the Use of Nonbiologic and Biologic Disease-Modifying Antirheumatic Drugs in Rheumatoid Arthritis. *Arthritis & Rheumatism (Arthritis Care & Research)*. 2008; 59(6):762-784.

Barclay L. Guidelines Issued for Management of Psoriatic Arthritis. (From guidelines in the October 24, 2008 Online First issue of the *Annals of the Rheumatic Disease*.)
<http://cme.medscape.com/viewarticle/582664>; accessed May 1, 2009.

U.S. Food and Drug Administration. Prescribing information. Retrieved 8/9/13 from:
http://www.accessdata.fda.gov/drugsatfda_docs/label/2011/125289s0064lbl.pdf

Medical director- 8/2013

Specialty Matched Consultant Review Panel- 2/2014

Specialty Matched Consultant Review Panel- 2/2015

Specialty Matched Consultant Review Panel- 2/2016

National Institute for Health and Clinical Excellence (NICE). Adalimumab, etanercept, infliximab, certolizumab pegol, golimumab, tocilizumab and abatacept for rheumatoid arthritis not previously treated with DMARDs or after conventional DMARDs only have failed. Technology Appraisal Guidance 375. London, UK: NICE; 2016

Singh JA, Saag KG, Bridges SL Jr, et al. 2015 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis. *Arthritis Rheumatol*. 2016; 68(1):1-26. Available at:
<http://www.rheumatology.org/Portals/0/Files/ACR%202015%20RA%20Guideline.pdf>

FDA Prescribing information available at:
https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/125289s1351lbl.pdf

Specialty Matched Consultant Advisory Panel- 2/2018

Golimumab (Simponi Aria®)

Medical Director Review- 3/2018

Specialty Matched Consultant Advisory Panel- 2/2019

Specialty Matched Consultant Advisory Panel- 2/2020

Janssen Biotech, Inc. Simponi Aria (golimumab) injection for intravenous use. Highlights of prescribing information. September 2020. Available at: <http://www.janssenlabels.com/package-insert/product-monograph/prescribing-information/SIMPONI+ARIA-pi.pdf>. Last accessed November 2020.

Medical Director review 11/2020

Policy Implementation/Update Information

- 10/1/13 New policy developed. New medical policy issued. Golimumab (Simponi® Aria™) may be medically necessary for the treatment of rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis and moderate to severe ulcerative colitis. Notification given 10/1/13 for effective date 1/1/14. (lpr)
- 10/29/13 Extensive revisions made to the “When Covered” and “When Not Covered” sections. Deleted the following statements from the “When Covered” section: 1.a) treatment of ankylosing spondylitis; 1.b) treatment of psoriatic arthritis; b.3) Rheumatoid or psoriatic arthritis is rapidly progressing and advancing; c.1 and 2) deleted the entire statement: moderate to server ulcerative colitis when the member requires continuous steroid or inadequate response or intolerance to prior steroid treatment; 3. Deleted entire statement: the member has been screened for the presence of latent TB infection.” Deleted statement: “The member previously used either etanercept (Enbrel) or adalimumab (Humira), and such drug was ineffective or not tolerated.” Revised description section and added Aria to any Simponi indication throughout the policy. Effective date remains 1/1/14. (lpr)
- 12/31/13 Added HCPCS code J1602 to “Billing/Coding” section for 1/1/14 code update. (lpr)
- 1/14/14 Under “When Covered” section: Statement #1 added Moderate to Severe and to #A: added the word **alone** to the statement (there has been a therapeutic failure/inadequate response with methotrexate **alone**, or). Medical director review 1/2014. (lpr)
- 3/11/14 Specialty Matched Consultant review meeting 2/25/2014. No change to policy statement. (lpr)
- 3/10/15 Specialty matched consultant advisory panel review meeting 2/25/2015. No change to policy statement. (lpr)
- 4/1/16 Specialty matched consultant advisory panel review meeting 2/24/16. No change to policy. –an
- 3/31/17 Updated Description section. Added FDA labeling information and definitions to Policy Guidelines. Added References. Specialty Matched Consultant Advisory Panel review meeting 2/22/17. No change to policy statement. (an)
- 12/15/17 Policy Statement revised to read: BCBSNC will provide coverage for Golimumab (Simponi Aria) for the treatment of rheumatoid arthritis, psoriatic arthritis or ankylosing spondylitis when it is determined to be medically necessary because the medical criteria

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and guidelines shown below are met. New indications added to the “When Covered” section. Reference added. (an)

- 12/29/17 Site of care criteria added to Policy Guidelines. Notification given 12/29/17 for policy effective date of 4/1/2018. (an)
- 1/26/18 Policy name “Nononcologic Uses of Rituximab” replaced with correct policy name “Rituximab for the Treatment of Rheumatoid Arthritis” in the Description section. Policy remains on noted for effective date 4/1/2018. (an)
- 5/11/18 Updated “When Covered” section criterion #1c to include a comprehensive list of biologic agents for clarity. Updated the following statement in “When Not Covered” section from “when used in combination with Abatacept, Anakinra, and live vaccines” to “when used in combination with Abatacept, Adalimumab, Anakinra, Certolizumab, Etanercept, Infliximab, Rituximab, Sarilumab, Secukinumab, Tocilizumab, Tofacitinib, and live vaccines” to provide a comprehensive list of biologic agents. References added. Specialty Matched Consultant Advisory Panel review 2/28/18. Medical Director review 3/2018. No change to policy intent. (krc)
- 3/12/19 Updated “When Covered” section with added ‘AND’ between rheumatoid arthritis criteria b. and c. for clarity. Specialty Matched Consultant Advisory Panel review 2/20/19. No change to policy intent. (krc)
- 3/10/20 Updated description section to include active psoriatic arthritis and active ankylosing spondylitis as approved indications for Simponi Aria. Minor typographical edits made throughout policy for clarity. Specialty Matched Consultant Advisory Panel review 2/19/2020. (krc)
- 11/10/20 Updated “When Covered” section to include active polyarticular juvenile idiopathic arthritis (pJIA) in patients 2 years of age and older, and expanded age for active psoriatic arthritis to 2 years of age and older. Updated Description and Policy Guidelines sections to include newly approved indication for pJIA. Reference added. Medical Director review 11/2020. (krc)

Medical policy is not an authorization, certification, explanation of benefits or a contract. Benefits and eligibility are determined before medical guidelines and payment guidelines are applied. Benefits are determined by the group contract and subscriber certificate that is in effect at the time services are rendered. This document is solely provided for informational purposes only and is based on research of current medical literature and review of common medical practices in the treatment and diagnosis of disease. Medical practices and knowledge are constantly changing and BCBSNC reserves the right to review and revise its medical policies periodically.