LOUISIANA BLUE

golimumab (Simponi Aria®, Simponi®)

Policy # 00223
Original Effective Date: 07/22/2009
Current Effective Date: 04/01/2025

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

When Services May Be Eligible for Coverage

Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- *Benefits are available in the member's contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

Simponi Aria®

When Services May Be Eligible for Coverage

Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- *Benefits are available in the member's contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

Rheumatoid Arthritis

Based on review of available data, the Company may consider the use of intravenous (IV) golimumab (Simponi Aria®)‡ for the treatment of rheumatoid arthritis to be **eligible for coverage.****

Patient Selection Criteria

Coverage eligibility for the use of IV golimumab (Simponi Aria) will be considered when all of the following criteria are met:

- Patient is 18 years of age or older; AND
- Patient has moderately to severely active rheumatoid arthritis; AND
- Simponi Aria is used in combination with methotrexate unless there is a contraindication to taking methotrexate or a history of methotrexate intolerance; AND
- Patient has failed treatment with one or more traditional disease-modifying anti-rheumatic drugs (DMARDs), such as methotrexate, unless there is clinical evidence or patient history that suggests the use of these products will be ineffective or cause an adverse reaction to the patient; AND
  *(Note: This specific patient selection criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met.)*

- Simponi Aria is NOT used in combination with other biologic DMARDs, such as adalimumab (Humira®, biosimilars)‡ OR other drugs such as apremilast (Otezla®)‡ or tofacitinib (Xeljanz/XR®)‡; AND
- Patient has a negative TB (tuberculosis) test (e.g., purified protein derivative [PPD], blood test) prior to treatment.

Psoriatic Arthritis

Based on review of available data, the Company may consider the use of IV golimumab (Simponi Aria) for the treatment of psoriatic arthritis to be **eligible for coverage**.**

Patient Selection Criteria

Coverage eligibility for the use of IV golimumab (Simponi Aria) will be considered when all of the following criteria are met:

- Patient is 2 years of age or older; AND
- Patient has active psoriatic arthritis; AND
- Patient has failed treatment with one or more traditional DMARDs, such as methotrexate, unless there is clinical evidence or patient history that suggests the use of these products will be ineffective or cause an adverse reaction to the patient; AND
  *(Note: This specific patient selection criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met.)*
- Simponi Aria is NOT used in combination with other biologic DMARDs, such as adalimumab (Humira, biosimilars) OR other drugs such as apremilast (Otezla) or tofacitinib (Xeljanz/XR); AND
- Patient has a negative TB test (e.g., PPD, blood test) prior to treatment.

Ankylosing Spondylitis

Based on review of available data, the Company may consider the use of IV golimumab (Simponi Aria) for the treatment of ankylosing spondylitis to be **eligible for coverage.****

Patient Selection Criteria

Coverage eligibility for the use of IV golimumab (Simponi Aria) will be considered when all of the following criteria are met:

- Patient is 18 years of age or older; AND
- Patient has active ankylosing spondylitis; AND
- Patient has failed treatment with non-steroidal anti-inflammatory drugs (NSAIDs) unless there is clinical evidence or patient history that suggests these products will be ineffective or cause an adverse reaction to the patient; AND
  *(Note: This specific patient selection criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met.)*

- Simponi Aria is NOT used in combination with other biologic DMARDs, such as adalimumab (Humira, biosimilars) OR other drugs such as apremilast (Otezla) or tofacitinib (Xeljanz/XR); AND
- Patient has a negative TB test (e.g., PPD, blood test) prior to treatment.

Polyarticular Juvenile Idiopathic Arthritis

Based on review of available data, the Company may consider the use of IV golimumab (Simponi Aria) for the treatment of polyarticular juvenile idiopathic arthritis to be **eligible for coverage.****

Patient Selection Criteria

Coverage eligibility for the use of IV golimumab (Simponi Aria) will be considered when all of the following criteria are met:

- Patient is 2 years of age or older; AND
- Patient has active polyarticular juvenile idiopathic arthritis; AND
- Requested drug is NOT used in combination with other biologic DMARDs, such as etanercept (Enbrel) OR other drugs such as tofacitinib (Xeljanz/XR) or apremilast (Otezla); AND
- Patient has failed treatment with one or more traditional DMARDs, such as methotrexate unless there is clinical evidence or patient history that suggests the use of these products will be ineffective or cause an adverse reaction to the patient; AND
  *(Note: This specific patient selection criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met).*
- Patient has a negative TB test (e.g., PPD, blood test) prior to treatment.

When Services Are Considered Not Medically Necessary

Based on review of available data, the Company considers the use of IV golimumab (Simponi Aria) when any of the following criteria for their respective disease listed below (and denoted in the patient selection criteria above) are not met to be **not medically necessary**:**

- For rheumatoid arthritis and psoriatic arthritis:
  - Patient has failed treatment with one or more traditional DMARDs
- For ankylosing spondylitis:
  - Patient has failed treatment with NSAIDs
- For polyarticular juvenile idiopathic arthritis:
  - Patient has failed treatment with one or more traditional DMARDs

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When Services Are Considered Investigational

Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers the use of IV golimumab (Simponi Aria) when patient selection criteria are not met to be **investigational*** (with the exception of those denoted above as not **medically necessary****).

Based on review of available data, the Company considers the use of IV golimumab (Simponi Aria) for indications other than those listed above to be **investigational.***

Simponi®

When Services May Be Eligible for Coverage

Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- *Benefits are available in the member's contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

Rheumatoid Arthritis

Based on review of available data, the Company may consider the use of subcutaneous (SubQ) golimumab (Simponi®)‡ for the treatment of rheumatoid arthritis to be **eligible for coverage.****

Patient Selection Criteria

Coverage eligibility for the use of SubQ golimumab (Simponi) be considered when all of the following criteria are met:

- Patient is 18 years of age or older; AND
- Patient has moderately to severely active rheumatoid arthritis; AND
- SubQ Simponi is used in combination with methotrexate unless there is a contraindication to taking methotrexate or a history of methotrexate intolerance; AND
- Patient has failed treatment with one or more traditional DMARDs, such as methotrexate, unless there is clinical evidence or patient history that suggests the use of these products will be ineffective or cause an adverse reaction to the patient; AND
  *(Note: This specific patient selection criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met.)*
- SubQ Simponi is NOT used in combination with other biologic DMARDs, such as adalimumab (Humira, biosimilars) OR other drugs such as apremilast (Otezla) or tofacitinib (Xeljanz/XR); AND

- Patient has failed treatment with TWO of the following after at least TWO months of therapy with EACH product: etanercept (Enbrel®)‡, adalimumab (Humira, Simlandi®, adalimumab-adaz)‡, tofacitinib (Xeljanz/XR), upadacitinib (Rinvoq™)‡, or SubQ tocilizumab (Actemra®)‡ unless there is clinical evidence or patient history that suggests the use of these products will be ineffective or cause an adverse reaction to the patient. A failure of a different adalimumab product other than those listed above would also count towards this criterion; AND
  *(Note: This specific patient selection criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met).*
- Patient has a negative TB test (e.g., PPD, blood test) prior to treatment.

Psoriatic Arthritis

Based on review of available data, the Company may consider the use of SubQ golimumab (Simponi) for the treatment of psoriatic arthritis to be **eligible for coverage.****

Patient Selection Criteria

Coverage eligibility for the use of SubQ golimumab (Simponi) will be considered when all of the following criteria are met:

- Patient is 18 years of age or older; AND
- Patient has active psoriatic arthritis; AND
- SubQ Simponi is used alone or in combination with methotrexate; AND
- Patient has failed treatment with one or more traditional DMARDs, such as methotrexate, unless there is clinical evidence or patient history that suggests the use of these products will be ineffective or cause an adverse reaction to the patient; AND
  *(Note: This specific patient selection criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met.)*
- SubQ Simponi is NOT used in combination with other biologic DMARDs, such as adalimumab (Humira, biosimilars) OR other drugs such as apremilast (Otezla) or tofacitinib (Xeljanz/XR); AND
- Patient has failed treatment with TWO of the following after at least TWO months of therapy with EACH product: etanercept (Enbrel), adalimumab (Humira, Simlandi, adalimumab-adaz), ustekinumab (Stelara®)‡, secukinumab (Cosentyx®)‡, tofacitinib (Xeljanz/XR), guselkumab (Tremfya®)‡, apremilast (Otezla), upadacitinib (Rinvoq), or risankizumab-rzaa (Skyrizi®)‡ unless there is clinical evidence or patient history that suggests the use of these products will be ineffective or cause an adverse reaction to the patient. A failure of a different adalimumab product other than those listed above would also count towards this criterion; AND
  *(Note: This specific patient selection criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met).*
- Patient has a negative TB test (e.g., PPD, blood test) prior to treatment.

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Ankylosing Spondylitis

Based on review of available data, the Company may consider the use of SubQ golimumab (Simponi) for the treatment of ankylosing spondylitis to be **eligible for coverage.****

Patient Selection Criteria

Coverage eligibility for the use of SubQ golimumab (Simponi) will be considered when all of the following criteria are met:

- Patient is 18 years of age or older; AND
- Patient has active ankylosing spondylitis; AND
- Patient has failed treatment with NSAIDs unless there is clinical evidence or patient history that suggests these products will be ineffective or cause an adverse reaction to the patient; AND
  *(Note: This specific patient selection criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met.)*
- SubQ Simponi is NOT used in combination with other biologic DMARDs, such as adalimumab (Humira, biosimilars) OR other drugs such as apremilast (Otezla) or tofacitinib (Xeljanz/XR); AND
- Patient has failed treatment with TWO of the following after at least TWO months of therapy with EACH product: etanercept (Enbrel), adalimumab (Humira, Simlandi, adalimumab-adaz), secukinumab (Cosentyx), tofacitinib (Xeljanz/XR), or upadacitinib (Rinvoq) unless there is clinical evidence or patient history that suggests the use of these products will be ineffective or cause an adverse reaction to the patient. A failure of a different adalimumab product other than those listed above would also count towards this criterion; AND
  *(Note: This specific patient selection criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met).*
- Patient has a negative TB test (e.g., PPD, blood test) prior to treatment.

Ulcerative Colitis

Based on review of available data, the Company may consider the use of SubQ golimumab (Simponi) for the treatment of ulcerative colitis to be **eligible for coverage.****

Patient Selection Criteria

Coverage eligibility for the use of SubQ golimumab (Simponi) will be considered when all of the following criteria are met:

- Patient is 18 years of age or older; AND
- Patient has moderately to severely active ulcerative colitis; AND
- Patient has demonstrated corticosteroid dependence OR has failed treatment with oral aminosalicylates, oral corticosteroids, azathioprine, or 6-mercaptopurine; AND
- SubQ Simponi is NOT used in combination with other biologic DMARDs, such as adalimumab (Humira, biosimilars) OR other drugs such as apremilast (Otezla) or tofacitinib (Xeljanz/XR); AND

- Patient has failed treatment with adalimumab (Humira, Simlandi, adalimumab-adaz) after at least TWO months of therapy, unless there is clinical evidence or patient history that suggests the use of adalimumab (Humira, Simlandi, adalimumab-adaz) will be ineffective or cause an adverse reaction to the patient. A failure of a different adalimumab product other than those listed above would also count towards this criterion; AND
  *(Note: This specific patient selection criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met.)*
- Patient has a negative TB test (e.g., PPD, blood test) prior to treatment.

When Services Are Considered Not Medically Necessary

Based on review of available data, the Company considers the use of SubQ golimumab (Simponi) when any of the following criteria for their respective disease listed below (and denoted in the patient selection criteria above) are not met to be **not medically necessary**:**

- For rheumatoid arthritis:
  - Patient has failed treatment with one or more traditional DMARDs
  - Patient has failed treatment with TWO of the following after at least TWO months of therapy with EACH product: etanercept (Enbrel), adalimumab (Humira, Simlandi, adalimumab-adaz), tofacitinib (Xeljanz/XR), upadacitinib (Rinvoq), or SubQ tocilizumab (Actemra)
- For psoriatic arthritis:
  - Patient has failed treatment with one or more traditional DMARDs
  - Patient has failed treatment with TWO of the following after at least TWO months of therapy with EACH product: etanercept (Enbrel), adalimumab (Humira, Simlandi, adalimumab-adaz), ustekinumab (Stelara), secukinumab (Cosentyx), tofacitinib (Xeljanz/XR), guselkumab (Tremfya), apremilast (Otezla), upadacitinib (Rinvoq), or risankizumab-rzaa (Skyrizi).
- For ankylosing spondylitis:
  - Patient has failed treatment with NSAIDs
  - Patient has failed treatment with TWO of the following after at least TWO months of therapy with EACH product: etanercept (Enbrel), adalimumab (Humira, Simlandi, adalimumab-adaz), secukinumab (Cosentyx), tofacitinib (Xeljanz/XR), or upadacitinib (Rinvoq)
- For ulcerative colitis:
  - Patient has failed treatment with adalimumab (Humira, Simlandi, adalimumab-adaz) after at least TWO months of therapy

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Based on review of available data, the Company considers the use of SubQ golimumab (Simponi) when patient selection criteria are not met to be **investigational*** (with the exception of those denoted above as not **medically necessary****).

Based on review of available data, the Company considers the use of SubQ golimumab (Simponi) for indications other than those listed above to be **investigational.***

Background/Overview

SubQ Simponi is a tumor necrosis factor (TNF) blocker approved for the treatment of rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis, and ulcerative colitis. An IV formulation, with the name of Simponi Aria, is approved for use in patients with rheumatoid arthritis, psoriatic arthritis (2 years and older), polyarticular juvenile idiopathic arthritis (2 years and older), and ankylosing spondylitis. TNF is a naturally occurring cytokine that is involved with the inflammatory and immune responses. Excessive activation of immune effector cells and overproduction of TNF can cause severe inflammation and tissue damage. Inhibition of TNF activity in certain inflammatory diseases may alleviate symptoms and prevent disease progression. For rheumatoid arthritis, psoriatic arthritis, and ankylosing spondylitis, the SubQ dosing is 50 mg once monthly. For ulcerative colitis, the SubQ dosing is 200 mg initially, then 100 mg at week 2, and then 100 mg every month thereafter. Simponi Aria is given at 2 mg/kg at weeks 0 and 4, then every 8 weeks in adult patients. In pediatric patients with polyarticular juvenile idiopathic arthritis or psoriatic arthritis, the dose is 80 mg/m^2 at weeks 0 and 4, then every 8 weeks thereafter.

Rheumatoid Arthritis

Rheumatoid arthritis is a chronic (long-term) disease that causes inflammation of the joints and surrounding tissues. It can also affect other organs. It is considered an autoimmune disease. In an autoimmune disease, the immune system confuses healthy tissue for foreign substances. Typically, first line treatments such as traditional DMARDs are used to treat this condition. An example of a traditional DMARD would include methotrexate.

Psoriatic Arthritis

Psoriatic Arthritis is an arthritis that is often associated with psoriasis of the skin. Typically, first line treatments such as traditional DMARDs are used to treat this condition. An example of a traditional DMARD would include methotrexate.

Ankylosing Spondylitis

Ankylosing spondylitis is a chronic inflammatory disease that affects the joints between the vertebrae of the spine, and the joints between the spine and the pelvis. It eventually causes the

affected vertebrae to fuse or grow together. Nonsteroidal anti-inflammatory drugs, such as ibuprofen or naproxen, are used to reduce inflammation and pain associated with the condition. Corticosteroid therapy or medications to suppress the immune system may be prescribed to control various symptoms.

Ulcerative Colitis
Ulcerative colitis is a chronic, episodic, inflammatory disease of the large intestine and rectum characterized by bloody diarrhea. This disease usually begins in the rectal area and may eventually extend through the entire large intestine. Repeated episodes of inflammation lead to thickening of the wall of the intestine and rectum with scar tissue. Death of colon tissue or sepsis may occur with severe disease. The goals of treatment are to control the acute attacks, prevent recurrent attacks and promote healing of the colon. Hospitalization is often required for severe attacks. Typically, first line treatments such as corticosteroids, 6-mercaptopurine and azathioprine are used to treat this condition.

Polyarticular Juvenile Idiopathic Arthritis
Polyarticular juvenile idiopathic arthritis includes the inflammation of joints and presence of arthritis in children. Polyarticular juvenile idiopathic arthritis typically occurs in a symmetrical manner with knees, wrists, and ankles most frequently affected. However certain subgroups of children do have predominantly asymmetrical involvement. Typically, first line treatments such as traditional DMARDs are used to treat this condition. An example of a traditional DMARD would include methotrexate.

Traditional Disease-Modifying Anti-Rheumatic Drugs
Traditional DMARDS are typically used to treat various inflammatory conditions. These drugs slow the disease process by modifying the immune system:

- methotrexate
- cyclosporine
- sulfasalazine
- mercaptopurine
- gold compounds

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)
SubQ Simponi is approved by the FDA for the treatment of adults with moderately to severely active rheumatoid arthritis in combination with methotrexate, active psoriatic arthritis, active ankylosing spondylitis, and moderate to severe ulcerative colitis. Simponi Aria is FDA approved for the treatment of adults with moderate to severe rheumatoid arthritis, psoriatic arthritis, and ankylosing spondylitis. Simponi Aria is also approved for patients 2 years of age and older with polyarticular juvenile idiopathic arthritis or psoriatic arthritis.

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Rationale/Source

This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. Food and Drug Administration approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, technology evaluation centers, reference to regulations, other plan medical policies, and accredited national guidelines.

Large, randomized, double-blind trials in patients with rheumatoid arthritis who were methotrexate-naïve (GO-BEFORE) or -experienced (GO-FORWARD) have shown that Simponi 50 or 100 mg every 4 weeks, in combination with methotrexate, was more effective than methotrexate alone for improving signs and symptoms of arthritis at weeks 14 and/or 24, according to ACR (American College of Rheumatology) criteria. In patients with active rheumatoid arthritis despite previous treatment with anti-TNF agents (GO-AFTER), Simponi 50 or 100 mg every 4 weeks was more effective than placebo for improving ACR responses at weeks 14 and 24; most patients in the study received concomitant methotrexate. In patients with psoriatic arthritis in the GO-REVEAL study, significantly more Simponi than placebo recipients achieved a ≥ 20% improvement in ACR criteria at week 14. Simponi was also superior to placebo for improving the signs and symptoms of ankylosing spondylitis in the GO-rheumatoid RAISE study; significantly more Simponi than placebo recipients achieved a ≥ 20% improvement in the Assessment in Ankylosing Spondylitis (ASAS) criteria at week 14. In the 5 phase III trials in patients with rheumatoid arthritis, psoriatic arthritis, or ankylosing spondylitis, there was no clear evidence of improved ACR or ASAS responses with the 100mg dosage compared with the 50 mg dosage of Simponi. The tolerability profile of Simponi was generally consistent with that of other anti-TNF agents.

Ulcerative colitis was studied in two trials, the UC-1 and UC-2 trials. In the UC-1 trial, a greater proportion of patients achieved clinical response, clinical remission and had improvement of endoscopic appearance of the mucosa. In UC-2, a greater proportion of patients maintained clinical response through week 54.

Simponi Aria for the treatment of rheumatoid arthritis was evaluated in one multi-center, randomized, double-blind, placebo-controlled trial in 592 adult patients. Patients were randomized to receive either Simponi Aria 2 mg/kg or placebo at weeks 0, 4, and every 8 weeks in addition to methotrexate. A greater percentage of patients treated with Simponi Aria plus methotrexate achieved ACR20 at week 14 and ACR 50 at week 24 versus patients treated with placebo. Simponi Aria was evaluated in active psoriatic arthritis in 480 patients. The primary endpoint was the percentage of patients achieving an ACR20 response at week 14. At week 14, 22% of the subjects in the placebo group achieved an ACR20 while 75% in the Simponi Aria group achieved an ACR20 at week 14. The efficacy of Simponi Aria in pediatric patients with psoriatic arthritis is based on the pharmacokinetic exposure and extrapolation of the established efficacy of Simponi Aria in adult psoriatic arthritis patients. The efficacy and safety of Simponi Aria in ankylosing spondylitis was evaluated in 208 patients. The primary endpoint was the percentage of patients achieving an

ASAS20 response at week 16. At week 16, 26% of placebo patients achieved an ASAS20 vs. 73% in the Simponi Aria group. The efficacy and safety of Simponi Aria in polyarticular juvenile idiopathic arthritis is based on pharmacokinetic exposure and extrapolation of the established safety and efficacy of Simponi Aria in patients with rheumatoid arthritis. Efficacy was also assessed in pediatric patients 2 to 18 years of age. The efficacy was generally consistent with responses in patients with rheumatoid arthritis.

References

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2. Simponi [package insert]. Janssen Biotech, Inc. Horsham, Pennsylvania. Updated September 2019.
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Policy History

Original Effective Date: 07/22/2009
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07/02/2009 Medical Director review
07/22/2009 Medical Policy Committee approval. New policy.
07/01/2010 Medical Director approval

07/21/2010	Medical Policy Implementation Committee approval. Changed the recommendation in the coverage section to read, "prior to receiving treatment with golimumab, all patients have a negative cancer history" instead of a "negative cancer screening".
07/07/2011	Medical Policy Committee review
07/20/2011	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
11/03/2011	Medical Policy Committee review
11/16/2011	Medical Policy Implementation Committee approval. Added criteria for rheumatoid arthritis, psoriatic arthritis, and ankylosing spondylitis stating that patients must have failed treatment with adalimumab (Humira) or etanercept (Enbrel) before using golimumab (Simponi) after two months of use. Noted that the reason for denial will be not medically necessary if this criterion is not met. The not medically necessary denial statement is also incorporated into the Investigational and Not Medically Necessary coverage sections.
02/07/2013	Medical Policy Committee review
02/20/2013	Medical Policy Implementation Committee approval. Cancer criteria removed from policy.
06/06/2013	Medical Policy Committee review
06/25/2013	Medical Policy Implementation Committee approval. Added a new indication for Ulcerative colitis with similar criteria as other similar drugs. Reworded the investigational and not medically necessary sections. Relocated PPD to each indication instead of a note. Updated some background info.
10/10/2013	Medical Policy Committee review
10/16/2013	Medical Policy Implementation Committee approval. Added "Simponi Aria" to the title. Modified the title since there is a new formulation of the drug that has been approved. Added new product: Simponi Aria and gave similar criteria as infused products with indication of Rheumatoid Arthritis. Changed the requirement for subcutaneous Simponi to trying both Humira AND Enbrel first for Rheumatoid Arthritis, Psoriatic Arthritis, and Ankylosing Spondylitis. Modified the not medically necessary section to reflect changes
07/16/2014	Coding updates due to new code for 2014, J1602- Golimumab being added for review.
10/02/2014	Medical Policy Committee review
10/15/2014	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
08/03/2015	Coding update: ICD10 Diagnosis code section added; ICD9 Procedure code section removed.
10/08/2015	Medical Policy Committee review
10/21/2015	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
10/06/2016	Medical Policy Committee review

10/19/2016	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
01/01/2017	Coding update: Removing ICD-9 Diagnosis Codes
11/02/2017	Medical Policy Committee review
11/15/2017	Medical Policy Implementation Committee approval. Changed first line drugs for rheumatoid arthritis to Actemra, Enbrel, Humira, Xeljanz/XR, AS to Enbrel, Humira, Cosentyx, PsA to Enbrel, Humira, Stelara, Cosentyx for SubQ Simponi. Updated background and rationale. Added new indications for Simponi Aria (psoriatic arthritis and ankylosing spondylitis).
10/04/2018	Medical Policy Committee review
10/17/2018	Medical Policy Implementation Committee approval. Added Xeljanz/XR as an option for use first line in Psoriatic Arthritis. Added Xeljanz as a requirement for use in ulcerative colitis. Updated background information.
12/05/2019	Medical Policy Committee review
12/11/2019	Medical Policy Implementation Committee approval. Added Rinvoq as a preferred option for rheumatoid arthritis prior to Simponi. Removed the requirement for Xeljanz use in ulcerative colitis.
07/02/2020	Medical Policy Committee review
07/08/2020	Medical Policy Implementation Committee approval. Added Otezla as a preferred option for psoriatic arthritis.
10/01/2020	Medical Policy Committee review
10/07/2020	Medical Policy Implementation Committee approval. For Simponi SubQ, Actemra was removed as a preferred option in rheumatoid arthritis. For Simponi SubQ, Tremyfa was added as a preferred option in psoriatic arthritis. Added a new indication for Simponi Aria for the treatment of polyarticular juvenile idiopathic arthritis in patients 2 years of age and older. Simponi Aria's psoriatic arthritis indication was also expanded to 2 years of age and older (previously adults).
10/07/2021	Medical Policy Committee review
10/13/2021	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
01/06/2022	Medical Policy Committee review
01/12/2022	Medical Policy Implementation Committee approval. Added SubQ Actemra to the list of products than can be tried and failed prior to use of Simponi in rheumatoid arthritis. Added Xeljanz/XR to the list of products that can be tried and failed prior to the use of Simponi in ankylosing spondylitis. Added Rinvoq to the list of products that can be tried and failed prior to the use of Simponi in psoriatic arthritis.
03/03/2022	Medical Policy Committee review
03/09/2022	Medical Policy Implementation Committee approval. Added Skyrizi to the list of products than can be tried and failed prior to use of Simponi in psoriatic arthritis.
03/02/2023	Medical Policy Committee review

03/08/2023 Medical Policy Implementation Committee approval. Added Rinvoq to the list of products than can be tried and failed prior to use of Simponi in ankylosing spondylitis.
03/07/2024 Medical Policy Committee review
03/13/2024 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
03/06/2025 Medical Policy Committee review
03/12/2025 Medical Policy Implementation Committee approval. Added Humira biosimilars to the list of products that can be tried and failed prior to Simponi where only Humira was mentioned.

Coding

The five character codes included in the Louisiana Blue Medical Policy Coverage Guidelines are obtained from Current Procedural Terminology (CPT®)‡, copyright 2024 by the American Medical Association (AMA). CPT is developed by the AMA as a listing of descriptive terms and five character identifying codes and modifiers for reporting medical services and procedures performed by physician.

The responsibility for the content of Louisiana Blue Medical Policy Coverage Guidelines is with Louisiana Blue and no endorsement by the AMA is intended or should be implied. The AMA disclaims responsibility for any consequences or liability attributable or related to any use, nonuse or interpretation of information contained in Louisiana Blue Medical Policy Coverage Guidelines. Fee schedules, relative value units, conversion factors and/or related components are not assigned by the AMA, are not part of CPT, and the AMA is not recommending their use. The AMA does not directly or indirectly practice medicine or dispense medical services. The AMA assumes no liability for data contained or not contained herein. Any use of CPT outside of Louisiana Blue Medical Policy Coverage Guidelines should refer to the most current Current Procedural Terminology which contains the complete and most current listing of CPT codes and descriptive terms. Applicable FARS/DFARS apply.

CPT is a registered trademark of the American Medical Association.

Codes used to identify services associated with this policy may include (but may not be limited to) the following:

Code Type	Code
CPT	No codes
HCPCS	J1602
ICD-10 Diagnosis	All related diagnoses

*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
    1. Consultation with technology evaluation center(s);
    2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
    3. Reference to federal regulations.

**Medically Necessary (or "Medical Necessity") - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

A. In accordance with nationally accepted standards of medical practice;
B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and
C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, "nationally accepted standards of medical practice" means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

NOTICE: If the Patient's health insurance contract contains language that differs from the BCBSLA Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

golimumab (Simponi Aria®, Simponi®)

Policy # 00223
Original Effective Date: 07/22/2009
Current Effective Date: 04/01/2025

NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.

NOTICE: Federal and State law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage.