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Last P&T Approval/Version: 10/25/2023
Next Review Due By: 10/2024
Policy Number: C10422-A

Simponi/Simponi Aria (golimumab)

PRODUCTS AFFECTED

Simponi (golimumab), Simponi Aria (golimumab)

COVERAGE POLICY

Coverage for services, procedures, medical devices, and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Coverage Guideline must be read in its entirety to determine coverage eligibility, if any. This Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide Molina Healthcare complete medical rationale when requesting any exceptions to these guidelines.

Documentation Requirements:
Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational, or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

DIAGNOSIS:
Moderately to severely active Rheumatoid Arthritis, Active Psoriatic Arthritis, Active Ankylosing Spondylitis, Ulcerative colitis (UC), Non-radiographic axial spondyloarthritis, Polyarticular juvenile idiopathic arthritis

REQUIRED MEDICAL INFORMATION:
This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. If a drug within this policy receives an updated FDA label within the last 180 days, medical necessity for the member will be reviewed using the updated FDA label information along with state and federal requirements, benefit being administered and formulary preferencing. Coverage will be determined on a case- by-case basis until the criteria can be updated through Molina Healthcare, Inc. clinical governance. Additional information may be required on a case-by-case basis to allow for adequate review. When the requested drug product for coverage is dosed by weight, body surface area or other member specific measurement, this data element is required as part of the medical necessity review. The Pharmacy and Therapeutics Committee has determined that the drug benefit shall be a mandatory generic and that generic drugs will be dispensed whenever available.

FOR ALL INDICATIONS:

1. (a) Prescriber attests, or clinical reviewer has found, member has had a negative TB screening* or TB test (if indicated)** result within the last 12 months for initial and continuation of therapy

requests
*MOLINA REVIEWER NOTE: TB SCREENING assesses patient for future or ongoing TB exposure or risk and includes reviewing if they have been exposed to tuberculosis, if they have resided or traveled to areas of endemic tuberculosis, if patient resides or works in a congregate setting (e.g., correctional facilities, long-term care facilities, homeless shelters), etc.
**MOLINA REVIEWER NOTE: TB SKIN TEST (TST, PPD) AND TB BLOOD TEST (QuantiFERON TB Gold, T-Spot) are not required or recommended in those without risk factors for tuberculosis
OR
(b) For members who have a positive test for latent TB, provider documents member has completed a treatment course (a negative chest x-ray is also required every 12 months) OR that member has been cleared by an infectious disease specialist to begin treatment
AND

2. Prescriber attests member has been evaluated and screened for the presence of hepatitis B virus (HBV) prior to initiating treatment
AND
3. Member is not on concurrent treatment or will not be used in combination with other TNF- inhibitor, biologic response modifier or other biologic DMARDs, Janus kinase Inhibitors, or Phosphodiesterase 4 inhibitor (i.e., apremilast, tofacitinib, baricitinib) as verified by prescriber attestation, member medication fill history, or submitted documentation
AND
4. Prescriber attests member does not have an active infection, including clinically important localized infections
AND
5. IF THIS IS A NON-FORMULARY/NON-PREFERRED PRODUCT: Documentation of trial/failure of or intolerance to a majority (not more than 3) of the preferred formulary/PDL alternatives for the given diagnosis. Submit documentation including medication(s) tried, dates of trial(s) and reason for treatment failure(s).

A. MODERATE TO SEVERE RHEUMATOID ARTHRITIS:
1. Documentation of moderate to severe rheumatoid arthritis diagnosis
AND
2. Documentation of prescriber baseline disease activity evaluation and goals for treatment to be used to evaluate efficacy of therapy at renewal [DOCUMENTATION REQUIRED]
AND
3. (a) Member is currently receiving maximally tolerated dose of methotrexate and is not at goal disease activity
OR
(b) Member has an FDA labeled contraindication or serious side effects to methotrexate, as determined by the prescribing physician AND Member has tried one additional disease- modifying antirheumatic drug (DMARD) (brand or generic; oral or injectable) for at least 3 months
(NOTE: An exception to the requirement for a trial of one conventional synthetic DMARD can be made if the member has already had a 3-month trial of at least one biologic. These members who have already tried a biologic for RA are not required to "step back" and try a conventional synthetic DMARD)

B. PSORIATIC ARTHRITIS (PsA):
1. Documentation of active psoriatic arthritis
AND
2. Documentation of prescriber baseline disease activity evaluation and goals for treatment to be used to evaluate efficacy of therapy at renewal [DOCUMENTATION REQUIRED]
AND
3. (a) Documented treatment failure, serious side effects or clinical contraindication to a minimum 3-month trial of ONE of the following: Leflunomide, Methotrexate, Sulfasalazine, Cyclosporine
OR
(b) Documentation member has severe psoriatic arthritis [erosive disease, elevated markers of inflammation, long term damage that interferes with function, highly active disease that causes a major impairment in quality of life, active PsA at many sites including dactylitis, enthesitis,

function- limiting PsA at a few sites or rapidly progressive disease]
OR
(c) Documentation member has severe psoriasis [PASI ≥12, BSA of >5-10%, significant involvement in specific areas (e.g., face, hands or feet, nails, intertriginous areas, scalp), impairment of physical or mental functioning with lower amount of surface area of skin involved]

C. ULCERATIVE COLITIS (UC) [SIMPONI SC ONLY]:
1. Documentation of ulcerative colitis diagnosis with evidence of moderate to severe disease activity
AND
2. (a) Documentation of treatment failure, serious side effects or clinical contraindication to a 2-month trial of one systemic agent (e.g., 6-mercaptopurine, azathioprine, cyclosporine, tacrolimus, or a corticosteroid such as prednisone, methylprednisolone) for ulcerative colitis or will continue to take concurrently.
NOTE: A previous trial of a biologic (e.g., an adalimumab product [e.g., Humira], Simponi SC [golimumab SC injection], or Entyvio [vedolizumab IV infusion)] also counts as a trial of one systemic agent for UC
OR
b) The Member has pouchitis AND has tried therapy with an antibiotic (e.g., metronidazole, ciprofloxacin), probiotic, corticosteroid enema [for example, Cortenema® (hydrocortisone enema, generics), or topical mesalamine
AND
3. Documentation of prescriber baseline disease activity evaluation and goals for treatment to be used to evaluate efficacy of therapy at renewal [DOCUMENTATION REQUIRED]

D. ANKYLOSING SPONDYLITIS:
1. Documented diagnosis of ankylosing spondylitis
AND
2. Documentation of treatment failure, serious side effects or clinical contraindication to TWO NSAIDs (e.g., ibuprofen, naproxen, etodolac, meloxicam, indomethacin) for ≥3 consecutive months at maximal recommended or tolerated anti- inflammatory doses
AND
3. FOR MEMBER WITH PROMINENT PERIPHERAL ARTHRITIS: Documentation of treatment failure, serious side effects or clinical contraindication to a trial (≥3 consecutive months) of methotrexate OR sulfasalazine
AND
4. Documentation of prescriber baseline disease activity evaluation and goals for treatment to be used to evaluate efficacy of therapy at renewal [DOCUMENTATION REQUIRED]

E. NON-RADIOGRAPHIC AXIAL SPONDYLOARTHRITIS [SIMPONI SC ONLY]:
1. Prescriber attests to diagnosis of adult-onset axial spondyloarthritis
AND
2. Documentation that C-reactive protein (CRP) levels are above the upper limit of normal and/or sacroiliitis on magnetic resonance imaging (MRI), indicative of inflammatory disease
AND
3. Documentation that there is no definitive radiographic evidence of structural damage on sacroiliac joints.
AND
4. Documentation member has active disease and prescriber provides baseline disease activity evaluation and goals for treatment to be used to evaluate efficacy of therapy at renewal [DOCUMENTATION REQUIRED]
AND
5. Documentation of treatment failure, serious side effects or clinical contraindication to TWO NSAIDs (e.g., ibuprofen, naproxen, etodolac, meloxicam, indomethacin) for ≥3 consecutive months at maximal recommended or tolerated anti- inflammatory doses

F. JUVENILE IDIOPATHIC ARTHRITIS [SIMPONI ARIA ONLY]:
1. Documented diagnosis of polyarticular juvenile idiopathic arthritis (PJIA) or juvenile idiopathic arthritis with sacroiliitis or enthesitis in a pediatric member
AND
2. Documentation of prescriber baseline disease activity evaluation and goals for treatment to be used to evaluate efficacy of therapy at renewal [DOCUMENTATION REQUIRED]
AND
3. (a) FOR POLYARTICULAR JUVENILE IDIOPATHIC ARTHRITIS: Documentation of treatment failure, serious side effects or clinical contraindication to an adequate trial (generally ≥12 weeks) of one or more of the following: Methotrexate, hydroxychloroquine, sulfasalazine, leflunomide
OR
(b) FOR JUVENILE IDIOPATHIC ARTHRITIS WITH SACROILIITIS OR ENTHESITIS: Documentation of treatment failure, serious side effects or clinical contraindication to an adequate trial of at least one NSAID

CONTINUATION OF THERAPY:

A. ALL INDICATIONS:
1. Adherence to therapy at least 85% of the time as verified by the prescriber or member medication fill history OR adherence less than 85% of the time due to the need for surgery or treatment of an infection, causing temporary discontinuation
AND
2. Prescriber attests to or clinical reviewer has found no evidence of intolerable adverse effects or drug toxicity
AND
3. Documentation of positive clinical response as demonstrated by low disease activity and/or improvements in the condition's signs and symptoms [DOCUMENTATION REQUIRED]
AND
4. (a) Prescriber attests, or clinical reviewer has found, member has had a negative TB screening* or TB test (if indicated)** result within the last 12 months for initial and continuation of therapy requests
*MOLINA REVIEWER NOTE: TB SCREENING assesses patient for future or ongoing TB exposure or risk and includes reviewing if they have been exposed to tuberculosis, if they have resided or traveled to areas of endemic tuberculosis, if patient resides or works in a congregate setting (e.g., correctional facilities, long-term care facilities, homeless shelters), etc.
**MOLINA REVIEWER NOTE: TB SKIN TEST (TST, PPD) AND TB BLOOD TEST (QuantiFERON TB Gold, T-Spot) are not required or recommended in those without risk factors for tuberculosis
OR
(b) For members who have a positive test for latent TB, provider documents member has completed a treatment course (a negative chest x-ray is also required every 12 months) OR that member has been cleared by an infectious disease specialist to begin treatment

DURATION OF APPROVAL:

Initial authorization: 6 months. Continuation of therapy: 12 months

PRESCRIBER REQUIREMENTS:

ULCERATIVE COLITIS (UC): Prescribed by or in consultation with a board-certified gastroenterologist.
ALL OTHER INDICATIONS: Prescribed by or in consultation with a board-certified rheumatologist or dermatologist.
[If prescribed in consultation, consultation notes must be submitted with initial request and reauthorization requests]

AGE RESTRICTIONS:

Rheumatoid Arthritis, Ankylosing Spondylitis, Non-Radiographic Axial Spondyloarthritis and Ulcerative Colitis:18 years of age or older

QUANTITY:
Simponi (prefilled syringe or SmartJect autoinjector):
RA, PsA, Ankylosing Spondylitis, Non-Radiographic Axial Spondyloarthritis: 50mg/dose once a month
UC: 200mg at week 0, then 100 mg at week 2, followed by maintenance therapy of 100 mg every 4 weeks

Simponi-Aria:
RA, PsA (adults), and Ankylosing Spondylitis: 2mg/kg/dose IV at weeks 0, 4, and then every 8 weeks thereafter
JIA and PsA (pediatric): 80 mg/m^2 at weeks 0, 4, and then every 8 weeks thereafter

PLACE OF ADMINISTRATION:
The recommendation is that injectable medications in this policy will be for pharmacy or medical benefit coverage and the subcutaneous injectable products administered in a place of service that is a non-hospital facility-based location.

The recommendation is that infused medications in this policy will be for pharmacy or medical benefit coverage administered in a place of service that is a non-hospital facility-based location as per the Molina Health Care Site of Care program.

Note: Site of Care Utilization Management Policy applies for Simponi Aria (golimumab) intravenous. For information on site of care, see
Specialty Medication Administration Site of Care Coverage Criteria (molinamarketplace.com)

DRUG INFORMATION

ROUTE OF ADMINISTRATION:
Intravenous, Subcutaneous

DRUG CLASS:
Anti-TNF-alpha - Monoclonal Antibodies

FDA-APPROVED USES:
SIMPONI is indicated for the treatment of adult patients with:
- Moderately to severely active rheumatoid arthritis (RA) in combination with methotrexate
- Active psoriatic arthritis (PsA) alone, or in combination with methotrexate
- Active ankylosing spondylitis
- Moderate to severe Ulcerative colitis (UC) with an inadequate response or intolerant to prior treatment or requiring continuous steroid therapy
    - Inducing and maintaining clinical response
    - Improving endoscopic appearance of the mucosa during induction
    - Inducing clinical remission
    - Achieving and sustaining clinical remission in induction responders

SIMPONI ARIA is indicated for the treatment of:
- Adult patients with moderately to severely active Rheumatoid Arthritis (RA) in combination with methotrexate
- Active Psoriatic Arthritis in patients 2 years of age and older
- Adult patients with active Ankylosing Spondylitis (AS)
- Active polyarticular Juvenile Idiopathic Arthritis (pJIA) in patients 2 years of age and older

COMPENDIAL APPROVED OFF-LABELED USES:

APPENDIX

APPENDIX:

To meet the CASPAR criteria, a patient must have inflammatory articular disease (joint, spine, or entheseal) with ≥3 points from any of the following five categories:
1. Evidence of current psoriasis,[b,c] a personal history of psoriasis, or a family history of psoriasis[d]
2. Typical psoriatic nail dystrophy[e] observed on current physical examination
3. A negative test result for rheumatoid factor
4. Either current dactylitis[f] or a history of dactylitis recorded by a rheumatologist
5. Radiographic evidence of juxtaarticular new bone formation[g] in the hand or foot

[a] Specificity of 99% and sensitivity of 91%. [b] Current psoriasis is assigned 2 points; all other features are assigned 1 point. [c] Psoriatic skin or scalp disease present at the time of examination, as judged by a rheumatologist or dermatologist. [d] H hyperkeratosis. [f] Swelling of an entire digit. [g] Ill-defined ossification near joint margins, excluding osteophyte formation.

Source: From W Taylor et al: Arthritis Rheum, 54:2665, 2006.

Psoriatic Arthritis
An estimated 1% of the U.S. adult population harbors cutaneous evidence of psoriasis, characterized by well-demarcated erythematous scaly plaques, some of whom develop a related arthritis. In fact, there are several distinct subsets of psoriatic arthritis, including (a) an asymmetric oligoarthritis affecting lower extremity joints; (b) a symmetric polyarthritis affecting upper and lower extremity joints; (c) monoarticular involvement of a distal interphalangeal joint alone; (d) a destructive finger joint arthritis that produces “telescoping,” a shortening of the digit as a consequence of aggressive bone destruction and resorption (arthritis mutilans); and (e) axial skeleton involvement (spondylitis, sacroiliitis).

BACKGROUND AND OTHER CONSIDERATIONS

BACKGROUND:

Simponi is a recombinant human monoclonal antibody specific for human tumor necrosis factor alpha (TNFα). Simponi neutralizes the biological activity of TNFα and inhibits binding of TNFα with its receptors. TNF, a naturally occurring cytokine, mediates inflammation and modulates cellular immune responses. Increased levels of TNF are found in inflammatory conditions, including the synovial fluid of patients with rheumatoid arthritis (RA), psoriatic arthritis (PsA), and ankylosing spondylitis (AS). TNF has an important role in both the pathologic inflammation and the joint destruction that are characteristic of these diseases. Simponi SC is also indicated for those with moderately to severely active ulcerative colitis who had an inadequate response or failure to oral aminosalicylates, oral corticosteroids, azathioprine, or 6-mercaptopurine.

Simponi Aria is a recombinant human monoclonal antibody specific for human tumor necrosis factor alpha (TNFα).1 Simponi Aria neutralizes the biological activity of TNFα and inhibits binding of TNFα with its receptors. TNF, a naturally occurring cytokine, mediates inflammation and modulates cellular immune responses. Increased levels of TNF are found in the synovial fluid of patients with inflammatory conditions, including rheumatoid arthritis (RA). TNF has an important role in both the pathologic inflammation and the joint destruction that are characteristic of RA. Simponi Aria is administered by intravenous (IV) infusion by a healthcare professional and is indicated in combination with methotrexate (MTX) for treatment of adult patients with moderately to severely active RA.

AGA Guidelines Moderate to Severe Ulcerative Colitis
Recommendations from the recent 2020 guideline update include:

- In adult outpatients with moderate to severe UC who are naïve to biologic agents, the AGA suggests using infliximab or vedolizumab rather than adalimumab, for induction of remission.
- Updated FDA recommendations (July 26, 2019) on indications for use of tofacitinib in UC recommends its use only after failure of or intolerance to TNF-a antagonists.
- In adult outpatients with moderate to severe UC who have previously been exposed to infliximab, particularly those with primary nonresponse, the AGA suggests using ustekinumab

or tofacitinib rather than vedolizumab or adalimumab for induction of remission.

- In adult outpatients with moderate to severe UC, the AGA suggests against using methotrexate monotherapy for induction or maintenance of remission
- In adult outpatients with active moderate to severe UC, the AGA suggests using biologic monotherapy (TNF-a antagonists, vedolizumab, or ustekinumab) or tofacitinib rather than thiopurine monotherapy for induction of remission.
- In adult outpatients with moderate to severe UC, the AGA suggests combining TNF-a antagonists, vedolizumab or ustekinumab with thiopurines or methotrexate rather than biologic monotherapy.
- In adult outpatients with moderate to severe UC who have achieved remission with biologic agents and/or immunomodulators or tofacitinib, the AGA suggests against continuing 5-ASA for induction and maintenance of remission.

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION:

All other uses of Simponi/Simponi Aria (golimumab) are considered experimental/investigational and therefore, will follow Molina's Off- Label policy. Contraindications to golimumab include: No labeled contraindications.

OTHER SPECIAL CONSIDERATIONS:

Golimumab has a Black Box Warning for serious infections and malignancy that both Simponi and Simponi Aria carry. Serious infections leading to hospitalization or death including tuberculosis (TB), bacterial sepsis, invasive fungal (such as histoplasmosis), and other opportunistic infections have occurred in patients receiving golimumab. Discontinue golimumab if a patient develops a serious infection or sepsis. Perform test for latent TB; if positive, start treatment for TB prior to starting golimumab. Monitor all patients for active TB during treatment, even if initial latent TB test is negative. Lymphoma and other malignancies, some fatal, have been reported in children and adolescent patients treated with TNF blockers, of which golimumab is a member.

CODING/BILLING INFORMATION

Note: 1) This list of codes may not be all-inclusive. 2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement

HCPCS CODE	DESCRIPTION
J3590	Simponi -Unclassified biologics
J1602	Simponi Aria--Injection, golimumab , 1mg, for intravenous use

AVAILABLE DOSAGE FORMS:

Simponi Aria SOLN 50MG/4ML single-dose vial
Simponi SOAJ Auto-injector 50MG/0.5ML, 100MG/ML
Simponi SOSY Prefilled Syringe 50MG/0.5ML, 100MG/ML

REFERENCES

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with active rheumatoid arthritis despite methotrexate therapy with responses as early as week 2: results of the phase 3, randomised, multicentre, double blind, placebo- controlled GO- FURTHER trial. Ann Rheum Dis. 2013;72(3):381-389.
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SUMMARY OF REVIEW/REVISIONS	DATE
REVISION- Notable revisions: Required Medical Information Continuation of Therapy FDA-Approved Uses Contraindications/Exclusions/Discontinuation Other Special Considerations References	Q4 2023
REVISION- Notable revisions: Required Medical Information Continuation of Therapy Prescriber Requirements FDA-Approved Uses Background References	Q4 2022
Q2 2022 Established tracking in new format	Historical changes on file