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Last P&T Approval/Version: 10/27/2021
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Policy Number: C10422-A

Simponi/Simponi Aria (golimumab)

PRODUCTS AFFECTED

Simponi/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 itscoverage 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 thedrugs 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 juvenileidiopathic 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 federalrequirements, 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

FOR ALL INDICATIONS:

1. (a) Prescriber attests member has had a negative TB screening or TB test result within the last 12 months for initial and continuation of therapy requests
   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

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 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. Member does not have an active infection, including clinically important localizedinfections
   AND
5. IF THIS IS A NON-FORMULARY/NON-PREFERRED PRODUCT: Documentation of trial/failure of or intolerance to amajority (not more than 3) of the preferred formulary/PDL alternatives for the given diagnosis. Ifyes, please 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
      AND
   3. (a) Member is concurrently receiving methotrexate OR
      (b) Member tried, failed, or has an FDA labeled contraindication or intolerance 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 at least one biologic. These patients who have already tried a biologic for RA are not required to "step back" and try a conventional synthetic DMARD*);
      OR
      (c) Member has early RA (defined as disease duration of < 6 months) with at least one of the following features of poor prognosis: functional limitation (e.g., based on Health Assessment Questionnaire Disability Index [HAQ-DI] score); extra articular disease such as rheumatoid nodules, RA vasculitis, or Felty's syndrome; positive rheumatoid factor or anti-cyclic citrullinated protein (anti-CCP) antibodies; or bony erosions by radiograph

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
      AND
   3. (a) Documented treatment failure with or FDA labeled 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 $\geq$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) Member has had a 2-month trial of one systemic agent (e.g., 6-mercaptopurine, azathioprine, cyclosporine, tacrolimus, or a corticosteroid such as prednisone, methylprednisolone) or was intolerant to one of these agents 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 Rowasa® (mesalamine) enema
AND
3. Documentation of prescriber baseline disease activity evaluation and goals for treatment to be used to evaluate efficacy of therapy at renewal

D. ANKYLOSING SPONDYLITIS:
1. Documentation of ankylosing spondylitis diagnosis
AND
2. Prescriber attestation of member having an inadequate response or FDA labeled contraindication toTWO NSAIDs (e.g., ibuprofen, naproxen, etodolac, meloxicam, indomethacin) for ≥3 consecutive months at maximal recommended or tolerated anti- inflammatory doses
AND
3. FOR THE MEMBER'S WITH PROMINENT PERIPHERAL ARTHRITIS: Documentation of trial (≥3 consecutive months) or FDA labeled contraindication to 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

E. NON-RADIOGRAPHIC AXIAL SPONDYLOARTHRITIS [SIMPONI SC ONLY]:
1. Prescriber attests to diagnosis of adult-onset active 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
AND
5. Prescriber attestation of member having an inadequate response or FDA labeled contraindication toTWO 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 ARIAONLY]:
1. Member must have a diagnosis of polyarticular juvenile idiopathic arthritis (PJIA) or juvenile idiopathic arthritis with sacrolitis or enthesitis in children 2 years of age or older
AND
2. Documentation of prescriber baseline disease activity evaluation and goals for treatment to be used to evaluate efficacy of therapy at renewal
AND
3. (a) FOR POLYARTICULAR JUVENILE IDIOPATHIC ARTHRITIS: Documentation of serious side effect, clinical contraindication, or treatment failure to an adequate trial (generally ≥12 weeks) of ≥1 of the following: Methotrexate, hydroxychloroquine, sulfasalazine, azathioprine,

leflunomide
OR
(b) FOR JUVENILE IDIOPATHIC ARTHRITIS WITH SACROLITIS OR ENTHESITIS: Documentation of drug failure or serious side effects, clinical contraindication, or treatment failure to an adequate trial to at least one NSAID, unless contraindicated or significant adverse reactions are experienced.

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 (documentation required)
   AND
2. Documentation of no intolerable adverse effects or drugtoxicity
   AND
3. Documentation of positive clinical response as demonstrated by low disease activity and/or improvements in the condition's signs and symptoms.
   AND
4. (a) Prescriber attests member has had a negative TB screening or TB test result within the last 12 months for initial and continuation of therapy requests
   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.

AGE RESTRICTIONS:

Rheumatoid Arthritis, Ankylosing Spondylitis, Non-Radiographic Axial Spondyloarthritis and Ulcerative Colitis:18 years of age or older
Polyarticular Juvenile Idiopathic Arthritis and Psoriatic Arthritis: 2 years of age and 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 ~~AK~~ Ankylosing Spondylitis: 2mg/kg/dose IV at weeks 0, 4, and then every 8 weeks thereafterPJIA 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.

Drug and Biologic Coverage Criteria

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). 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 orrequiring continuous steroid therapy

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
Active Ankylosing Spondylitis (AS)
And pediatric patients with polyarticular Juvenile Idiopathic Arthritis and Psoriatic Arthritis

COMPENDIAL APPROVED OFF-LABELED USES:
Axial spondyloarthritis (active, nonradiographic)

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 or a history of dactylitis recorded by a rheumatologist
5.	Radiographic evidence of juxtaarticular new bone information[g] in the hand or foot

[a] Specifity of 99% and sensitivity of 91%. [b] Current psoriasis is assigned 2 points; all other features assigned 1 point. Psoriatic skin or scalp disease 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 asymmetricoligoarthritis 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

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION:

All other uses of Simponi/Simponi Aria (golimumab) are considered experimental/investigational and therefore, will follow Molina’s Off- Label policy.

OTHER SPECIAL CONSIDERATIONS:

None

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	(NOC)-Unclassified biologics (Simponi)
J1602	Injection, golimumab(Simponi Aria), 1mg, for intravenous use

AVAILABLE DOSAGE FORMS:
Simponi Aria SOLN 50MG/4ML(4ml vial)
Simponi Auto-injector 50MG/0.5ML , 100mg/1mL
Simponi Prefilled Syringe 50MG/0.5ML , 100mg/1mL

REFERENCES

1. Simponi™Aria® injection for intravenous use [prescribing information]. Horsham, PA: Janssen Biotech, Inc; February 2021
2. Simponi® injection [prescribing information]. Horsham, PA: Janssen Biotech Inc; September 2019.
3. Kornbluth A, Sachar DB; Practice Parameters Committee of the American College of Gastroenterology. Ulcerative colitis practice guidelines in adults: American College of Gastroenterology, Practice Parameters Committee. Am J Gastroenterol. 2010;105(3):501-523
4. Weinblatt ME, Bingham CO 3rd, Mendelsohn AM, et al. Intravenous golimumab is effective in patients with active rheumatoid arthritis despite methotrexate therapy with responses as early as week 2: results of the phase 3, randomised, multicentre, doubleblind, placebo- controlled GO-FURTHER trial.Ann Rheum Dis. 2013;72(3):381-389.
5. Singh JA, Furst DE, Bharat A, et al. 2012 update of the 2008 American College of Rheumatology recommendations for the use of disease-modifying antirheumatic drugs andbiologic agents in the treatment of rheumatoid arthritis. Arthritis Care Res (Hoboken). 2012;64(5):625-639.
6. Furst DE, Keystone EC, So AK, et al. Updated consensus statement on biological agents for the treatment of rheumatic diseases, 2012. Ann Rheum Dis. 2013;72 Suppl 2:ii2-34.
7. Golimumab. Lexicomp from UpToDate database. Accessed September 1, 2021. https://www.uptodate.com/contents/golimumab-drug-information?search=simponi&usage_type=panel&kp_tab=drug_general&source=panel_search_result&selectedTitle=1~65&display_rank=1.
8. Rutgeerts P, Feagan BG, Marano CW, et al. Randomised clinical trial: a placebo-controlled study of intravenous golimumab induction therapy for ulcerative colitis. Aliment Pharmacol Ther. 2015 Sep;42(5):504-14.