CareSource Rxinnovations

PHARMACY POLICY STATEMENT
Georgia Medicaid

DRUG NAME	Simponi Aria (golimumab)
BILLING CODE	J1602
BENEFIT TYPE	Medical
SITE OF SERVICE ALLOWED	Office/Outpatient
STATUS	Prior Authorization Required

Simponi Aria is a tumor necrosis factor (TNF) alpha-inhibitor initially approved by the FDA in 2017 for rheumatoid arthritis. Since that time, Simponi Aria has been approved for three additional indications: Psoriatic Arthritis, Ankylosing Spondylitis and Polyarticular Juvenile Idiopathic Arthritis. This medication is given as an intravenous infusion.

Simponi Aria (golimumab) will be considered for coverage when the following criteria are met:

Ankylosing Spondylitis (AS)

For **initial** authorization:

1. Member must be 18 years of age or older; AND
2. Member has a documented diagnosis of active ankylosing spondylitis (AS); AND
3. Medication must be prescribed by or in consultation with a rheumatologist; AND
4. Member has had a negative tuberculosis test within the past 12 months; AND
5. Member has had back pain for 3 months or more that began before the age of 50; AND
6. Current imaging results show an inflammation of one or both of the sacroiliac joints (sacroiliitis); AND
7. Member has tried and failed to respond to treatment with at least **two** NSAIDs taken at the maximum recommended dosages. Treatment failure requires at least 4 weeks of therapy with each NSAID without an adequate response; AND
8. Member has tried and failed at least two preferred biologic DMARDs for at least 3 months each, one of which must be another TNF inhibitor (same class as Simponi Aria).
9. **Dosage allowed/Quantity limit:** 2 mg/kg intravenous infusion at weeks 0 and 4, and every 8 weeks thereafter.

If all the above requirements are met, the medication will be approved for 12 months.

For **reauthorization**:

1. Chart notes have been provided that show improvement of signs and symptoms of disease (ie. decreased morning stiffness, tenderness or inflammatory back pain, improved quality of life, etc).

If all the above requirements are met, the medication will be approved for an additional 12 months.

Polyarticular Juvenile Idiopathic Arthritis (pJIA)

For **initial** authorization:

1. Member must be 2 years of age or older; AND
2. Member has a confirmed diagnosis of active pJIA; AND
3. Member has had a negative tuberculosis test within the past 12 months; AND
4. Medication must be prescribed by or in consultation with a rheumatologist; AND

5. Member has had an adequate trial and failure of a non-biologic DMARD (e.g., methotrexate, leflunomide, etc.) for 8 weeks, unless not tolerated or contraindicated; AND
6. Member must have tried and failed treatment with **both** Enbrel and Actemra. Treatment failure requires at least 12 weeks of therapy with each drug.
7. **Dosage allowed/Quantity limit:** 80 mg/m^2 (body surface area) intravenous infusion at week 0 and 4, and every 8 weeks thereafter.

If all the above requirements are met, the medication will be approved for 12 months.

For **reauthorization**:
1. Chart notes have been provided showing improvement of signs and symptoms of disease.

If all the above requirements are met, the medication will be approved for an additional 12 months.

Psoriatic Arthritis (PsA)

For **initial** authorization:
1. Member must be 2 years of age or older; AND
2. Medication must be prescribed by or in consultation with a rheumatologist or a dermatologist; AND
3. Member has a documented diagnosis of active psoriatic arthritis (PsA); AND
4. Member has had a negative tuberculosis test within the past 12 months;
5. Member has met a 4-week trial of an NSAID taken at maximally tolerated dose AND a 3-month trial of a non-biologic DMARD agent (e.g., methotrexate, sulfasalazine, cyclosporine, etc.) unless one of the following situations is met:
   a) Non-biologic DMARD is not required for:
      i) Concomitant axial disease (i.e., involving sacroiliac joint and spine) or enthesitis; OR
   b) NSAID and non-biologic DMARD are not required for:
      i) Severe PsA (defined as having at least one of the following: erosive disease, active PsA at many sites including dactylitis or enthesitis, elevated levels of ESR or CRP, joint deformities, or major impairment in quality of life); AND
6. Member has tried and failed at least two preferred biologic DMARDs for at least 3 months each, one of which must be another TNF inhibitor (same class as Simponi Aria).
7. **Dosage allowed/Quantity limit:**
   Adults: 2 mg/kg intravenous infusion at weeks 0 and 4, and every 8 weeks thereafter.
   Pediatrics: 80 mg/m2 (BSA) intravenous infusion at weeks 0 and 4, and every 8 weeks thereafter.

If all the above requirements are met, the medication will be approved for 6 months.

For **reauthorization**:
1. Chart notes have been provided showing improvement of signs and symptoms of disease (ie. decreased joint swelling and pain, improved skin appearance, improved quality of life, etc).

If all the above requirements are met, the medication will be approved for an additional 12 months.

Rheumatoid Arthritis (RA)

For **initial** authorization:
1. Member must be 18 years of age or older; AND
2. Medication must be prescribed by or in consultation with a rheumatologist; AND
3. Member has a documented diagnosis of moderately to severely active RA; AND
4. Member must have a trial and failure of, or intolerance to methotrexate for at least 3 months;

Note: If methotrexate is contraindicated, one of the following conventional DMARDs must be trialed instead: leflunomide, sulfasalazine, or hydroxychloroquine; AND

5. Simponi Aria will be given in combination with methotrexate or with another conventional DMARD if member is unable to tolerate methotrexate; AND
6. Member has tried and failed at least two preferred biologic DMARDs for at least 3 months each, one of which must be another TNF inhibitor (same class as Simponi Aria); AND
7. Member has had a negative tuberculosis test within the past 12 months.
8. **Dosage allowed/Quantity limit:** 2 mg/kg intravenous infusion at weeks 0 and 4, and every 8 weeks thereafter.

If all the above requirements are met, the medication will be approved for 12 months.

For **reauthorization**:

1. Chart notes demonstrate improvement of RA signs and symptoms (e.g. fewer number of painful and swollen joints, achievement of remission, slowed progression of joint damage, etc.).

If all the above requirements are met, the medication will be approved for an additional 12 months.

CareSource considers Simponi Aria (golimumab) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.

DATE	ACTION/DESCRIPTION
05/10/2017	New policy for Simponi Aria created. Policy SRx-0042 archived. List of diagnoses considered not medically necessary was added.
11/13/2017	New indications of AS and PsA added.
02/26/2019	Dosing information corrected. Humira was removed from criteria; Actemra, Cimzia, Cosentyx, Kevzara, Olumiant, Otezla and Xeljanz added to trial agents list. TB test allowed to be done within 12 months prior to initiation of therapy; chest x-ray option removed. References added. Symptoms of back pain for AS extended till before age of 50. Other drugs options allowed for PsA if there is an intolerance or contraindication to methotrexate.
10/12/2020	New diagnosis of pJIA added. Replaced list of excluded diagnoses with the generic statement. Updated references. For all diagnoses: Removed repeat TB in reauth for all diagnoses. For AS: Removed list of symptoms of spondyloarthritis because imaging result should be sufficient. Removed peripheral arthritis requirement – not relevant for this diagnosis. For PsA: Age requirement expanded to 2 years or older. Updated dosing and biologic trials reflective of age label change. Added requirement of diagnosis of PsA. Changed the trial section to be 4 weeks of an NSAID AND 3 months of a DMARD unless other circumstances apply (e.g., concomitant axial disease, severe PsA, etc.). For RA: Changed the trials to require methotrexate as one of the non-biologic DMARD trials; only one trial is needed if member has poor prognostic factors.
01/24/2022	Transferred to new template. RA: Added new reference. Edited the terminology “non-biologic” DMARD to “conventional” DMARD. Changed from requiring 2 csDMARD to just 1. Removed Xeljanz, Olumiant from try first options per recent JAK inhibitor label changes; also changed from other specific drug names to say 2 preferred biologics one of which is a TNF inhibitor. Added preferred biologic trial with TNFi and Clarified reauth criteria for PsA and AS.

References:

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