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PHARMACY POLICY STATEMENT **Ohio Medicaid**	
DRUG NAME	Simponi Aria (golimumab)
BILLING CODE	J1602 (1 unit = 1 mg)
BENEFIT TYPE	Medical
SITE OF SERVICE ALLOWED	Outpatient/Office
COVERAGE REQUIREMENTS	Prior Authorization Required (Non-Preferred Product) Alternative preferred products include Enbrel, Humira, Taltz, Xeljanz 5 mg tablet QUANTITY LIMIT— see Dosage allowed
LIST OF DIAGNOSES CONSIDERED **NOT** MEDICALLY NECESSARY	Click Here

Simponi Aria (golimumab) is a **non-preferred** product and will only be considered for coverage under the **medical** benefit when the following criteria are met:

Members must be clinically diagnosed with one of the following disease states and meet their individual criteria as stated.

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. Must have a documented negative TB test (i.e., tuberculosis skin test (PPD), interferon-gamma release assay (IGRA)) within 12 months prior to starting therapy; 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 must have tried and failed treatment with at least **two** of the following: Enbrel, Humira, or Taltz. Treatment failure requires at least 12 weeks of therapy with each drug. Note: if member previously tried a non-preferred IL-17 inhibitor (e.g., Cosentyx) or TNF inhibitor (e.g., Cimzia) that is indicated for AS, then the trial can be accepted.
9. **Dosage allowed:** 2 mg/kg intravenous infusion at weeks 0 and 4, and every 8 weeks thereafter.

If member meets all the requirements listed above, the medication will be approved for 12 months.

For **reauthorization**:

1. Member must be in compliance with all other initial criteria; AND
2. Chart notes have been provided that show improvement of signs and symptoms of disease.

If member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.

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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. Must have a documented negative TB test (i.e., tuberculosis skin test (PPD), interferon-gamma release assay (IGRA)) within 12 months prior to starting therapy; 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 at least **two** of the following: Enbrel, Humira, or Xeljanz 5mg tablet. Treatment failure requires at least 12 weeks of therapy with each drug. Note: if member previously tried a non-preferred TNF inhibitor (e.g., Simponi Aria) that is indicated for pJIA, then the trial can be accepted.
7. **Dosage allowed:** 80 mg/m^2 (body surface area) intravenous infusion at week 0 and 4, and every 8 weeks thereafter.

If member meets all the requirements listed above, the medication will be approved for 12 months.

For **reauthorization**:

1. Member must be in compliance with all other initial criteria; AND
2. Chart notes have been provided showing improvement of signs and symptoms of disease.

If member meets all the reauthorization requirements above, 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. Must have a documented negative TB test (i.e., tuberculosis skin test (PPD), interferon-gamma release assay (IGRA)) within 12 months prior to starting therapy; AND
5. Member has met a 4-week trial of an NSAID taken at maximally tolerated doses 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).
6. For adult 18 years or older only: Member has tried and failed treatment with at least **two** of the following: Humira, Enbrel, Taltz, or Xeljanz 5mg tablet. Treatment failure requires at least 12 weeks of therapy with each drug. Note: if member previously tried a non-preferred IL-17 inhibitor (e.g., Cosentyx) or TNF inhibitor (e.g., Cimzia) that is indicated for PsA, then the trial can be accepted.
7. **Dosage allowed:** Adults: 2 mg/kg intravenous infusion at weeks 0 and 4, and every 8 weeks thereafter. Pediatrics: 80 mg/m^2 (BSA) intravenous infusion at weeks 0 and 4, and every 8 weeks thereafter.

If member meets all the requirements listed above, the medication will be approved for 12 months.

For **reauthorization**:
1. Member must be in compliance with all other initial criteria; AND
2. Chart notes have been provided showing improvement of signs and symptoms of disease.

If member meets all the reauthorization requirements above, 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 with moderately to severely active RA; AND
2. Must have a documented negative TB test (i.e., tuberculosis skin test (PPD), interferon-gamma release assay (IGRA)) within 12 months prior to starting therapy; AND
3. Medication must be prescribed by or in consultation with a rheumatologist; AND
4. Member must have a trial and failure of, or intolerance to methotrexate and **one** other non-biologic DMARD (i.e., hydroxychloroquine, sulfasalazine, and leflunomide) for 3 months per trial, either together or separately; AND
   Note: only one non-biologic DMARD is required if member has a poor prognostic factor such as high swollen joint count, presence of early joint erosions, presence of autoantibodies (RF and/or ACPA).
5. Medication is being given in combination with methotrexate or with another non-biologic DMARD if member is unable to tolerate methotrexate; AND
6. Member has tried and failed treatment with at least **two** of the following: Humira, Enbrel, Taltz, or Xeljanz 5mg tablet. Treatment failure requires at least 12 weeks of therapy with each drug. Note: if member previously tried a non-preferred IL-17 inhibitor (e.g., Cosentyx) or TNF inhibitor (e.g., Cimzia) or JAK inhibitor (e.g., Kevzara) that is indicated for RA, then the trial can be accepted.
7. **Dosage allowed:** 2 mg/kg intravenous infusion at weeks 0 and 4, and every 8 weeks thereafter.

If member meets all the requirements listed above, the medication will be approved for 12 months.

For **reauthorization**:
1. Member must be in compliance with all other initial criteria; AND
2. 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 member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.

CareSource considers Simponi Aria (golimumab) not medically necessary for the treatment of the diseases that are not listed in this document.

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.
01/23/2020	Updated trial agents to match Ohio Department of Medicaid Unified Preferred Drug List.

11/01/2020	Updated list of preferred agents and drug trials for all diagnoses to match Ohio Department of Medicaid Unified Preferred Drug List. Added that if member previously tried a non-preferred option in the same drug class as preferred options, the trial is accepted.
11/12/2020	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.

References:

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