Updated: 02/2019
PARP Approved: 03/2019

Prior Authorization Criteria

Simponi Aria/Simponi (golimumab)

All requests for Brand Name (generic name) require a prior authorization and will be screened for medical necessity and appropriateness using the criteria listed below.

For all requests for Simponi Aria/Simponi (golimumab) all of the following criteria must be met:

- Member is an adult age of 18 years of older.
- Medication must be prescribed by or in association with rheumatologist, gastroenterologist, or dermatologist.
- The requested dose and frequency is in accordance with FDA-approved labeling, nationally recognized compendia, and/or evidence-based practice guidelines.

Coverage may be provided with a diagnosis of **moderately active Rheumatoid Arthritis** and the following criteria is met:

- Member must have a history of trial and failure, contraindication, or intolerance of at least 3 months of treatment with methotrexate or another DMARD.
- Medication will be used in combination with Methotrexate (if not contraindicated or member does not have intolerance to methotrexate).
- Member must have a history of trial and failure, contraindication, or intolerance of at least 3 months of treatment to Enbrel* OR Humira*.
- **Initial Duration of Approval:** 6 months
- **Reauthorization criteria**
    - Member must have positive clinical response involving the following clinical/laboratory parameters: Number of swollen joints, number of tender joints, patient's assessment of pain, member's global assessment of disease activity, HAQ score, and/or CRP (C-Reactive Protein).
- **Reauthorization Duration of approval:** 12 months

Coverage may be provided with a diagnosis of **Active Psoriatic Arthritis** and the following criteria is met:

- Member has active psoriatic arthritis or clinical features that suggest psoriatic arthritis in the absence of psoriasis.
- Member must have a history of trial and failure, contraindication, or intolerance of at least 3 months of treatment to Enbrel* OR Humira*.
- **Initial Duration of Approval:** 6 months
- **Reauthorization criteria**
    - Reauthorization benefit will be approved if there is evidence of positive clinical response involving the following clinical/laboratory parameters: Number of swollen joints, number of tender joints, patient's assessment of pain, member's global assessment of disease activity, HAQ score, and/or CRP (C-Reactive Protein).
- **Reauthorization Duration of approval:** 12 months

Coverage may be provided with a diagnosis of **Ankylosing Spondylitis** and the following criteria is met:

- Member must have a history of trial and failure, contraindication, or intolerance to a four- week trial each of at least 2 NSAIDs
- Member must have a history of trial and failure, contraindication, or intolerance of at least 3 months of treatment to Enbrel* OR Humira*.
- **Initial Duration of Approval:** 14 weeks
- **Reauthorization criteria**
    - Reauthorization benefit will be approved if there is evidence of positive clinical response involving the following clinical/laboratory parameters: Patient global assessment, back pain, BASFI (Bath Ankylosing Spondylitis Functional Index, CRP, Modified Schober's test, chest expansion, and/or occiput-to-wall measurement.
- **Reauthorization Duration of approval:** 12 months

Coverage may be provided with a diagnosis of **Ulcerative Colitis** and the following criteria is met:

- Prescribed medication is Simponi.
- Member must have a history of trial and failure, contraindication, or intolerance to conventional treatments including ONE of the following for at least 3 months:
    - Aminosalicylates, 5-ASAs (*i.e.*, Sulfasalazine, Pentasa®, Asacol®, Colazal®)
    - Steroids (*i.e.*, prednisone)
    - Immunomodulators (*i.e.*, Azathioprine, 6-Mercaptopurine, Methotrexate)
- Member must have a history of trial and failure, contraindication, or intolerance of at least 2 months of treatment with Humira*.
- **Initial Duration of Approval:** 12 months
- **Reauthorization criteria**
    - Reauthorization benefit will be approved if there is documented, significant improvement with prior courses of treatment
- **Reauthorization Duration of approval:** 12 months

*Enbrel and Humira both require prior authorization. Members that are currently established on Simponi/Simponi Aria will not be required to change to a preformulary product.

Coverage may be provided for any non-FDA labeled indication if it is determined that the use is a medically accepted indication supported by nationally recognized pharmacy compendia or peer-reviewed medical literature for treatment of the diagnosis(es) for which it is prescribed. These requests will be reviewed on a case by case basis to determine medical necessity.

When criteria are not met, the request will be forwarded to a Medical Director for review. The physician reviewer must override criteria when, in their professional judgment, the requested medication is medically necessary.

Gateway Health

Updated: 02/2019
PARP Approved: 03/2019

Simponi Aria/Simponi(golimumab)
PRIOR AUTHORIZATION FORM

Please complete and fax all requested information below including any progress notes, laboratory test results, or chart documentation as applicable to Gateway Health℠ Pharmacy Services. **FAX:** (888) 245-2049
If needed, you may call to speak to a Pharmacy Services Representative.
PHONE: (800) 392-1147 Monday through Friday 8:30am to 5:00pm

PROVIDER INFORMATION

Requesting Provider:	NPI:
Provider Specialty:	Office Contact:
Office Address:	Office Phone:
	Office Fax:

MEMBER INFORMATION

Member Name:	DOB:
Gateway Health ID:	Member weight: _____pounds or _____kg

REQUESTED DRUG INFORMATION

Medication:	Strength:
Frequency:	Duration:
Is the member currently receiving requested medication? ☐ Yes ☐ No	Date Medication Initiated:

Billing Information

This medication will be billed: ☐ at a pharmacy **OR**
☐ medically (if medically please provide a JCODE:_____

Place of Service: ☐ Hospital ☐ Provider's office ☐ Member's home ☐ Other

Place of Service Information

Name:	NPI:
Address:	Phone:

MEDICAL HISTORY (Complete for ALL requests)

Diagnosis:
☐ **Moderately active Rheumatoid Arthritis**
☐ **Active Psoriatic Arthritis**
☐ **Ankylosing Spondylitis**
☐ **Ulcerative Colitis**
☐ **Other** _____

Is the member an adult 18 years of age or older? ☐ Yes ☐ No
Is the medication being prescribed by or in association with a rheumatologist, gastroenterologist, or dermatologist? ☐ Yes ☐ No

For Moderately active Rheumatoid Arthritis:
Does the member have a history of trial and failure, contraindication or intolerance of at least 3 months of treatment with methotrexate or another DMARD? ☐ Yes ☐ No
Will the medication be used in combination with methotrexate, unless the member has a contraindication or intolerance to MTX? ☐ Yes ☐ No
Has the member trialed and failed for at least 3 months or have a contraindication or intolerance to Enbrel OR Humira?
☐ Yes ☐ No

For Active Psoriatic Arthritis:

Does the member have psoriatic arthritis or clinical manifestations of psoriatic arthritis in the absence of psoriasis?
☐ Yes ☐ No

Does the member have a history of trial and failure, contraindication, or intolerance of at least 3 months of treatment of either Enbrel OR Humira?

☐ Yes ☐ No

For Ankylosing Spondylitis:
Does the member have a history of trial and failure, contraindication, or intolerance to 4 week trial each of at least 2 NSAIDs?
☐ Yes ☐ No

Does the member have a history of trial and failure, contraindication, or intolerance of at least 3 months of treatment of either Enbrel OR Humira?
☐ Yes ☐ No

For Ulcerative Colitis:
Does the member have a history of trial and failure, contraindication, or intolerance to (for at least 3 months duration) to:

- Aminosalicylates, 5-ASAs (*i.e.*, Sulfasalazine, Pentasa®, Asacol®, Colazal®)? ☐ Yes ☐ No
- Steroids (*i.e.*, prednisone)? ☐ Yes ☐ No
- Immunomodulators (*i.e.*, Azathioprine, 6-Mercaptopurine, Methotrexate)? ☐ Yes ☐ No

Does the member have a history of trial and failure, contraindication, or intolerance of at least 2 months of Humira?
☐ Yes ☐ No

CURRENT or PREVIOUS THERAPY

Medication Name	Strength/ Frequency	Dates of Therapy	Status (Discontinued & Why / Current)

REAUTHORIZATION

Which diagnosis is the medication being used for:
☐ **Moderately active Rheumatoid Arthritis, if checked please answer the following:**

- Does the prescriber attest that member has positive clinical response involving the following clinical laboratory/ parameters: Number of swollen joints, number of tender joints, patient's assessment of pain, member's global assessment of disease activity, HAQ score, and/or CRP (C-Reactive Protein)?
  ☐ Yes ☐ No

☐ **Active Psoriatic Arthritis, if checked please answer the following:**

- Does the prescriber attest that member has positive clinical response involving the following clinical laboratory/ parameters: Number of swollen joints, number of tender joints, patient's assessment of pain, member's global assessment of disease activity, HAQ score, and/or CRP (C-Reactive Protein)?
  ☐ Yes ☐ No

☐ **Ankylosing Spondylitis**

- Does the prescriber attest that member has positive clinical response involving the following clinical laboratory/ parameters: Patient global assessment, back pain, BASFI (Bath Ankylosing Spondylitis Functional Index, CRP, Modified Schober's test, chest expansion, and/or occiput-to-wall measurement?
  ☐ Yes ☐ No

☐ **Ulcerative Colitis**

- Does the prescriber attest that member has documented, positive clinical response to therapy?
  ☐ Yes ☐ No

☐ **Other _____**

_____

SUPPORTING INFORMATION or CLINICAL RATIONALE

Prescribing Provider Signature	Date