Premier Health Plan

POLICY AND PROCEDURE

POLICY TITLE: ***Simponi Aria® (Golimumab) Intravenous***
DEPARTMENT: **Clinical Pharmacy Services – Utilization Management**
ORIGINAL DATE: ***December 2013 (as adopted from UPMC Health Plan)***

Last P & T Committee Approval Date: *May 2018*

Product Applicability: *mark all applicable products below:*

COMMERCIAL	[ ] HMO [ ] PPO *Products*: [ ] Small [ ] Indiv. [ ] Large *Exchange*: [ ] Shop [ ] Indiv. [x] All
OTHER	[x] Self-funded/ASO

PURPOSE

The purpose of this policy is to define the prior authorization process for Simponi Aria® (golimumab) intravenous (IV).

Simponi Aria® (golimumab) IV is indicated for the treatment of adult patients with:

- Moderately to severely active rheumatoid arthritis in combination with methotrexate.
- Active psoriatic arthritis
- Active ankylosing spondylitis

DEFINITIONS

N/A

POLICY

It is the policy of the Health Plan to maintain a prior authorization process that promotes appropriate utilization of specific drugs with potential for misuse or limited indications.

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This process involves a review using Food and Drug Administration (FDA) criteria to make a determination of Medical Necessity, and approval by the Pharmacy & Therapeutics Committee of the criteria for prior authorization, as described in RX.002 Pharmacy and Therapeutics Committee and RX.003-Prior Authorization Process.

The drug, Simponi Aria® (golimumab) IV, is subject to the prior authorization process.

PROCEDURE

Initial Authorization Clinical Criteria:
Must meet all of the criteria listed under the respective diagnosis:

1. **Rheumatoid Arthritis:**
   - Must have a negative tuberculosis skin test [such as Tuberculin PPD (purified protein derivative) test] or Interferon-Gamma Release Assay (IGRA) whole-blood test [such as QuantiFERON®-TB Gold In-Tube test (QFT-GIT) or T-SPOT®.TB test (T-Spot)]
   - Must be prescribed by a rheumatologist
   - Must be age 18 or older
   - Must have a diagnosis of moderately to severely active rheumatoid arthritis
   - Must have an adequate trial (of at least 3 months) of methotrexate with an inadequate response or significant side effects/toxicity or have a contraindication to this therapy
   - Must be on concurrent methotrexate therapy
   - Must currently not be using a tumor necrosis factor (TNF)-blocking agent or other biologic agents in combination with Simponi Aria®
   - Must have no evidence of infection
   - **For pharmacy billed requests:** Must have an adequate trial and failure of Humira® AND Enbrel®

2. **Psoriatic Arthritis:**
   - Must be prescribed by a rheumatologist or dermatologist
   - Must be age 18 years or older
   - Must have a diagnosis of active psoriatic arthritis
   - For peripheral disease and dactylitis:
     - Must have an adequate trial of at least 4 weeks with a Non-steroidal anti-inflammatory drugs (NSAIDs) at an anti-inflammatory target dose, with an

inadequate response, significant side effects/toxicity, or have a contraindication to these therapies.
    - Must have an adequate trial of at least 3 months of a conventional systemic therapy (methotrexate, sulfasalazine, or leflunomide) with an inadequate response, significant side effects /toxicity, or have a contraindication to these therapies
- For axial disease and enthesitis:
    - Must have an adequate trial for at least 4 weeks each with 2 non-steroidal anti-inflammatory drugs (NSAIDs) at anti-inflammatory doses with an inadequate response or significant side effects/toxicity or have a contraindication to this therapy
- For Skin or Nail Psoriatic Arthritis
    - Must have an adequate trial of topical treatments, phototherapy, or photochemotherapy with an inadequate response or significant side effects /toxicity or have a contraindication to these therapies
    - Must have an adequate trial of at least 3 months of a conventional systemic therapy (methotrexate, cyclosporine, or acitretin) with an inadequate response or significant side effects /toxicity or have a contraindication to these therapies
- **For pharmacy billed requests**: Must have an adequate trial and failure of Humira AND Enbrel

3. Ankylosing Spondylitis:

- Must be prescribed by a rheumatologist
- Must be age 18 years or older
- Must have a diagnosis of ankylosing spondylitis
- Must have an adequate trial of at least 4 weeks with 2 non-steroidal anti-inflammatory drugs (NSAIDs) at anti-inflammatory dose, with an inadequate response, significant side effects/toxicity, or have a contraindication to these therapies
- **For pharmacy billed requests**: Must have an adequate trial and failure of Humira AND Enbrel

Reauthorization Criteria:

All prior authorization renewals are reviewed on an annual basis to determine the Medical Necessity for continuation of therapy. Authorization may be extended at 1-year intervals based upon chart documentation from the prescriber that the member's condition has improved based upon the prescriber's assessment while on therapy and there is no evidence of infection.

Limitations:

Length of Authorization (if above criteria met)	
Initial Authorization	Up to 1 year
Reauthorization	Same as initial

If the established criteria are not met, the request is referred to a Medical Director for review.

REFERENCES

1. Simponi Aria [package insert]. Horsham, PA: Janssen Biotech, Inc.; February 2018.
2. Saag KG, Teng GG, Patkar NM et al. American College of Rheumatology 2008 Recommendations for the use of nonbiologic and biologic disease-modifying antirheumatic drugs in rheumatoid arthritis. Arthritis Rheum 2008;59(6):762-784
3. Updated Guidelines for Using Interferon Gamma Release Assays to Detect Mycobacterium tuberculosis infection – United States 2010. Department of Health and Human Services Centers for Disease Control and Prevention [U.S.]. vol 59, RR-5. 2010 June 25.
4. Interferon-Gamma Release Assays (IGRAs) – Blood Tests for TB Infection. http://www.cdc.gov/tb/publications/factsheets/testing/IGRA.htm. Accessed 10/29/2012.
5. Singh JA, Saag KG, Bridges SL, Akl EA, Bannuru RR, Sullivan MC, Vaysbrot E, McNaughton C, Osani M, Shmerling RH, Curtis JR, Furst DE, Parks D, Kavanaugh A, O'Dell J, King C, Leong A, Matteson E, Schousboe JT, Drevlow B, Ginsberg S, Grober J, St.Clair EW, Tindall E, Miller AS and McAlindon T (2016), 2015 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis. Arthritis & Rheumatology, 68: 1–26.

RECORD RETENTION

Records Retention for Evolent Health documents, regardless of medium, are provided within the Evolent Health records retention policy and as indicated in CORP.028.E Records Retention Policy and Procedure.

REVIEW HISTORY

DESCRIPTION OF REVIEW / REVISION	DATE APPROVED
Annual review	*02/16, 02/17, 02/18*
Criteria update	*10/16, 04/17, 05/18*
Preferred Product Update (effective 4/1/18)	*02/18*