Policy Title:	Simponi Aria (golimumab) (Intravenous)		
		Department:	PHA
Effective Date:	01/01/2020		
Review Date:	9/25/2019, 12/20/19, 1/22/20		
Revision Date:	9/25/2019, 12/20/19, 1/22/20		

Purpose: To support safe, effective and appropriate use of Simponi Aria (golimumab).

Scope: Medicaid, Exchange, Medicare-Medicaid Plan (MMP)

Policy Statement:

Simponi Aria (golimumab) is covered under the Medical Benefit when used within the following guidelines. Use outside of these guidelines may result in non-payment unless approved under an exception process.

Procedure:

Coverage of Simponi Aria (golimumab) will be reviewed prospectively via the prior authorization process based on criteria below.

Initial Criteria:

- Patient is 18 years or older; AND
- Patient has been evaluated and screened for the presence of latent TB infection prior to initiating treatment; AND
- Patient has been evaluated and screened for the presence hepatitis B virus (HBV) prior to initiating treatment; AND
- Patient does not have an active infection, including clinically important localized infections; AND
- Must not be administered concurrently with live vaccines; AND
- Patient is not on concurrent treatment with another TNF inhibitor, biologic response modifier or other non-biologic agent; AND
- Physician has assessed baseline disease severity utilizing an objective measure/tool; OR
- MMP members who have previously received this medication within the past 365 days are not subject to Step Therapy Requirements

Rheumatoid Arthritis (RA)

- Must be prescribed by, or in consultation with, a specialist in rheumatology; AND
- Documented moderate to severe active disease; AND

- Patient has had at least a 3 month trial and failure of previous therapy with ONE formulary oral disease modifying anti-rheumatic agent (DMARD); AND
- Prescribed in combination with methotrexate unless contraindicated

Psoriatic Arthritis (PsA)

- Must be prescribed by, or in consultation with, a specialist in dermatology or rheumatology; AND
- Documented moderate to severe active disease; AND
- For patients with predominantly axial disease OR active enthesitis and/or dactylitis, an adequate trial and failure of at least TWO (2) non-steroidal anti-inflammatory agents (NSAIDs), unless use is contraindicated; OR
- For patients with peripheral arthritis, a trial and failure of at least a 3 month trial of ONE formulary oral disease-modifying anti-rheumatic agent (DMARD)

Ankylosing Spondylitis

- Must be prescribed by, or in consultation with, a specialist in rheumatology; AND
- Documented active disease; AND
- Patient had an adequate trial and failure of at least TWO (2) non-steroidal anti-inflammatory agents (NSAIDs), unless use is contraindicated

Continuation of Therapy Criteria:

- Patient continues to meet initial criteria; AND
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include the following: serious infections, cardiotoxicity/heart failure, malignancy, demyelinating disorders, lupus-like syndrome, severe hypersensitivity reactions, severe hematologic cytopenias (e.g., pancytopenia, leukopenia, neutropenia, thrombocytopenia, etc.), etc.; AND
- Patient is receiving ongoing monitoring for presence of TB or other active infections; AND

Rheumatoid Arthritis

- Disease response as indicated by improvement in signs and symptoms compared to baseline such as the number of tender and swollen joint counts, reduction of C-reactive protein, improvement of patient global assessment, and/or an improvement on a disease activity scoring tool [e.g. an improvement on a composite scoring index such as Disease Activity Score-28 (DAS28) of 1.2 points or more or a ≥20% improvement on the American College of Rheumatology-20 (ACR20) criteria].

Psoriatic Arthritis

- Disease response as indicated by improvement in signs and symptoms compared to baseline such as the number of tender and swollen joint counts and/or an improvement on a disease activity scoring tool [e.g. defined as an improvement in at least 2 of the 4 Psoriatic Arthritis
- Response Criteria (PsARC), 1 of which must be joint tenderness or swelling score, with no worsening in any of the 4 criteria.]

Ankylosing Spondylitis

- Disease response as indicated by improvement in signs and symptoms compared to baseline such as total back pain, physical function, morning stiffness, and/or an improvement on a disease activity scoring tool (e.g. ≥ 1.1 improvement on the Ankylosing Spondylitis Disease Activity Score (ASDAS) or an improvement of ≥ 2 on the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI)).

Coverage durations:

- Initial coverage: 6 months
- Continuation of therapy coverage: 6 months

*** Requests will also be reviewed to National Coverage Determination (NCD) and Local Coverage Determinations (LCDs) if applicable. ***

Dosage/Administration:

Indication	**Dose**	**Maximum dose (1 billable unit = 1 mg)**
All Indications	2 mg/kg intravenous infusion at weeks 0, and 4, then every 8 weeks thereafter.	Loading Dose: 250 billable units on weeks 0 and 4 Maintenance: 250 billable units every 8 weeks

Investigational use: All therapies are considered investigational when used at a dose or for a condition other than those that are recognized as medically accepted indications as defined in any one of the following standard reference compendia: American Hospital Formulary Service Drug information (AHFS-DI), Thomson Micromedex DrugDex, Clinical Pharmacology, Wolters Kluwer Lexi-Drugs, or Peer-reviewed published medical literature indicating that sufficient evidence exists to support use. Neighborhood does not provide coverage for drugs when used for investigational purposes.

Applicable Codes:
Below is a list of billing codes applicable for covered treatment options. The below tables are provided for reference purposes and may not be all-inclusive. Requests received with codes from tables below do not guarantee coverage. Requests must meet all criteria provided in the procedure section.

The following HCPCS/CPT code is:

HCPCS/CPT Code	Description
J1602	Injection, golimumab, 1 mg

References:

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