RX.PA.073.MPC Simponi Aria IV (golimumab)

PURPOSE

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

Simponi Aria (golimumab) is indicated for the following:

- **Ankylosing spondylitis**, in adults with active disease.
- **Polyarticular juvenile idiopathic arthritis**, in patients ≥ 2 years of age with active disease.
- **Psoriatic arthritis**, in patients ≥ 2 years of age with active disease.
- **Rheumatoid arthritis**, in combination with methotrexate for treatment of adults with moderately to severely active disease.

PROCEDURE

A. Initial Authorization Criteria:

Must meet all of the criteria listed under the respective diagnosis:

1. Ankylosing Spondylitis. Approve for the duration noted if the patient meets the following:

Initial Therapy. Approve for 3 months if the patient meets the following criteria:

- Patient is ≥ 18 years of age; AND
- Patient has documented diagnosis of active ankylosing spondylitis; AND
- Patient has documented intolerance, contraindication to, or failed treatment for at least 3 months with preferred TNF inhibitors, Enbrel (etanercept) and Humira (adalimumab)
- Patient has documented intolerance, contraindication to, or failed treatment for at least 3 months with Xeljanz (tofacitinib)
- Dose does not exceed FDA approved label dosing for indication
- The agent is prescribed by or in consultation with a rheumatologist
- Patient must not be concurrently using Simponi Aria with other biologics or targeted synthetic disease-modifying antirheumatic drugs (DMARDs).
    - Note: Examples of biologics and DMARDs consist of infliximab products, Otezla, Rinvoq, Xeljanz, etc.

Patient is Currently Receiving Simponi Aria. Approve for 1 year if the patient meets ONE of the following:
MPC Renewal

- Patient has received an MPC prior authorization and has been established on therapy for least 3 months and has had a documented clinically significant response, as determined by the provider
- Patient meets one of the following:
    - When assessed by at least one objective measure, patient experienced a beneficial documented clinical response from baseline; OR
      Note: Examples of objective measures include Ankylosing Spondylitis Disease Activity Score (ASDAS), Ankylosing Spondylitis Quality of Life Scale (ASQoL), Bath Ankylosing Spondylitis Disease Activity Index (BASDAI), Bath Ankylosing Spondylitis Functional Index (BASFI), Bath Ankylosing Spondylitis Global Score (BAS-G), Bath Ankylosing Spondylitis Metrology Index (BASMI), Dougados Functional Index (DFI), Health Assessment Questionnaire for the Spondylarthropathies (HAQ-S), and/or serum markers (e.g., C-reactive protein, erythrocyte sedimentation rate).
    - Compared with baseline, patient experienced an improvement in at least one symptom, such as decreased pain or stiffness, or improvement in function or activities of daily living.
- Patient must not be concurrently using Simponi Aria with other biologics or targeted synthetic disease-modifying antirheumatic drugs (DMARDs).
    - Note: Examples of biologics and DMARDs consist of infliximab products, Otezla, Rinvoq, Xeljanz, etc.

OR

Renewal from Previous Insurer

- Members who have received prior approval (from insurer other than MPC) and have been taking Simponi Aria have been receiving medication samples, should be considered under criterion A (Initial Authorization Criteria).; AND
- Patient has been established on therapy for at least 3 months and has had a documented clinically significant response, as determined by the provider

2. Polyarticular juvenile Idiopathic Arthritis (JIA) [or Juvenile Rheumatoid Arthritis] (regardless of type of onset) [Note: This includes patients with juvenile spondyloarthropathy/active sacroiliac arthritis]. Approve for the duration noted if the patient meets the following:
Initial Therapy. Approve for 3 months if the patient meets the following criteria:

- Patient is ≥ 2 years of age; AND
- The patient has tried at least TWO systemic agents for this condition for at least 3 months or has a documented intolerance to at least TWO other agents
    - Note: Examples of one other agent tried include methotrexate (MTX), sulfasalazine, leflunomide, or a nonsteroidal anti-inflammatory drug (NSAID). OR
- The patient has aggressive disease, as determined by the prescriber; AND
- Patient has documented intolerance, contraindication to, or failed treatment for at least 3 months with preferred TNF inhibitors, Enbrel (etanercept) and Humira (adalimumab)
- Patient has documented intolerance, contraindication to, or failed treatment for at least 3 months with Xeljanz (tofacitinib)
- Dose does not exceed FDA approved label dosing for indication
- Simponi Aria is prescribed by or in consultation with a rheumatologist
- Patient must not be concurrently using Simponi Aria with other biologics or targeted synthetic disease-modifying antirheumatic drugs (DMARDs).
    - Note: Examples of biologics and DMARDs consist of infliximab products, Otezla, Rinvoq, Xeljanz, etc.

<u>Patient is Currently Receiving Simponi Aria.</u> Approve for 1 year if the patient meets ONE of the following:
<u>MPC Renewal</u>

- Patient has received and MPC prior authorization and has been established on therapy for at least 3 months; AND
    - Note: A patient who has received < 3 months of therapy or who is restarting therapy with Simponi Aria is reviewed under criterion A (Initial Therapy).
- Patient meets at least one of the following:
    - When assessed by at least one objective measure, patient experienced a beneficial clinical response from baseline; OR
      Note: Examples of objective measures include Physician Global Assessment (MD global), Parent/Patient Global Assessment of Overall Well-Being (PGA), Parent/Patient Global Assessment of Disease Activity (PDA), Juvenile Arthritis Disease Activity Score (JDAS), Clinical Juvenile Arthritis Disease Activity Score (cJDAS), Juvenile Spondyloarthritis Disease Activity Index (JSpADA), serum markers (e.g., C-reactive protein, erythrocyte sedimentation rate), and/or reduced dosage of corticosteroids.
    - Compared with baseline, patient experienced an improvement in at least one symptom, such as improvement in limitation of motion, less joint pain or tenderness, decreased duration of morning stiffness or fatigue, improved function or activities of daily living.
- Patient must not be concurrently using Simponi Aria with other biologics or targeted synthetic disease-modifying antirheumatic drugs (DMARDs).
    - Note: Examples of biologics and DMARDs consist of infliximab products, Otezla, Rinvoq, Xeljanz, etc.

OR

Renewal from Previous Insurer

- Members who have received prior approval (from insurer other than MPC) and have been taking Simponi Aria have been receiving medication samples, should be considered under criterion A (Initial Authorization Criteria).; AND
- Patient has been established on therapy for at least 3 months; AND
- Patient meets at least one of the following:
    - When assessed by at least one objective measure, patient experienced a beneficial clinical response from baseline; OR
      Note: Examples of objective measures include Physician Global Assessment (MD global), Parent/Patient Global Assessment of Overall Well-Being (PGA), Parent/Patient Global Assessment of Disease Activity (PDA), Juvenile Arthritis Disease Activity Score (JDAS), Clinical Juvenile Arthritis Disease Activity Score (cJDAS), Juvenile Spondyloarthritis Disease Activity Index (JSpADA), serum markers (e.g., C-reactive protein, erythrocyte sedimentation rate), and/or reduced dosage of corticosteroids.
    - Compared with baseline, patient experienced an improvement in at least one symptom, such as improvement in limitation of motion, less joint pain or tenderness, decreased duration of morning stiffness or fatigue, improved function or activities of daily living.

3. Psoriatic Arthritis. Approve for the duration noted if the patient meets the following:
Initial Therapy. Approve for 3 months if the patient meets the following criteria:

- Patient is ≥ 2years of age; AND
- Patient has tried TWO conventional synthetic disease-modifying antirheumatic drug (DMARD) for at least 3 months or has a documented intolerance to at least TWO conventional synthetic DMARDs
    - Note: Examples of conventional synthetic DMARDs include methotrexate (oral or injectable), leflunomide, hydroxychloroquine and sulfasalazine.
- Patient has documented intolerance, contraindication to, or failed treatment for at least 3 months with preferred TNF inhibitors, Enbrel (etanercept) and Humira (adalimumab)
- Patient has documented intolerance, contraindication to, or failed treatment for at least 3 months with Xeljanz (tofacitinib)
- Dose does not exceed FDA approved label dosing for indication
- The agent is prescribed by or in consultation with a rheumatologist or a dermatologist
- Patient must not be concurrently using Simponi Aria with other biologics or targeted synthetic disease-modifying antirheumatic drugs (DMARDs).
    - Note: Examples of biologics and DMARDs consist of infliximab products, Otezla, Rinvoq, Xeljanz, etc.

Patient is Currently Receiving Simponi Aria. Approve for 1 year if the patient meets ONE of the following:

MPC Renewal

- Patient has received an MPC prior authorization and has been established on therapy for at least 3months; AND
    - Note: A patient who has received < 3 months of therapy or who is restarting therapy with Simponi Aria is reviewed under criterion A (Initial Therapy).
- Patient meets at least one of the following:
    - When assessed by at least one objective measure, patient experienced a beneficial clinical response from baseline; OR
      Note: Examples of objective measures of disease activity include Disease Activity Index for Psoriatic Arthritis (DAPSA), Composite Psoriatic Disease Activity Index (CPDAI), Psoriatic Arthritis Disease Activity Score (PsA DAS), Grace Index, Leeds Enthesitis Score (LEI), Spondyloarthritis Consortium of Canada (SPARCC) enthesitis score, Leeds Dactylitis Instrument Score, Minimal Disease Activity (MDA), Psoriatic Arthritis Impact of Disease (PsAID-12), and/or serum markers (e.g., C-reactive protein, erythrocyte sedimentation rate).
    - Compared with baseline, patient experienced an improvement in at least one symptom, such as less joint pain, morning stiffness, or fatigue; improved function or activities of daily living; or decreased soft tissue swelling in joints or tendon sheaths.
- Patient must not be concurrently using Simponi Aria with other biologics or targeted synthetic disease-modifying antirheumatic drugs (DMARDs).
    - Note: Examples of biologics and DMARDs consist of infliximab products, Otezla, Rinvoq, Xeljanz, etc.

OR

Renewal from Previous Insurer

- Members who have received prior approval (from insurer other than MPC) and have been taking Simponi Aria have been receiving medication samples, should be considered under criterion A (Initial Authorization Criteria).; AND
- Patient has been established on therapy for at least 3 months; AND
- Patient meets at least one of the following:
    - When assessed by at least one objective measure, patient experienced a beneficial clinical response from baseline; OR
      Note: Examples of objective measures of disease activity include Disease Activity Index for Psoriatic Arthritis (DAPSA), Composite Psoriatic Disease Activity Index (CPDAI), Psoriatic Arthritis Disease Activity Score (PsA DAS), Grace Index, Leeds Enthesitis Score (LEI), Spondyloarthritis Consortium of Canada (SPARCC) enthesitis score, Leeds Dactylitis Instrument Score, Minimal Disease Activity (MDA), Psoriatic Arthritis Impact of Disease (PsAID-12), and/or serum markers (e.g., C-reactive protein, erythrocyte sedimentation rate).
    - Compared with baseline, patient experienced an improvement in at least one symptom, such as less joint pain, morning stiffness, or fatigue; improved

function or activities of daily living; or decreased soft tissue swelling in joints or tendon sheaths

4. Rheumatoid Arthritis. Approve for the duration noted if the patient meets the following:
Initial Therapy: Approve for 3 months if the patient meets the following criteria:

- Patient is ≥ 18 years of age; AND
- The patient has tried TWO conventional synthetic disease-modifying antirheumatic drug (DMARD) for at least 3 months or has documented intolerance to at least TWO conventional synthetic agents
    - Note: Examples of conventional synthetic DMARDs include methotrexate (oral or injectable), leflunomide, hydroxychloroquine, and sulfasalazine. AND
- Patient has documented intolerance, contraindication to, or failed treatment for at least 3 months with preferred TNF inhibitors, Enbrel (etanercept) and Humira (adalimumab)
- Patient has documented intolerance, contraindication to, or failed treatment for at least 3 months with Xeljanz (tofacitinib)
- Dose does not exceed FDA approved label dosing for indication
- The agent is prescribed by or in consultation with a rheumatologist.
- Patient must not be concurrently using Simponi Aria with other biologics or targeted synthetic disease-modifying antirheumatic drugs (DMARDs).
    - Note: Examples of biologics and DMARDs consist of infliximab products, Otezla, Rinvoq, Xeljanz, etc.

Patient is Currently Receiving Simponi Aria. Approve for 1 year if the patient meets ONE of the following:
MPC Renewal

- Patient has received and MPC prior authorization and has been established on therapy for at least 3 months; AND
    - Note: A patient who has received < 3 months of therapy or who is restarting therapy with Simponi Aria is reviewed under criterion A (Initial Therapy).
- Patient meets at least one of the following:
    - Patient experienced a beneficial clinical response when assessed by at least one objective measure; OR
      Note: Examples of standardized and validated measures of disease activity include Clinical Disease Activity Index (CDAI), Disease Activity Score (DAS) 28 using erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP), Patient Activity Scale (PAS)-II, Rapid Assessment of Patient Index Data 3 (RAPID-3), and/or Simplified Disease Activity Index (SDAI).
    - Patient experienced an improvement in at least one symptom, such as decreased joint pain, morning stiffness, or fatigue; improved function or activities of daily living; decreased soft tissue swelling in joints or tendon sheaths.
- Patient must not be concurrently using Simponi Aria with other biologics or targeted synthetic disease-modifying antirheumatic drugs (DMARDs).

- Note: Examples of biologics and DMARDs consist of infliximab products, Otezla, Rinvoq, Xeljanz, etc.

OR

Renewal from Previous Insurer

- Members who have received prior approval (from insurer other than MPC) and have been taking Simponi Aria have been receiving medication samples, should be considered under criterion A (Initial Authorization Criteria).; AND
- Patient has been established on therapy for at least 3 months; AND
- Patient meets at least one of the following:
  - Patient experienced a beneficial clinical response when assessed by at least one objective measure; OR
    Note: Examples of standardized and validated measures of disease activity include Clinical Disease Activity Index (CDAI), Disease Activity Score (DAS) 28 using erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP), Patient Activity Scale (PAS)-II, Rapid Assessment of Patient Index Data 3 (RAPID-3), and/or Simplified Disease Activity Index (SDAI).
  - Patient experienced an improvement in at least one symptom, such as decreased joint pain, morning stiffness, or fatigue; improved function or activities of daily living; decreased soft tissue swelling in joints or tendon sheaths.

B. Must be prescribed at a dose within the manufacturer's dosing guidelines (based on diagnosis, weight, etc) listed in the FDA approved labeling.

C. Simponi Aria will be considered investigational or experimental for any other use and will not be covered.

Limitations:

Length of Authorization (if above criteria met)	
Initial Authorization	Up to 3 months
Reauthorization	Up to 1 year

If the established criteria are not met, the request is referred to a Medical Director for review, if required for the plan and level of request.

APPLICABLE CODES:	
CODE	**DESCRIPTION**
J1602	Injection, golimumab, 1 mg

REFERENCES

1. Simponi Aria® injection for intravenous use [prescribing information]. Horsham, PA: Janssen Biotech, Inc; September 2020.
2. Ward MM, Deodhar A, Gensler LS, et al. 2019 update of the American College of Rheumatology/Spondylitis Association of America/Spondyloarthritis Research and Treatment Network recommendations for the treatment of ankylosing spondylitis and nonradiographic axial spondyloarthritis. 2019;(10):1599-1613.
3. Ringold S, Angeles-Han ST, Beukelman T, et al. 2019 American College of Rheumatology/Arthritis Foundation guideline for the treatment of juvenile idiopathic arthritis: therapeutic approaches for non-systemic polyarthritis, sacroiliitis, and enthesitis. Arthritis Rheumatol. 2019;71(6):846-863.
4. Ringold S, Weiss PF, Beukelman T, et al. 2013 update of the 2011 American College of Rheumatology recommendations for the treatment of juvenile idiopathic arthritis: recommendations for the medical therapy of children with systemic juvenile idiopathic arthritis and tuberculosis screening among children receiving biologic medications. Arthritis Rheum. 2013;65(10):2499-2512.
5. Singh JA, Guyatt G, Ogdie A, et al. 2018 American College of Rheumatology/National Psoriasis Foundation Guideline for the treatment of psoriatic arthritis. Arthritis Care Res (Hoboken). 2019;71(1):2-29.
6. Singh JA, Saag KG, Bridges SL Jr, et al. 2015 American College of Rheumatology Guideline for the treatment of rheumatoid arthritis. Arthritis Rheumatol. 2016;68(1):1-26.
7. Simponi injection [prescribing information]. Horsham, PA: Centocor Ortho Biotech Inc; September 2019.
8. Rutgeerts P, Feagan BG, Marano CW, et al. Randomised clinical trial: a placebo-controlled study of intravenous golimumab induction therapy for ulcerative colitis. Aliment Pharmacol Ther. 2015;42(5):504-514.

REVIEW HISTORY

DESCRIPTION OF REVIEW / REVISION	DATE APPROVED
Annual Revision *Patients Established on Simponi Aria or Subcutaneous: Change approval duration to 1 year (previously was 3 years) to align with Simponi Aria Medical Policy.*	*10/10/2018*
Annual Revision *No criteria changes.*	*10/16/2019*
Annual Revision *Juvenile Idiopathic Arthritis: This approval condition was added to align with the new FDA approval. Criteria approve for 3 months if prescribed by or in consultation with a rheumatologist, and if the patient has tried one other medication for this condition, or if, according to the prescriber, the patient has aggressive disease. For a patient already taking Simponi Aria or subcutaneous, criteria approve for 1 year if the patient has responded to initial therapy.*	*10/07/2020*

Rheumatoid Arthritis: Examples of biologics were moved to be included in the Appendix (previously listed in a Note in the criteria section).	
MPC Revision *Addition of treatment failure requirements of Humira and Enbrel for applicable indications. Clarification of systemic treatment failure agents and addition of FDA dosing requirements. Addition of specialist requirement for prescribing.*	*02/2022*
Expansion of initial authorization criteria; Addition of MPC vs Non-MPC renewal; Additional requirement of treatment failure with Xeljanz for RA, PsA, JIA, and AS	*11/2022*
Annual Review	*02/2023*
Annual policy review. Update to reauthorization criteria for non-MPC renewals	*02/2024*