Reference number
2394-A

STANDARD MEDICARE PART B MANAGEMENT

SIMPONI ARIA (golimumab)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

A. FDA-Approved Indications
   1. Treatment of adult patients with moderately to severely active rheumatoid arthritis (RA) in combination with methotrexate
   2. Treatment of active psoriatic arthritis (PsA) in patients 2 years of age and older
   3. Treatment of adult patients with active ankylosing spondylitis (AS)
   4. Treatment of active polyarticular juvenile idiopathic arthritis (pJIA) in patients 2 years of age and older

B. Compendial Uses
   1. Non-radiographic axial spondyloarthritis
   2. Oligoarticular juvenile idiopathic arthritis
   3. Immune checkpoint inhibitor-related toxicities – inflammatory arthritis

All other indications will be assessed on an individual basis. Submissions for indications other than those enumerated in this policy should be accompanied by supporting evidence from Medicare approved compendia.

II. DOCUMENTATION

The following documentation must be available, upon request, for all submissions:

A. Rheumatoid arthritis (RA)
   1. For initial requests: Chart notes, medical record documentation, or claims history supporting previous medications tried (if applicable), including response to therapy. If therapy is not advisable, documentation of clinical reason to avoid therapy.
   2. For continuation requests: Chart notes or medical record documentation supporting benefit from therapy.

B. Psoriatic arthritis (PsA), ankylosing spondylitis (AS), non-radiographic axial spondyloarthritis (nr-axSpA), and articular juvenile idiopathic arthritis (JIA)
   For continuation requests: Chart notes or medical record documentation supporting benefit from therapy.

C. Immune checkpoint inhibitor-related toxicity
   For initial requests: Chart notes, medical record documentation, or claims history supporting previous medications tried (if applicable), including response to therapy.

III. CRITERIA FOR INITIAL APPROVAL

A. Rheumatoid arthritis (RA)
Authorization of 12 months may be granted for treatment of moderately to severely active rheumatoid arthritis when either of the following criteria is met:
1. Simponi Aria will be used in combination with methotrexate.
2. The member has a clinical reason to avoid methotrexate (e.g., breastfeeding, pregnancy or currently planning pregnancy, renal or hepatic impairment, previous intolerance to methotrexate).

B. Psoriatic arthritis (PsA)
Authorization of 12 months may be granted for treatment of active psoriatic arthritis.

C. Ankylosing spondylitis (AS) and non-radiographic axial spondyloarthritis (nr-axSpA)
Authorization of 12 months may be granted tor treatment of active ankylosing spondylitis or active non-radiographic axial spondyloarthritis.

D. Articular juvenile idiopathic arthritis (JIA)
Authorization of 12 months may be granted for treatment of active articular juvenile idiopathic arthritis.

E. Immune checkpoint inhibitor-related toxicity
Authorization of 12 months may be granted for treatment of refractory or severe immunotherapy-related inflammatory arthritis that has not responded to systemic corticosteroids.

IV. CONTINUATION OF THERAPY

All members (including new members) requesting authorization for continuation of therapy must be currently receiving therapy with the requested agent.

A. Immune checkpoint inhibitor-related toxicity
All members (including new members) requesting authorization for continuation of therapy must meet all initial authorization criteria.

B. All other indications
Authorization for 12 months may be granted when all of the following criteria are met:
1. The member is currently receiving therapy with Simponi Aria.
2. Simponi Aria is being used to treat an indication enumerated in Section III.
3. The member is receiving benefit from therapy.

V. SUMMARY OF EVIDENCE

The contents of this policy were created after examining the following resources:
1. The prescribing information for Simponi Aria.
2. The available compendium
    a. National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium
    b. Micromedex DrugDex
    c. American Hospital Formulary Service- Drug Information (AHFS-DI)
    d. Lexi-Drugs
3. EULAR recommendations for the management of rheumatoid arthritis with synthetic and biological disease-modifying antirheumatic drugs: 2019 update
4. 2021 American College of Rheumatology guideline for the treatment of rheumatoid arthritis

5. 2018 American College of Rheumatology/National Psoriasis Foundation Guideline for the treatment of psoriatic arthritis
6. EULAR recommendations for management of psoriatic arthritis with pharmacological therapies: 2019 update
7. 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 Non radiographic axial spondyloarthritis
8. 2016 update of the international ASAS-EULAR management recommendations for axial spondyloarthritis
9. 2019 American College of Rheumatology/Arthritis Foundation guideline for the treatment of juvenile idiopathic arthritis: therapeutic approaches for non-systemic polyarthritis, sacroiliitis, and enthesitis
10. 2021 American College of Rheumatology guideline for the treatment of juvenile idiopathic arthritis: therapeutic approaches for oligoarthritis, temporomandibular joint arthritis, and systemic juvenile idiopathic arthritis
11. NCCN guideline: Management of immunotherapy-related toxicities

After reviewing the information in the above resources, the FDA-approved indications listed in the prescribing information for Simponi Aria are covered in addition to the following:

A. Non-radiographic axial spondyloarthritis
B. Oligoarticular juvenile idiopathic arthritis
C. Immune checkpoint inhibitor-related toxicity – inflammatory arthritis

VI. EXPLANATION OF RATIONALE

Support for FDA-approved indications can be found in the manufacturer's prescribing information.

According to the 2021 American College of Rheumatology guideline for the treatment of rheumatoid arthritis, in patients who are DMARD-naïve (disease-modifying antirheumatic drug) methotrexate is strongly recommended over hydroxychloroquine or sulfasalazine in patients with moderate-to-high disease activity. Methotrexate is conditionally recommended over leflunomide.

Non-radiographic axial spondyloarthritis is listed as an approvable indication along with ankylosing spondylitis. The 2016 update of the ASAS-EULAR recommendations for the treatment of non-radiographic axial spondyloarthritis support golimumab along with other TNF inhibitors. Support for including non-radiographic axial spondyloarthritis can be found in the 2019 update of the American College of Rheumatology/Spondylitis Association of America/Spondyloarthritis Research and Treatment Network guidelines. In adults with active ankylosing spondylitis or active non-radiographic axial spondyloarthritis despite treatment with NSAIDs, tumor necrosis factor inhibitors (TNFs) are strongly recommended over no treatment with TNFs.

Support for using Simponi Aria for oligoarticular juvenile idiopathic arthritis can be found in the 2021 American College of Rheumatology guideline for the treatment of juvenile idiopathic arthritis: therapeutic approaches for oligoarthritis, temporomandibular joint arthritis, and systemic juvenile idiopathic arthritis. For patients who have had an inadequate response or intolerance to non-biologic DMARDs, the next step is a biologic DMARD such as golimumab. The guideline indicates there is no preferred agent.

Support for using Simponi Aria to manage immune checkpoint inhibitor-related toxicity can be found in the National Comprehensive Cancer Network's guideline for the management of immunotherapy-related toxicities. The NCCN Guideline for the management of immunotherapy-related toxicities supports the use of adding Simponi Aria for moderate or severe inflammatory arthritis as additional disease modifying antirheumatic drug (DMARD) therapy if no improvement after holding immunotherapy and treating with oral corticosteroids or if unable to taper corticosteroids, or no response to conventional synthetic DMARDs.

VII. REFERENCES

1. Simponi Aria [package insert]. Horsham, PA: Janssen Biotech, Inc.; February 2021.
2. Smolen JS, Landewé RBM, Bijlsma JWJ, et al. EULAR recommendations for the management of rheumatoid arthritis with synthetic and biological disease-modifying antirheumatic drugs: 2019 update. *Ann Rheum Dis.* 2020;79(6):685-699. doi:10.1136/annrheumdis-2019-216655.
3. Fraenkel L, Bathon JM, England BR, et al. 2021 American College of Rheumatology guideline for the treatment of rheumatoid arthritis. *Arthrit Care Res*. 2021;0:1-16.
4. Singh JA, Guyatt G, Ogdie A, et al. 2018 American College of Rheumatology/National Psoriasis Foundation Guideline for the Treatment of Psoriatic Arthritis. *Arthritis Rheum*. 2018;71:5-32.
5. Gossec L, Baraliakos X, Kerschbaumer A. EULAR recommendations for the management of psoriatic arthritis with pharmacological therapies: 2019 update. *Ann Rheum Dis*. 2020;79(6):700-712.
6. 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. *Arthritis Rheumatol.* 2019;71(10):1599-1613. doi:10.1002/art.41042.
7. van der Heijde D, Ramiro S, Landewe R, et al. 2016 Update of the international ASAS-EULAR management recommendations for axial spondyloarthritis. *Ann Rheum Dis.* 2017;76(6):978-991.
8. Ringold S, Angeles-Han S, 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. *American College of Rheumatology.* 2019;1-18.
9. Onel KB, Horton DB, Lovell DJ, et al. 2021 American College of Rheumatology guideline for the treatment of juvenile idiopathic arthritis: therapeutic approaches for oligoarthritis, temporomandibular joint arthritis, and systemic juvenile idiopathic arthritis. *Arthritis Rheumatol*. 2022;74(4):553-569.
10. The NCCN Drugs & Biologics Compendium® © 2023 National Comprehensive Cancer Network, Inc. Available at: https://www.nccn.org. Accessed June 9, 2023.