Clinical Policy Title:	golimumab
Policy Number:	RxA.727
Drug(s) Applied:	Simponi®, Simponi Aria®
Original Policy Date:	04/18/2022
Last Review Date:	08/27/2024
Line of Business Policy Applies to:	All lines of business (except Medicare)

Criteria

I. Initial Approval Criteria

A. Ankylosing spondylitis (must meet all):

1. Diagnosis of active ankylosing spondylitis (AS);
2. Trial and failure of at least two (2) non-steroidal anti-inflammatory drugs (NSAIDs) at up to maximally indicated doses, each used for at ≥ 4 weeks unless contraindicated or clinically significant adverse effects are experienced.

Approval Duration

All Lines of Business (except Medicare): 12 months

B. Psoriatic Arthritis (must meet all):

1. Diagnosis of Psoriatic Arthritis (PsA).
2. **Approval Duration**

All Lines of Business (except Medicare): 12 months

C. Rheumatoid arthritis (must meet all):

1. Diagnosis of Rheumatoid Arthritis (RA);
2. Trial and failure of ≥ 3 months of at least one conventional systemic therapy (methotrexate [MTX], sulfasalazine, leflunomide, hydroxychloroquine) at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced;
   *Exception: If one biologic DMARD that is FDA-approved for rheumatoid arthritis has been previously tried, then trial of a conventional systemic agent is not required.

Approval Duration

All Lines of Business (except Medicare): 12 months

D. Ulcerative Colitis (must meet all)**:**

1. Diagnosis of Ulcerative Colitis (UC);
2. Request is for Simponi ®;
3. Member meets one of the following (a or b):
   a. Trial and failure of ≥ 3 months of at least one (1) conventional agent (azathioprine, 6-mercaptopurine, aminosalicylate) unless contraindicated or clinically significant adverse effects are experienced;
   b. Trial and failure of corticosteroids (e.g., prednisone, methylprednisolone, budesonide) unless contraindicated or significant adverse effects experienced;

*Exception: If one biologic DMARD that is FDA-approved for ulcerative colitis has been previously tried, then trial of a conventional systemic agent is not required.

Approval Duration
All Lines of Business (except Medicare): 12 months

E. Polyarticular Juvenile Idiopathic Arthritis (must meet all):
1. Diagnosis of Polyarticular Juvenile Idiopathic Arthritis (PJIA);
2. Request is for Simponi Aria®;
3. Trial and failure of ≥ 3 months of at least one (1) conventional systemic therapy (methotrexate or leflunomide [Arava®]) at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced.

Approval Duration
All Lines of Business (except Medicare): 12 months

II. Continued Therapy Approval

A. All indications in section I (must meet all):

1. Auto-approval based on lookback functionality within the past 120 days as a proxy for member responding positively to therapy.

Approval Duration
All Lines of Business (except Medicare): 12 months

References

1. Boulos P, Dougados M, MacLeod SM, et al. Pharmacological Treatment of Ankylosing Spondylitis. Drugs. 2005; 65: 2111-2127. Available at: https://pubmed.ncbi.nlm.nih.gov/16225367/. Accessed December 13, 2023.
2. Braun J, Davis J, Dougados M, et al. First update of the international ASAS consensus statement for the use of anti-TNF agents in patients with ankylosing spondylitis. Ann Rheum Dis. 2006; 65:316-320. Available at: https://pubmed.ncbi.nlm.nih.gov/16096329/. Accessed December 13, 2023.
3. Braun J, van den Berg R, Baraliako X, et al. 2010 Update of the ASAS/EULAR recommendations for the management of ankylosing spondylitis. Ann Rheum Dis 2011; 70:896-904. Available at: https://pubmed.ncbi.nlm.nih.gov/21540199/. Accessed December 13, 2023.
4. Zochling J, van der Heijde D, Burgos-Vargas, R, et al. ASAS/EULAR recommendations for the management of ankylosing spondylitis. Ann Rheum Dis. 2006; 65:442-452. Available at: https://pubmed.ncbi.nlm.nih.gov/16126791/. Accessed December 13, 2023.
5. Menter A, Gottlieb A, Feldman, SR, et al. American Academy of Dermatology. Guidelines of care for the management of psoriasis and psoriatic arthritis: Section 2. Psoriatic arthritis: overview and guidelines of care for treatment with an emphasis on the biologics. J Am Acad Dermatol May 2008; 58(5): 826-50. Available at: https://pubmed.ncbi.nlm.nih.gov/18423260/. Accessed December 13, 2023.
6. Gossec L, Smolen JS, Ramiro S, et al. European League Against Rheumatism (EULAR) recommendations for the management of psoriatic arthritis with pharmacological therapies: 2015 update. Ann Rheum Dis 2015; 0:1-12. doi:10.1136/annrheumdis-2015-208337. Available at: https://pubmed.ncbi.nlm.nih.gov/26644232/. Accessed December 13, 2023.
7. Singh JA, Guyatt G, Ogdie A, et al. 2018 American College of Rheumatology/National Psoriasis Foundation Guideline for the treatment of psoriatic arthritis. American College of Rheumatology. 2019; 71(1):5-32. doi: 10.1002/art.40726. Available at: https://pubmed.ncbi.nlm.nih.gov/30499246/. Accessed December 13, 2023.
8. Aletaha D, Neogi T, Silman AJ, et al. 2010 Rheumatoid Arthritis Classification Criteria. Arthritis and Rheumatism September 2010;62(9):2569-2581. Available at: https://pubmed.ncbi.nlm.nih.gov/20872595/. Accessed December 13, 2023.
9. Feuerstein JD, Isaacs KL, Schneider Y, et al. Aga clinical practice guidelines on the management of moderate to

severe ulcerative colitis. Gastroenterology. 2020;158(5):1450-1461. Available at: https://www.gastrojournal.org/article/S0016-5085(20)30018-4/fulltext?referrer=https%3A%2F%2Fpubmed.ncbi.nlm.nih.gov%2F. Accessed December 13, 2023.

Review/Revision History	Review/Revision Date	P&T Approval Date
RxA.592.Biologic_DMARDs was last reviewed and updated on 01/05/2022 and archived on 04/18/2022. For details, please refer to RxA.592.Biologic_DMARDs.	01/05/2022	04/18/2022
Drug specific policy for Simponi®_Simponi Aria® was created based on RxA.592.Biologic_DMARDs 1. Initial Approval Criteria, I.E.5: Updated to remove prior failure and criteria "Failure of a trial of ≥ 3 consecutive months of MTX at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced". 2. Initial Approval Criteria, I.E.5: Updated to include new trial and failure criteria Trial and failure of ≥ 3 consecutive months of at least one (1) conventional systemic therapy (methotrexate[MTX] or leflunomide [Arava®]) at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced. 3. References were reviewed and updated.	02/16/2022	04/18/2022
Policy was reviewed: 1. Initial Approval Criteria, 1.A.5.b: Updated dosing criteria for Simponi Aria® from dose does not exceed 2 mg/kg every 8 weeks to Simponi Aria® 2 mg/kg intravenously at weeks 0 and 4, followed by maintenance dose of 2 mg/kg every 8 weeks. 2. Initial Approval Criteria, 1.B.4.b: Updated dosing criteria For Simponi Aria® dose does not exceed 2 mg/kg every 8 weeks to Simponi Aria® (i or ii): i. Adults: 2 mg/kg intravenously at weeks 0 and 4, followed by maintenance dose of 2 mg/kg every 8 weeks;	03/27/2023	04/13/2023

ii. Pediatrics: 80 mg/m2 intravenously at weeks 0 and 4, followed by maintenance dose of 80 mg/m2 every 8 weeks. 3. Initial Approval Criteria, 1.C.6.b: Updated dosing criteria for For Simponi Aria® dose does not exceed 2 mg/kg every 8 weeks to For Simponi Aria®: 2 mg/kg intravenously at weeks 0 and 4, followed by maintenance dose of 2 mg/kg every 8 weeks. 4. Initial Approval Criteria, 1.D.7: Updated dosing criteria for Simponi® Does does not exceed 100 mg every 4 weeks to Dose does not exceed 200 mg at week 0, 100 mg at week 2, followed by maintenance dose of 100 mg every 4 weeks. 5. Initial Approval Criteria, I.D.5: Updated to include new documentation criteria, Documentation of a Mayo Score ≥ 6. 6. Initial Approval Criteria, 1.E.6: Updated dosing criteria for Simponi® Dose does not exceed 80 mg/m2 every 8 weeks to Dose does not exceed 80 mg/m^2 intravenously at weeks 0 and 4, followed by maintenance dose of 80 mg/m^2 every 8 weeks. 7. References were reviewed and updated.		
Policy was reviewed: 1. Removed prior age criteria. 2. Removed prior dosing criteria. 3. References were reviewed and updated.	12/13/2023	1/1/2024
Policy was reviewed. 1. Removed prescriber requirement. 2. Removed Mayo score for UC. 3. Updated lookback period for continued therapy to 120 days.	8/27/2024	09/12/2024