

Clinical Policy Title:	golimumab
Policy Number:	RxA.727
Drug(s) Applied:	Simponi®, Simponi Aria®
Original Policy Date:	04/18/2022
Last Review Date:	12/11/2025
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).

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, aminosalicilate) 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;

This clinical policy has been developed to authorize, modify, or determine coverage for individuals with similar conditions. Specific care and treatment may vary depending on individual need and benefits covered by the plan. This policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. This document may contain prescription brand name drugs that are trademarks of pharmaceutical manufacturers that are not affiliated with RxAdvance.

*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.
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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. Aa 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](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 <ol style="list-style-type: none"> 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". 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. References were reviewed and updated. 	02/16/2022	04/18/2022
Policy was reviewed: <ol style="list-style-type: none"> 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. 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): <ol style="list-style-type: none"> 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

<p>ii. Pediatrics: 80 mg/m² intravenously at weeks 0 and 4, followed by maintenance dose of 80 mg/m² every 8 weeks.</p> <p>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.</p> <p>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.</p> <p>5. Initial Approval Criteria, I.D.5: Updated to include new documentation criteria, Documentation of a Mayo Score ≥ 6.</p> <p>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/m² intravenously at weeks 0 and 4, followed by maintenance dose of 80 mg/m² every 8 weeks.</p> <p>7. References were reviewed and updated.</p>		
<p>Policy was reviewed:</p> <ol style="list-style-type: none"> 1. Removed prior age criteria. 2. Removed prior dosing criteria. 3. References were reviewed and updated. 	12/13/2023	1/1/2024
<p>Policy was reviewed.</p> <ol style="list-style-type: none"> 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
<p>Policy was reviewed.</p>	12/05/2024	N/A
<p>Policy reviewed.</p>	12/11/2025	12/11/2025