

Generic Name: Golimumab**Therapeutic Class or Brand Name:** Simponi®**Applicable Drugs (if Therapeutic Class):** N/A**Preferred:** N/A**Non-preferred:** N/A**Date of Origin:** 2/1/2013**Date Last Reviewed / Revised:** 1/13/2021**PRIOR AUTHORIZATION CRITERIA**

(May be considered medically necessary when criteria I through V are met)

- I. Documented diagnosis of one of the following conditions A through D AND must meet criteria listed under applicable diagnosis:
 - A. Active Ankylosing Spondylitis and criterion 1 is met:
 1. Diagnosis must be established by a rheumatologist.
 - B. Moderately to Severely Active Rheumatoid Arthritis and criteria 1 and 2 are met:
 1. History of treatment failure, intolerance, or contraindication to methotrexate, or one other DMARD or second line drug (azathioprine, sulfasalazine, leflunomide, penicillamine, hydroxychloroquine, etc.).
 2. Diagnosis must be established by a rheumatologist.
 - C. Active Psoriatic Arthritis (PsA) and criterion 1 through 3 are met:
 1. History of treatment failure, intolerance to, or contraindication to methotrexate or a second line DMARD.
 2. Patient has severe PsA and severe psoriasis or has predominantly axial disease. See Table 1 under Appendix.
 3. Diagnosis must be established by a rheumatologist or dermatologist.
 - D. Moderate to Severe Ulcerative Colitis and criteria 1 and 2 are met:
 1. History of treatment failure, intolerance, or contraindication to conventional therapy (i.e. 5-aminosalicylates, antibiotics, methotrexate, 6-mercaptopurine, azathioprine, corticosteroids, budesonide, etc.).
 2. Treatment must be prescribed by a gastroenterologist.
- II. Absence of active serious infection or sepsis.
- III. Negative TB skin test within the previous 12 months or history of treatment for latent TB infection.
- IV. Minimum age requirement: 18 years old.
- V. Refer to plan document for the list of preferred products. If requested agent is not listed as a preferred product, must have a documented failure, intolerance, or contraindication to preferred product(s).

EXCLUSION CRITERIA

- Coadministration of Simponi® with another targeted immune modulator. Examples of targeted immune modulators include the following:
 - Actemra® (tocilizumab)
 - Cosentyx® (secukinumab)
 - Dupixent® (dupilumab)
 - Entyvio® (vedolizumab)
 - Ilaris® (canakinumab)
 - Ilumya™ (tildrakizumab-asmn)
 - Kevzara® (sarilumab)
 - Kineret® (anakinra)
 - Olumiant® (baricitinib)
 - Orencia® (abatacept)
 - Otezla® (apremilast)
 - Riabni™ (rituximab-arrx)
 - Rinvoq™ (upadacitinib)
 - Rituxan® (rituximab)
 - Ruxience® (rituximab-pvvr)
 - Siliq™ (brodalumab)
 - Stelara® (ustekinumab)
 - Skyrizi® (risankizumab)
 - Taltz® (Ixekizumab)
 - TNF inhibitors [Avsola® (infliximab-axxq), Cimzia® (certolizumab pegol), Enbrel® (etanercept), Humira® (adalimumab), Inflectra® (infliximab-dyyb), Remicade® (infliximab), Renflexis® (infliximab-abda), Simponi®/Simponi® Aria® (golimumab)]
 - Tremfya™ (guselkumab)
 - Truxima® (rituximab-abbs)
 - Tysabri® (natalizumab)
 - Xeljanz®/XR (tofacitinib)

OTHER CRITERIA

- N/A

QUANTITY / DAYS SUPPLY RESTRICTIONS

- Rheumatologic conditions (Ankylosing Spondylitis, Rheumatoid Arthritis, Psoriatic Arthritis):
 - Quantities of up to 1 of the 50mg syringes every 28 days.
- Ulcerative Colitis:
 - Quantities of up to 3 of the 100mg syringes for the first month, then in quantities of up to 1 of the 100mg syringes every 28 days thereafter.

APPROVAL LENGTH

- **Authorization:** 4 months.
- **Re-Authorization:** 1 year, with an updated letter of medical necessity or progress notes showing improvement or maintenance with medication.

APPENDIX

- Table 1 - Examples of severe psoriatic arthritis and severe psoriasis:

Severe Psoriatic Arthritis	Severe Psoriasis
<ul style="list-style-type: none">• Erosive disease• Elevated markers of inflammation (ESR, CRP) attributable to PsA• Long-term damage that interferes with function (i.e., joint deformities)• Highly active disease that causes a major impairment in quality of life• Active PsA at many sites including dactylitis, enthesitis• Function-limiting PsA at a few sites• Rapidly progressive disease	<ul style="list-style-type: none">• PASI of 12 or more• BSA of 5-10% or more• Significant involvement in specific areas<ul style="list-style-type: none">• (e.g., face, hands or feet, nails, intertriginous areas, scalp) where the burden of the disease causes significant disability• Impairment of physical or mental functioning can warrant a designation of moderate-to-severe disease despite the lower amount of surface area of skin involved

REFERENCES

1. Menter A., et. al. Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with biologics. J Am Acad Dermatol. 2019 Apr;80(4):1029-1072. doi: 10.1016/j.jaad.2018.11.057. Epub 2019 Feb 13.
2. Singh JA, et. al., Special Article: 2018 American College of Rheumatology/National Psoriasis Foundation Guideline for the Treatment of Psoriatic Arthritis. Arthritis Rheumatol. 2019

- Jan;71(1):5-32. doi: 10.1002/art.40726. Epub 2018 Nov 30. Available at:
<https://www.rheumatology.org/Portals/0/Files/PsA-Guideline-2018.pdf>
3. Singh JA, et. al., 2015 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis. Arthritis Rheumatol. 2016 Jan;68(1):1-26. doi:10.1002/art.39480. Epub 2015 Nov 6. Available at:
<https://www.rheumatology.org/Portals/0/Files/ACR%202015%20RA%20Guideline.pdf>
 4. Singh, JA, et. al., 2015 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis. Arthritis Care & Research. 2015. DOI 10.1002/acr.22783.
 5. Ward MM, et. al, American College of Rheumatology/Spondylitis Association of America/Spondyloarthritis Research and Treatment Network 2015 Recommendations for the Treatment of Ankylosing Spondylitis and Nonradiographic Axial Spondyloarthritis. Arthritis Rheumatol. 2016 Feb;68(2):282-98. doi: 10.1002/art.39298. Epub 2015 Sep 24. Available at:
<https://www.ncbi.nlm.nih.gov/pubmed/26401991>
 6. Rubin DT, et. al, ACG Clinical Guideline Ulcerative Colitis in Adults. Am J Gastroenterol. 2019 Mar;114(3):384-413. doi: 10.14309/ajg.00000000000000152. Available at:
https://journals.lww.com/ajg/Fulltext/2019/03000/ACG_Clinical_Guideline_Ulcerative_Colitis_in.10.aspx
 7. Medispan®
 8. Simponi® [Package insert] Horsham, PA: Janssen Biotech; September 2019. Available at:
<http://www.janssenlabels.com/package-insert/product-monograph/prescribing-information/SIMPONI-pi.pdf>

DISCLAIMER: Medication Policies are developed to help ensure safe, effective and appropriate use of selected medications. They offer a guide to coverage and are not intended to dictate to providers how to practice medicine. Refer to Plan for individual adoption of specific Medication Policies. Providers are expected to exercise their medical judgement in providing the most appropriate care for their patients.