MEDICATION POLICY:

Simponi®

Generic Name: Golimumab

Therapeutic Class or Brand Name: Simponi®

Applicable Drugs (if Therapeutic Class): N/A

GPI Code: 66270040002020

Preferred: N/A

Non-preferred: N/A

Date of Origin: 2/1/2013

Date Last Reviewed / Revised: 5/30/2019

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 and criterion 1 is met:

      1. 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 a preferred product(s).

EXCLUSION CRITERIA

- Coadministration of Simponi® with another biologic DMARD, Otezla® (apremilast), or Xeljanz®/ XR (tofacitinib). Examples of biologic DMARDs include the following:

- Actemra® (tocilizumab)
- Cosentyx® (secukinumab)
- Entyvio® (vedolizumab)
- Kevzara® (sarilumab)
- Kineret® (anakinra)
- Orencia® (abatacept)
- Rinvoq™ (upadacitinib)
- Rituxan® (rituximab)
- Siliq™ (brodalumab)
- Stelara® (ustekinumab)
- Skyrizi™ (risankizumab)
- Taltz® (Ixekizumab)
- TNF inhibitors [Cimzia® (certolizumab pegol), Enbrel® (etanercept), Humira® (adalimumab), Inflectra® (infliximab-dyyb), Remicade® (infliximab), Renflexis™ (infliximab-abda), Simponi® Aria® (golimumab)]
- Tremfya™ (guselkumab)
- Tysabri® (natalizumab)

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:** 1 year.
- **Re-Authorization:** Insert content here. An updated letter of medical necessity or progress notes showing improvement or maintenance with medication.

Appendix

N/A

REFERENCES

1. 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
2. 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
3. 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
4. Rubin DT, et. al, ACG Clinical Guideline Ulcerative Colitis in Adults. Am J Gastroenterol. 2019 Mar;114(3):384-413. doi: 10.14309/ajg.0000000000000152. Available at: https://journals.lww.com/ajg/Fulltext/2019/03000/ACG_Clinical_Guideline__Ulcerative_Colitis_in.10.aspx
5. Simponi® [Package insert] Horsham, PA: Janssen Biotech; May 2018. Available at: http://www.janssenlabels.com/package-insert/product-monograph/prescribing-information/SIMPONI-pi.pdf

HISTORICAL TRACKING OF CHANGES MADE TO POLICY

Date	Notes/Changes
5/30/2019	1. **Added** "Rinvoq" and "Skyrizi" **under Coadministration Exclusion Criteria**. 2. **Deleted** "https://npsonline.pti-nps.com". **Added** "https://www.rheumatology.org/Portals/0/Files/PsA-Guideline-2018.pdf" "https://www.rheumatology.org/Portals/0/Files/ACR%202015%20RA%20Guideline.pdf" "https://www.ncbi.nlm.nih.gov/pubmed/26401991" "https://journals.lww.com/ajg/Fulltext/2019/03000/ACG_Clinical_Guideline__Ulcerative_Colitis_in.10.aspx" **under References**.
2/8/2019	1. **Deleted** obsolete URLs **under References** http://blue.regence.com/trgmedpol/drugs/dru183.pdf. http://blue.regence.com/trgmedpol/drugs/dru183b.pdf .
11/21/2017	1. **Added** "Kevzara® (sarilumab)", "Siliq™ (brodalumab)", **and** "Tremfya™ (guselkumab)" **to list under Exclusion Criteria**. **Added** "Inflectra® (infliximab-dyyb)" **and** "Renflexis™ (infliximab-abda)" **following TNF Inhibitors to list under Exclusion Criteria**.

9/20/2016	1. **Reinserted** "Refer to Plan for individual adoption of specific Medication Policies" **in disclaimer**.
8/26/2016	1. **Changed** "V. Refer to plan document for the list of preferred products. If Simponi® is not listed as a preferred product, must have a documented failure, intolerance, or contraindication to a preferred product" **to** "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 a preferred product(s)" **under Prior Authorization Criteria**. 2. **Changed** "Coadministration of Simponi® with…Xeljanz® (tofacitinib)…" **to** "Coadministration of Simponi® with…Xeljanz®/ XR (tofacitinib)…" **under Exclusion Criteria**. 3. **Changed** "Cosentyx™" **to** "Cosentyx®" **under Exclusion Criteria**. 4. **Added** "Taltz® (Ixekizumab)" **to list under Exclusion Criteria**. 5. **Removed** "https://medicaid.utah.gov/pharmacy/priorauthorization/pdf/Simponi%20UC%202014-12-26.pdf" **and** https://medicaid.utah.gov/pdf/Simponi%20RA,%20PA%20&%20AS%202014-12-26.pdf **from under References** (links no longer valid).
3/2/2015	2. **Added** "Cosentyx™ (secukinumab)" **to list under Exclusion Criteria.**
2/28/2015	1. **Changed** "Documented diagnosis of one of the following conditions A through C…: A. Moderate to Severe Rheumatoid Arthritis or Psoriatic Arthritis and criteria 1 through 3 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. The number of swollen joints and tender joints must be 3 or more; 3. Diagnosis must be established by a rheumatologist; B. Ankylosing Spondylitis…; C. Moderate to Severe Ulcerative Colitis and criteria 1 and 2 are met: 1. History of treatment failure, intolerance, or contraindication with each of the following a through c: a. At least one adequate course of systemic corticosteroids (i.e. more than 20mg per day for at least 14 days or less than 20mg per day for at least 40 days); b. At least one aminosalicylate (i.e. mesalamine, balsalazide, sulfasalazine); c. At least one oral systemic agent for ulcerative colitis [i.e. azathioprine or 6-mercaptopurine (6-MP)]…" **to** "Documented diagnosis of one of the following conditions A through D…: A. Active Ankylosing Spondylitis…; 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 and criterion 1 is met: 1. 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.)…" **under Prior Authorization Criteria**. 2. **Changed** "Absence of active bacterial or viral infection, malignancy, or immunosuppressive condition" **to** "Absence of active serious infection or sepsis" **under Prior Authorization Criteria**. 3. **Changed** "Simponi® may not be given with other biologic agents such as Interferon, experimental medications, or combinations" **to** "Coadministration of Simponi® with another biologic DMARD, Otezla® (apremilast), or Xeljanz® (tofacitinib). Examples of

	biologic DMARDs include the following: Actemra® (tocilizumab); Entyvio® (vedolizumab); Kineret® (anakinra); Orencia® (abatacept); Rituxan® (rituximab); Stelara® (ustekinumab); TNF inhibitors [Cimzia® (certolizumab pegol), Enbrel® (etanercept), Humira® (adalimumab), Remicade® (infliximab), Simponi® Aria® (golimumab)]; Tysabri® (natalizumab)" **under Exclusion Criteria**. 4. **Changed listed** "Rheumatologic conditions (Rheumatoid Arthritis, Psoriatic Arthritis, Ankylosing Spondylitis): Quantities of up to 1 of the 50mg syringes per month" **to** "Rheumatologic conditions (Ankylosing Spondylitis, Rheumatoid Arthritis, Psoriatic Arthritis): Quantities of up to 1 of the 50mg syringes every 28 days" **under Quantity/Days Supply Restrictions**. 5. **Added** "http://blue.regence.com/trgmedpol/drugs/dru183b.pdf" **under References**. 6. **Updated** "http://www.health.utah.gov/medicaid/pharmacy/priorauthorization/allentries.php" to "https://medicaid.utah.gov/pharmacy/priorauthorization/pdf/Simponi%20RA,%20PA%20&%20AS%202014-12-26.pdf" **and** "https://medicaid.utah.gov/pharmacy/priorauthorization/pdf/Simponi%20UC%202014-12-26.pdf" **under References**.
10/15/2013	1. **Adapted policy to new format**. 2. **Changed** "Documented failure on or intolerance to a preferred product (Humira or Cimzia) **requirement to** "Refer to plan document for the list of preferred products. If Simponi® is not listed as a preferred product, must have a documented failure, intolerance, or contraindication to a preferred product" **requirement**. 3. **Changed criteria for Moderate to Severe Rheumatoid Arthritis or Psoriatic Arthritis from:** "History of treatment, incomplete response, or intolerance to Methotrexate, or one other DMARD or second line drug (azathioprine, sulphadiazine, leflunomide, penicillamine, hydroxychloroquine, etc.); The number of swollen joints must be 6 or more and the number of tender joints must be 9 or more (WRITE SPECIFIC NUMBER IN NOTES OR LETTER)" **to** "History of treatment failure, intolerance, or contraindication to Methotrexate, or one other DMARD or second line drug (azathioprine, sulfasalazine, leflunomide, penicillamine, hydroxychloroquine, etc.); The number of swollen joints and tender joints must be 3 or more; Diagnosis must be established by a rheumatologist". 4. **Added** "Diagnosis must be established by a rheumatologist" as **criterion for Ankylosing Spondylitis**. 5. **Added "Moderate to Severe Ulcerative Colitis" as a covered diagnosis**, and **assigned** the following **criteria** to this diagnosis: "History of treatment failure, intolerance, or contraindication with each of the following a through c: a. At least one adequate course of systemic corticosteroids (i.e. more than 20mg per day for at least 14 days or less than 20mg per day for at least 40 days); b. At least one aminosalicylate (i.e. mesalamine, balsalazide, sulfasalazine); c. At least one oral systemic agent for ulcerative colitis [i.e. azathioprine or 6-mercaptopurine (6-MP)]; Treatment must be prescribed by a gastroenterologist." 6. **Added the following quantity restriction** under "Quantity/Days Supply Restrictions" section: "Rheumatologic conditions (Rheumatoid Arthritis, Psoriatic Arthritis, Ankylosing Spondylitis): Quantities of up to 1 of the 50mg syringes per month; 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."

	7. **Updated references** to include Simponi Prescribing Information.

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.