MEDICATION POLICY

Generic Name: Golimumab

Therapeutic Class or Brand Name: Simponi®

Applicable Drugs (if Therapeutic Class)**:** N/A

Date of Origin: 2/1/13 **Date Last Reviewed/Revised:** 11/21/17

GPI Code: 66270040002020

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).

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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)
  - Rituxan® (rituximab)
  - Siliq™ (brodalumab)
  - Stelara® (ustekinumab)
  - 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:** An updated letter of medical necessity or progress notes showing improvement or maintenance with medication.

Appendix:

N/A

References:

1. http://blue.regence.com/trgmedpol/drugs/dru183.pdf.
2. http://blue.regence.com/trgmedpol/drugs/dru183b.pdf.
3. https://npsonline.pti-nps.com.
4. http://www.simponi.com/shared/product/simponi/prescribing-information.pdf.

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Historical Tracking Of Changes Made To Policy	
11/21/2017	1. **Added** "Kevzara® (sarilumab)"**,** "Siliq™ (brodalumab)"**, and** "Tremfya™ (guselkumab)" **to list under Exclusion Criteria**. 2. **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/pharmacy/priorauthorization/pdf/Simponi%20RA,%20PA%20&%20AS%202014-12-26.pdf" **from under References** (links no longer valid).
3/2/2015	1. **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**.

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	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.