



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: 9/20/16

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)
 - Kineret® (anakinra)
 - Orencia® (abatacept)
 - Rituxan® (rituximab)
 - Stelara® (ustekinumab)
 - Taltz® (Ixekizumab)
 - TNF inhibitors [Cimzia® (certolizumab pegol), Enbrel® (etanercept), Humira® (adalimumab), Remicade® (infliximab), Simponi® Aria® (golimumab)]
 - 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.

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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	
9/20/2016	1. Reinserted “Refer to Plan for individual adoption of specific Medication Policies” in disclaimer.
8/26/2016	<p>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.</p> <p>2. Changed “Coadministration of Simponi® with...Xeljanz® (tofacitinib)...” to “Coadministration of Simponi® with...Xeljanz®/ XR (tofacitinib)...” under Exclusion Criteria.</p> <p>3. Changed “Cosentyx™” to “Cosentyx®” under Exclusion Criteria.</p> <p>4. Added “Taltz® (Ixekizumab)” to list under Exclusion Criteria.</p> <p>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).</p>
3/2/2015	1. Added “Cosentyx™ (secukinumab)” to list under Exclusion Criteria.
2/28/2015	<p>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.</p> <p>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.</p> <p>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.</p> <p>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.</p>

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Historical Tracking Of Changes Made To Policy	
	<p>5. Added “http://blue.regence.com/trgmedpol/drugs/dru183b.pdf” under References.</p> <p>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.</p>
10/15/2013	<p>1. Adapted policy to new format.</p> <p>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.</p> <p>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”.</p> <p>4. Added “Diagnosis must be established by a rheumatologist” as criterion for Ankylosing Spondylitis.</p> <p>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.”</p> <p>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.”</p> <p>7. Updated references to include Simponi Prescribing Information.</p>

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