Humana. CareSource™

PHARMACY POLICY STATEMENT
Kentucky Medicaid

DRUG NAME	Simponi (golimumab)
BILLING CODE	Must use valid NDC code
BENEFIT TYPE	Pharmacy
SITE OF SERVICE ALLOWED	Home
COVERAGE REQUIREMENTS	Prior Authorization Required (Non-Preferred Product) Alternative preferred products include Actemra, Enbrel, Cimzia, Cosentyx, Kevzara, Olumiant, Otezla and Xeljanz QUANTITY LIMIT— 1 per 28 days
LIST OF DIAGNOSES CONSIDERED **NOT** MEDICALLY NECESSARY	Click Here

Simponi (golimumab) is a **non-preferred** product and will only be considered for coverage under the **pharmacy** benefit when the following criteria are met:

Members must be clinically diagnosed with one of the following disease states and meet their individual criteria as stated.

ANKYLOSING SPONDYLITIS (AS)

For **initial** authorization:

1. Member must be 18 years of age or older; AND
2. Must have a documented negative TB test (i.e., tuberculosis skin test (PPD), an interferon-release assay (IGRA)) within 12 months prior to starting therapy; AND
3. Medication must be prescribed by a rheumatologist; AND
4. Member has had back pain for 3 months or more that began before the age of 50; AND
5. Current imaging results show an inflammation of one or both of the sacroiliac joints; AND
6. Member shows at least **one** of the following signs or symptoms of Spondyloarthritis:
   a) Arthritis;
   b) Elevated serum C-reactive protein;
   c) Inflammation at the tendon, ligament or joint capsule insertions;
   d) Positive HLA-B27 test;
   e) Limited chest expansion;
   f) Morning stiffness for 1 hour or more; AND
7. Member meets at least **one** of the following scenarios:
   a) Member has Axial (spinal) disease;
   b) Member has peripheral arthritis without axial involvement and has tried and failed treatment with methotrexate or sulfasalazine. Treatment failure requires at least 30 days of therapy without an adequate response; AND
8. Member has tried and failed to respond to treatment with at least **two** prescription NSAIDs taken at the maximum recommended dosages. Treatment failure requires at least 30 days of therapy without an adequate response; AND
9. Member must have tried and failed treatment with at least **two** of the following: Enbrel, Cimzia and Cosentyx. Treatment failure requires at least for 30 days of therapy with each drug.

10. **Dosage allowed:** 50 mg subcutaneously once a month.

If member meets all the requirements listed above, the medication will be approved for 12 months.

For **reauthorization**:
1. Must have been retested for TB with a negative result within the past 12 months; AND
2. Member must be in compliance with all other initial criteria; AND
3. Chart notes have been provided that show the member has shown improvement of signs and symptoms of disease.

If member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.

PSORIATIC ARTHRITIS (PsA)

For **initial** authorization:
1. Member must be 18 years of age or older; AND
2. Must have a documented negative TB test (i.e., tuberculosis skin test (PPD), an interferon-release assay (IGRA)) within 12 months prior to starting therapy; AND
3. Medication must be prescribed by a rheumatologist or dermatologist; AND
4. Member must have tried and failed treatment with at least **two** of the following: Enbrel, Cimzia, Cosentyx, Otezla and Xeljanz. Treatment failure requires at least for 30 days of therapy with each drug; AND
5. Member meets at least **one** of the following scenarios:
   a. Member has predominantly axial disease (i.e., sacroiliitis or spondylitis) as indicated by radiographic evidence;
   b. Member has shown symptoms of predominantly axial disease (i.e., sacroiliitis or spondylitis) for more than 3 months (i.e., limited spinal range of motion, spinal morning stiffness for more than 30 minutes) AND has tried and failed to respond to treatment with at least 2 prescription NSAIDs taken at the maximum recommended dosages. Treatment failure requires at least 30 days of therapy without an adequate response;
   c. Member has predominately non-axial disease (e.g., peripheral synovitis or dactylitis or nail involvement) and has tried and failed to respond to treatment with at least 30-day trial of methotrexate and NSAID taken at the maximum recommended dosages (if unable to tolerate or has contraindication to methotrexate than 30-day trial of sulfasalazine or azathioprine or cyclosporine).
6. **Dosage allowed:** 50 mg subcutaneously once a month.

If member meets all the requirements listed above, the medication will be approved for 12 months.

For **reauthorization**:
1. Must have been retested for TB with a negative result within the past 12 months; AND
2. Member must be in compliance with all other initial criteria; AND
3. Chart notes have been provided that show the member has shown improvement of signs and symptoms of disease.

If member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.

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RHEUMATOID ARTHRITIS (RA)

For **initial** authorization:

1. Member must be 18 years of age or older with moderate to severe active RA; AND
2. Must have a documented negative TB test (i.e., tuberculosis skin test (PPD), an interferon-release assay (IGRA)) within 12 months prior to starting therapy; AND
3. Medication must be prescribed by a rheumatologist; AND
4. Medication is being given in combination with methotrexate or with another immunosuppressive agent if the member cannot tolerate methotrexate; AND
5. Member must have tried and failed treatment with at least **two** non-biologic DMARDS (i.e., methotrexate, hydroxychloroquine, sulfasalazine, azathioprine, cyclosporine and leflunomide) or must have documented contraindication to all non-biologic DMARDS. Treatment trial duration with each non-biologic DMARD agent must have been at least 30 days; AND
6. Member has tried and failed treatment with at least **two** of the following: Actemra, Cimzia, Enbrel, Kevzara, Olumiant and Xeljanz. Treatment failure requires at least for 30 days of therapy with each drug.
7. **Dosage allowed:** 50 mg subcutaneously once a month.

If member meets all the requirements listed above, the medication will be approved for 12 months.

For **reauthorization**:

1. Must have been retested for TB with a negative result within the past 12 months; AND
2. Member must be in compliance with all other initial criteria; AND
3. Chart notes have been provided that show the member has shown improvement of signs and symptoms of disease.

If member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.

ULCERATIVE COLITIS (UC)

For **initial** authorization:

1. Member is 18 years of age or older with moderate to severe active UC; AND
2. Must have a documented negative TB test (i.e., tuberculosis skin test (PPD), an interferon-release assay (IGRA)) within 12 months prior to starting therapy; AND
3. Medication must be prescribed by a gastroenterologist; AND
4. Member must meet at least **one** of the following:
   a) Member was hospitalized with fulminant ulcerative colitis (i.e., severe ulcerative colitis with more than 10 stools per day, continuous bleeding, abdominal pain, and distension, and acute, severe toxic symptoms including fever and anoxia);
   b) Member was hospitalized and after three days of intravenous steroids still has a CRP greater than 45 or more than 8 bloody bowel movements;
   c) Member is refractory to or requires continuous immunosuppression with corticosteroids (e.g., methylprednisolone, prednisone at a dose of 40 to 60 mg/day (or equivalent), cortisone, etc.) AND is refractory to or has a contraindication to 5-aminosalicylic acid agents (e.g., balsalazide, mesalamine, sulfasalazine) and immunosuppressants (azathioprine and 6-mercaptopurine); AND
5. **Dosage allowed:** 200 mg subcutaneously at week 0, then 100 mg at week 3, followed by 100 mg every 4 weeks thereafter.

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If member meets all the requirements listed above, the medication will be approved for 12 months.

For **reauthorization**:
1. Must have been retested for TB with a negative result within the past 12 months; AND
2. Member must be in compliance with all other initial criteria; AND
3. Chart notes have been provided that show the member has shown improvement of signs and symptoms of disease.

If member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.

CareSource considers Simponi (golimumab) not medically necessary for the treatment of the following disease states based on a lack of robust clinical controlled trials showing superior efficacy compared to currently available treatments:

- Active infections
- Asthma
- Cellulitis
- Crohn's disease
- Dissecting scalp cellulitis
- For use in combination with TNF-inhibitors (i.e., Enbrel, Humira, Remicade, Kineret)
- Giant-cell arteritis
- Infectious uveitis
- Lupus perino
- Osteoarthritis
- Relapsing polychondritis
- Sarcoidosis
- Sciatica
- Spondyloarthritis
- Takayasu's arteritis
- Vogt-Koyanagi

DATE	ACTION/DESCRIPTION
05/15/2017	New policy for Simponi created. Policies SRx-0041 and SRx-0042 archived. For diagnoses of AS and RA: trial of Humira and Enbrel was added. For UC: trial of Humira required. List of diagnoses considered not medically necessary was added.
02/26/2019	Humira was removed from criteria; Actemra, Cimzia, Cosentyx, Kevzara, Olumiant, Otezla and Xeljanz added to trial agents list. TB test allowed to be done within 12 months prior to initiation of therapy; chest x-ray option removed. References added. Symptoms of back pain for AS extended till before age of 50. Other drugs options allowed for PsA if there is an intolerance or contraindication to methotrexate.

References:

1. Simponi [prescribing information]. Horsham, PA; Janssen Biotech, Inc.: January, 2014.

2. Menter A, Korman NJ, Elmets CA, et al. Guidelines of care for the management of psoriasis and psoriatic arthritis Section 6. Guidelines of care for the treatment of psoriasis and psoriatic arthritis: Case-based presentations and evidence-based conclusions. J Am Acad Dermatol. 2011 Feb 7.
3. Singh, J., et.al.,(2012). 2012 Update of the 2008 American College of Rheumatology Recommendations for the Use of Disease-Modifying Anti-rheumatic Drugs and Biologic Agents in the Treatment of Rheumatoid Arthritis. Arthritis Care & Research, 64(5), 625-639, May 2012.
4. Terdiman JP, Gruss CB, Heidelbaugh JJ, Sultan S, Falck-Ytter YT; AGA Institute Clinical Practice and Quality Management Committee. American Gastroenterological Association Institute guideline on the use of thiopurines, methotrexate, and anti-TNF-α biologic drugs for the induction and maintenance of remission in inflammatory Crohn's disease. Gastroenterology. 2013 Dec;145(6):1459-63.
5. Higgins J, Green S, editors. Cochrane handbook for systematic reviews of interventions, Version 5.1.0 [updated March 2011]. The Cochrane Collaboration. Available from: URL:www.cochrane-handbook.org.
6. FDA Approves New Drug for Rheumatoid Arthritis; Pharmacist's Letter; March 2010; Vol: 26 Rheumatoid arthritis: the role of DMARDs. Pharmacist's Letter/Prescriber's Letter July 2012;25(2):250210.
7. Li Z, et al. Efficacy and safety results from a Phase 3, randomized, placebo-controlled trial of subcutaneous golimumab in Chinese patients with active rheumatoid arthritis despite methotrexate therapy. Int J Rheum Dis. 2016 Nov;19(11):1143-1156.
8. Smolen JS. Insights into the efficacy of golimumab plus methotrexate in patients with active rheumatoid arthritis who discontinued prior anti-tumour necrosis factor therapy: post-hoc analyses from the GO-AFTER study. Ann Rheum Dis. 2014 Oct;73(10):1811-8.
9. Michelon MA, et al. Role of golimumab, a TNF-alpha inhibitor, in the treatment of the psoriatic arthritis. Clin Cosmet Investig Dermatol. 2010;3:79-84.
10. Kavanaugh A, et al. Golimumab in psoriatic arthritis: one-year clinical efficacy, radiographic, and safety results from a phase III, randomized, placebo-controlled trial. Arthritis Rheum. 2012 Aug;64(8):2504-17.
11. Sieper J, et al. A randomized, double-blind, placebo-controlled, sixteen-week study of subcutaneous golimumab in patients with active nonradiographic axial spondyloarthritis. Arthritis Rheumatol. 2015 Oct;67(10):2702-12.
12. Inman RD, et al. Efficacy and safety of golimumab in patients with ankylosing spondylitis: results of a randomized, double-blind, placebo-controlled, phase III trial. Arthritis Rheum. 2008 Nov;58(11):3402-12.

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