Effective Date **6/1/2024**
Coverage Policy Number **IP0237**

Golimumab Subcutaneous

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Related Coverage Resources

INSTRUCTIONS FOR USE
The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

Overview

This policy supports medical necessity review for golimumab subcutaneous (**Simponi®**).

Receipt of sample product does not satisfy any criteria requirements for coverage.

Medical Necessity Criteria

Golimumab subcutaneous (Simponi) is considered medically necessary when the following are met:

1. **Ankylosing Spondylitis.** Individual meets **BOTH** of the following criteria:
    A. Documentation of **ONE** of the following:
        i. Failure, contraindication, or intolerance to **ONE** non-steroidal anti-inflammatory drug (NSAID)
        ii. Already tried a biologic or targeted synthetic DMARD (tsDMARD)
    B. Medication is prescribed by, or in consultation with a rheumatologist
    C. Non-Preferred product criteria is met, refer to below table(s) [Employer Group Plans, Individual and Family Plan]

2. **Non-radiographic Axial Spondyloarthritis**. Individual meets **ALL** of the following criteria:
    A. Objective signs of inflammation, defined as **ONE** of the following:
        i. C-reactive protein (CRP) elevated beyond the upper limit of normal for the reporting laboratory
        ii. Sacroiliitis reported on magnetic resonance imaging (MRI)
    B. Documentation of **ONE** of the following:
        i. Failure, contraindication or intolerance to **ONE** non-steroidal anti-inflammatory drug (NSAID)
        ii. Already tried a biologic or targeted synthetic DMARD (tsDMARD) for Non-radiographic Axial Spondyloarthritis
    C. Medication is prescribed by, or in consultation with, a rheumatologist or prescriber who specializes in Non-radiographic Axial Spondyloarthritis

3. **Psoriatic Arthritis.** Individual meets **BOTH** of the following criteria:
    A. Medication is being prescribed by, or in consultation with a rheumatologist or dermatologist
    B. Non-Preferred product criteria is met, refer to below table(s) [Employer Group Plans, Individual and Family Plan]

4. **Rheumatoid Arthritis.** Individual meets **ALL** of the following criteria:
    A. Documentation of **ONE** of the following:
        i. Failure to **ONE** disease-modifying antirheumatic drug (DMARD), unless contraindicated or intolerant
        ii. Already tried a biologic or targeted synthetic DMARD (tsDMARD) for Rheumatoid Arthritis
    B. Medication is prescribed by, or in consultation with a rheumatologist
    C. Non-Preferred product criteria is met, refer to below table(s) [Employer Group Plans, Individual and Family Plan]

5. **Spondyloarthritis (non-axial disease): Reactive Arthritis (Reiter's disease) and Undifferentiated Arthritis.** Individual meets **ALL** of the following criteria:
    A. Has arthritis primarily in the knees, ankles, elbows, wrists, hands, and/or feet
    B. Documentation of **ONE** of the following:
        i. Failure to **ONE** conventional synthetic disease-modifying anti-rheumatic drug (csDMARD), unless contraindicated or intolerant
        ii. Already tried a biologic for non-axial spondyloarthritis
    C. Medication is prescribed by, or in consultation with, a rheumatologist

6. **Ulcerative Colitis.** Individual meets **ALL** of the following:
    A. 18 years of age or older
    B. Documentation of **ONE** of the following:
        i. Failure to **ONE** conventional systemic therapy, unless contraindicated or intolerant
        ii. Already tried a biologic or targeted synthetic DMARD (tsDMARD) used in Ulcerative Colitis
        iii. Has pouchitis AND has tried therapy with an antibiotic (for example, metronidazole, ciprofloxacin), corticosteroid enema or suppository, or mesalamine enema or suppository
    C. Medication is prescribed by, or in consultation with, a gastroenterologist
    D. Non-Preferred product criteria is met, refer to below table(s) [Employer Group Plans, Individual and Family Plan]

Coverage varies across plans and may require the use of Preferred Products. Refer to the customer's benefit plan document for coverage details.

Employer Group Plans	
Condition	**Non-Preferred Product Criteria**
Ankylosing Spondylitis	**For Simponi 50 mg,** documentation of failure, contraindication, or intolerance to **TWO** of the following: A. **Adalimumab Product: Adalimumab-adaz/Hyrimoz** (by Sandoz/Novartis)**, Adalimumab – adbm/Cyltezo**, **Adalimumab-ryvk/Simlandi,** or **Humira** (by AbbVie) [requires prior authorization] B. **Cimzia** [requires prior authorization] C. **Enbrel** [requires prior authorization] D. **Taltz** [requires prior authorization]
Psoriatic Arthritis	**For Simponi 50 mg,** documentation of failure, contraindication, or intolerance to **TWO** of the following from at least two different drug classes: A. IL-12/23 Blocker: **Stelara SC** [requires prior authorization] B. IL-17 Blocker: **Taltz** [requires prior authorization] C. IL-23 Blocker: **Skyrizi SC, Tremfya** [requires prior authorization] D. JAK inhibitor: **Rinvoq, Xeljanz/XR** [requires prior authorization] E. PDE Type 4 Inhibitor: **Otezla** [requires prior authorization] F. TNF Inhibitors: **Adalimumab Product** (**Adalimumab-adaz/Hyrimoz** [by Sandoz/Novartis]**, Adalimumab – adbm/Cyltezo**, **Adalimumab-ryvk/Simlandi,** or **Humira** [by AbbVie]), **Cimzia**, **Enbrel** [requires prior authorization]
Rheumatoid Arthritis	**For Simponi 50 mg,** documentation of failure, contraindication, or intolerance to **TWO** of the following: A. **Actemra** [requires prior authorization] B. **Adalimumab Product** (**Adalimumab-adaz/Hyrimoz** [by Sandoz/Novartis]**, Adalimumab – adbm/Cyltezo**, **Adalimumab-ryvk/Simlandi,** or **Humira** [by AbbVie]) [requires prior authorization] C. **Cimzia** [requires prior authorization] D. **Enbrel** [requires prior authorization] E. **Rinvoq** [requires prior authorization] F. **Xeljanz/XR** [requires prior authorization]
Ulcerative Colitis - Adult	**For Simponi 100 mg,** documentation of failure, contraindication, or intolerance to **ONE** of the following **adalimumab products:** A. **Adalimumab-adaz or Hyrimoz** (by Sandoz/Novartis) [requires prior authorization] B. **Adalimumab – adbm or Cyltezo** [requires prior authorization] C. **Adalimumab-ryvk or Simlandi** [requires prior authorization] D. **Humira** (by AbbVie) [requires prior authorization]

Individual and Family Plan Prescription	
Condition	**Non-Preferred Product Criteria**
Ankylosing Spondylitis	**For Simponi 50 mg,** documentation of failure, contraindication, or intolerance to **TWO** of the following:

Individual and Family Plan Prescription	
Condition	**Non-Preferred Product Criteria**
	A. **Adalimumab Product: Adalimumab-adaz/Hyrimoz** (by Sandoz/Novartis)**, Adalimumab – adbm/Cyltezo**, **Adalimumab-ryvk/Simlandi,** or **Humira** (by AbbVie) [requires prior authorization] B. **Cimzia** [requires prior authorization] C. **Cosentyx** [requires prior authorization] D. **Enbrel** [requires prior authorization]
Psoriatic Arthritis	**For Simponi 50 mg,** documentation of failure, contraindication, or intolerance to **TWO** of the following from at least two different drug classes: A. IL-12/23 Blocker: **Stelara SC** [requires prior authorization] B. IL-17 Blocker: **Cosentyx** [requires prior authorization] C. IL-23 Blocker: **Skyrizi SC, Tremfya** [requires prior authorization] D. JAK inhibitor: **Rinvoq, Xeljanz/XR** [requires prior authorization] E. PDE Type 4 Inhibitor: **Otezla** [requires prior authorization] F. TNF Inhibitors: **Adalimumab Product** (**Adalimumab-adaz/Hyrimoz** (by Sandoz/Novartis)**, Adalimumab – adbm/Cyltezo**, **Adalimumab-ryvk/Simlandi,** or **Humira** [by AbbVie]), **Cimzia**, **Enbrel** [requires prior authorization]
Rheumatoid Arthritis	**For Simponi 50 mg,** documentation of failure, contraindication, or intolerance to **TWO** of the following: A. **Actemra SC** [requires prior authorization] B. **Adalimumab Product: Adalimumab-adaz/Hyrimoz** (by Sandoz/Novartis)**, Adalimumab – adbm/Cyltezo**, **Adalimumab-ryvk/Simlandi,** or **Humira** (by AbbVie) [requires prior authorization] C. **Cimzia** [requires prior authorization] D. **Enbrel** [requires prior authorization] E. **Rinvoq** [requires prior authorization] F. **Xeljanz/ XR** [requires prior authorization]
Ulcerative Colitis - Adult	**For Simponi 100 mg,** documentation of failure, contraindication, or intolerance to **ONE** of the following a**dalimumab products:** A. **Adalimumab-adaz or Hyrimoz** (by Sandoz/Novartis) [requires prior authorization] B. **Adalimumab – adbm or Cyltezo** [requires prior authorization] C. **Adalimumab-ryvk or Simlandi** [requires prior authorization] D. **Humira** (by AbbVie) [requires prior authorization]

When coverage is available and medically necessary, the dosage, frequency, duration of therapy, and site of care should be reasonable, clinically appropriate, and supported by evidence-based literature and adjusted based upon severity, alternative available treatments, and previous response to therapy.

Reauthorization Criteria

Continuation of golimumab subcutaneous (Simponi) is considered medically necessary for **ALL** covered diagnoses when initial criteria are met AND beneficial response is demonstrated.

Authorization Duration

Initial approval duration is up to 12 months.
Reauthorization approval duration is up to 12 months.

Conditions Not Covered

Golimumab subcutaneous (Simponi) is considered experimental, investigational or unproven for **ANY** other use including the following (this list may not be all inclusive):

1. **Concurrent Use with a Biologic or with a Targeted Synthetic Disease-Modifying Antirheumatic Drug (DMARD).** Simponi subcutaneous should not be administered in combination with another biologic or with a targeted synthetic DMARD used for an inflammatory condition. Combination therapy is generally not recommended due to a potentially higher rate of adverse events with combinations and lack of data supportive of additional efficacy.
   This does not exclude the use of conventional synthetic DMARDs (e.g., methotrexate, leflunomide, hydroxychloroquine, and sulfasalazine) in combination with Simponi subcutaneous.

2. **Plaque Psoriasis without Psoriatic Arthritis.** Simponi subcutaneous is indicated in patients with psoriatic arthritis, but it has not been evaluated and it is not indicated in patients with plaque psoriasis without psoriatic arthritis. Prospective, controlled trials are needed to determine safety and efficacy in plaque psoriasis. Other TNFis (e.g., etanercept, adalimumab, and infliximab products, Cimzia® [certolizumab pegol subcutaneous injection]) are indicated for the treatment of plaque psoriasis.

Background

OVERVIEW
Simponi Subcutaneous, a tumor necrosis factor inhibitor (TNFi), is approved for the following uses:[1]

- **Ankylosing spondylitis,** for treatment of adults with active disease either alone or in combination with methotrexate or other non-biologic disease-modifying antirheumatic drugs (DMARDs).
- **Psoriatic arthritis,** for treatment of adults with active disease either alone or in combination with methotrexate or other non-biologic DMARDs.
- **Rheumatoid arthritis,** for treatment of adults with moderate to severe active disease in combination with methotrexate.
- **Ulcerative colitis,** for inducing and maintaining clinical response, improving endoscopic appearance of the mucosa during induction, inducing clinical remission, and achieving and sustaining clinical remission in induction responders in adults with moderate to severe disease who have demonstrated corticosteroid dependence or who have had an inadequate response to or failed to tolerate oral aminosalicylates, oral corticosteroids, azathioprine, or 6-mercaptopurine.

Guidelines
TNFis feature prominently in guidelines for treatment of inflammatory conditions.

- **Psoriatic Arthritis:** Guidelines from American College of Rheumatology (ACR) [2019] recommend TNFis over other biologics for use in treatment-naïve patients and in those who were previously treated with an oral therapy.[3]
- **Rheumatoid Arthritis:** Guidelines from ACR (2015) have TNFis and non-TNF biologics, administered with or without methotrexate, equally positioned as a recommended therapy following a trial of a conventional synthetic DMARD (e.g., methotrexate, leflunomide, hydroxychloroquine, sulfasalazine).[4]
- **Spondyloarthritis:** Guidelines for ankylosing spondylitis and non-radiographic axial spondylitis are published by the ACR/Spondylitis Association of America/Spondyloarthritis Research and Treatment Network (2019).[2] TNFis are recommended for the initial biologic. In those who are secondary non-responders to a TNFi, a second TNFi is recommended over switching out of the class.
- **Ulcerative Colitis:** Updated American College of Gastroenterology guidelines for ulcerative colitis (2019) note that the following agents can be used for induction of remission in moderately to severely active disease: budesonide tablets; oral or intravenous systemic corticosteroids, Entyvio® (vedolizumab intravenous infusion), Xeljanz®/XR (tofacitinib tablets/extended-release tablets), or TNFis (adalimumab, Simponi subcutaneous, infliximab).[5] In addition to the approved indication, clinical guidelines for the management of pouchitis, published in 2009, indicate that first-line therapy for pouchitis is antibiotic therapy (e.g. metronidazole, ciprofloxacin).[8] Other treatment options include maintenance probiotics,

oral or topical budesonide, anti-inflammatory drugs (e.g., mesalamine), or immunosuppressive drugs (e.g., infliximab).

References

1. Simponi® injection [prescribing information]. Horsham, PA: Janssen Biotech Inc; September 2019.
2. Ward MM, Deodhar A, Gensler LS, et al. 2019 update of the American College of Rheumatology/Spondylitis Association of America/Spondyloarthritis Research and Treatment Network recommendations for the treatment of ankylosing spondylitis and nonradiographic axial spondyloarthritis. *Arthritis Rheumatol*. 2019;71(10):1599-1613.
3. Singh JA, Guyatt G, Ogdie A, et al. 2018 American College of Rheumatology/National Psoriasis Foundation Guideline for the treatment of psoriatic arthritis. *Arthritis Care Res (Hoboken).* 2019;71(1):2-29.
4. Singh JA, Saag KG, Bridges SL Jr, et al. 2015 American College of Rheumatology Guideline for the treatment of rheumatoid arthritis. *Arthritis Rheumatol*. 2016;68(1):1-26.
5. Rubin DT, Ananthakrishnan AN, Siegel CA, et al. ACG clinical guideline: ulcerative colitis in adults. *Am J Gastroenterol*. 2019;114(3):384-413.
6. Furst DE, Keystone EC, So AK, et al. Updated consensus statement on biological agents for the treatment of rheumatic diseases, 2012. *Ann Rheum Dis*. 2013;72 Suppl 2:ii2-34.
7. Kavanaugh A, McInnes I, Mease P, et al. Golimumab, a new human tumor necrosis factor alpha antibody, administered every four weeks as a subcutaneous injection in psoriatic arthritis: Twenty-four-week efficacy and safety results of a randomized, placebo-controlled study. *Arthritis Rheum.* 2009;60:976-986.

Appendix

Table 1. Approved TNFis for Targeted Indications.

	Rheumatology					Dermatology	Gastroenterology	
	RA	JIA	AS	nr-axSpA	PsA	PsO	CD	UC
Tumor Necrosis Factor Inhibitors								
Cimzia	√	--	√	√	√	√	√	--
Enbrel	√	√	√	--	√	√	--	--
Humira	√	√	√	--	√	√	√	√
Infliximab Products	√	--	√	--	√	√	√	√
Simponi Subcutaneous	√	--	√	--	√	--	--	√
Simponi Aria	√	√	√	--	√	--	--	--

TNFis – Tumor necrosis factor inhibitors; RA – Rheumatoid arthritis; JIA – Juvenile idiopathic arthritis; AS – Ankylosing spondylitis; nr-axSpA – Non-radiographic spondyloarthritis; PsA – Psoriatic arthritis; PsO – Plaque psoriasis; CD – Crohn's disease; UC – Ulcerative colitis.

Table 2. Approved IL-17, IL-23, and IL-12/23 Blockers for Targeted Indications.

	Rheumatology			Dermatology	Gastroenterology	
	Ankylosing Spondylitis	nr-axSpA	Psoriatic Arthritis	Plaque Psoriasis	Crohn's Disease	Ulcerative Colitis
Interleukin-17 Blockers						
Cosentyx	√	√	√	√	--	--
Siliq	--	--	--	√	--	--
Taltz	√	√	√	√	--	--
Interleukin-23 Blockers						
Ilumya	--	--	--	√	√	--
Skyrizi Intravenous	--	--	--	--	√[#]	--
Skyrizi Subcutaneous	--	--	√	√	√[^]	--
Tremfya	--	--	√	√	--	--
Interleukin-12/23 Blockers						
Stelara Subcutaneous	--	--	√	√	√[^]	√[^]
Stelara Intravenous	--	--	--	--	√[#]	√[#]

IL – Interleukin; nr-axSpA – Non-radiographic spondyloarthritis; [^] Maintenance dosing only; [#] Induction dosing only.

Table 3. Approved Oral tsDMARDs for Targeted Indications.

	Rheumatology					Dermatology	Gastro-enterology
	Rheumatoid Arthritis	Juvenile Idiopathic Arthritis	Ankylosing Spondylitis	nr-axSpA	Psoriatic Arthritis	Plaque Psoriasis	Ulcerative Colitis
Janus Kinases Inhibitors							
Olumiant	√	--	--	--	--	--	--
Rinvoq	√	--	√	√	√	--	√
Xeljanz tablets	√	√[#]	√	--	√	--	√
Xeljanz oral solution	--	√[#]	--	--	--	--	--
Xeljanz XR	√	--	√	--	√	--	√
Phosphodiesterase Type 4 Inhibitor							
Otezla	--	--	--	--	√	√	--
Sphingosine 1-Phosphate Receptor Modulator							
Zeposia	--	--	--	--	--	--	√
Tyrosine Kinase 2 Inhibitor							
Sotyktu	--	--	--	--	--	√	--

tsDMARDs – Targeted synthetic disease-modifying antirheumatic drugs; [#] Indicated in polyarticular JIA.

Table 4. Other Approved Biologics for Targeted Indications.

	Rheumatology		
	Rheumatoid Arthritis	**Juvenile Idiopathic Arthritis**	**Psoriatic Arthritis**
Interleukin-6 Blockers			
Actemra Intravenous	√	√^	--
Actemra Subcutaneous	√	√^	--
Kevzara	√	--	--
Interleukin-1 Blocker			
Kineret	√	--	--
T-Cell Costimulation Modulator			
Orencia Intravenous	√	√#	√
Orencia Subcutaneous	√	√#	√
CD20-Directed Cytolytic Antibody			
Rituximab Intravenous Products	√	--	--

^ Indicated in polyarticular and systemic JIA; # Indicated in polyarticular JIA.

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