Effective Date **6/1/2024**
Coverage Policy Number **IP0233**

Sarilumab

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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 sarilumab (Kevzara™).

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

Medical Necessity Criteria

Sarilumab (Kevzara) is considered medically necessary when ONE of the following are met:

1. **Polymyalgia Rheumatica**. Individual meets **ALL** of the following criteria:
   A. 18 years of age or older
   B. Documentation of failure, contraindication or intolerance to **ONE** systemic corticosteroid
   C. Medication is prescribed by, or in consultation with, a rheumatologist

2. **Rheumatoid Arthritis.** Individual meets **ALL** of the following criteria:
   A. Documentation of **ONE** of the following:

i. Failure to **ONE** conventional synthetic disease-modifying anti-rheumatic drug (csDMARD)
ii. Contraindication or intolerance to **ALL** csDMARDs
iii. Already tried a biologic or targeted synthetic DMARD (tsDMARD) for Rheumatoid Arthritis

B. Medication is being prescribed by, or in consultation with, a rheumatologist
C. Non-Preferred Product Criteria is met, refer to the below table(s) [Employer Group Plans, Individual and Family Plans]

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

Employer Group Plans	
Condition	**Non-Preferred Product Criteria**
Rheumatoid Arthritis	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]

Individual and Family Plan	
Condition	**Non-Preferred Product Criteria**
Rheumatoid Arthritis	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]

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 sarilumab (Kevzara) is considered medically necessary for **ALL** covered diagnoses when the above medical necessity 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

Any other use is considered experimental, investigational or unproven, including the following (this list may not be all inclusive):

1. **Ankylosing Spondylitis.** In a Phase II study, Kevzara did not demonstrate efficacy in patients with AS.[3]

2. **Concurrent use with a Biologic or with a Targeted Synthetic DMARD.** Kevzara should not be administered in combination with another biologic or targeted synthetic DMARD used for an inflammatory condition (see Appendix for examples). Combination therapy is generally not recommended due to a potential for a higher rate of adverse effects with combinations and lack of evidence for additive efficacy.

   This does NOT exclude the use of conventional synthetic DMARDs (e.g., methotrexate, leflunomide, hydroxychloroquine, and sulfasalazine) in combination with Kevzara.

3. **COVID-19 (Coronavirus Disease 2019).**[4-6] This includes requests for cytokine release syndrome associated with COVID-19.

Background

OVERVIEW

Kevzara, an interleukin-6 receptor inhibitor, is indicated for the treatment of the following conditions:[1]

- **Rheumatoid arthritis**, in adults with moderate to severe active disease who have had an inadequate response or intolerance to one or more disease-modifying antirheumatic drugs (DMARDs).
- **Polymyalgia rheumatica**, in adults who have had an inadequate response to corticosteroids or who cannot tolerate corticosteroid taper.

Guidelines

Kevzara is addressed in the following guidelines:

- **Rheumatoid Arthritis:** Guidelines from the American College of Rheumatology (ACR) [2021] recommend addition of a biologic or a targeted synthetic DMARD for a patient taking the maximum tolerated dose of methotrexate who is not at target.[2]
- **Polymyalgia Rheumatica:** Guidelines from the European League Against Rheumatism (EULAR)/ACR (2015) were published prior to approval of Kevzara of this condition.[7] The minimum effective individualized duration of glucocorticosteroid therapy is strongly recommended.

References

1. Kevzara® subcutaneous injection [prescribing information]. Bridgewater, NJ: Regeneron/Sanofi-Aventis; February 2023.
2. Fraenkel L, Bathon JM, England BR, et al. 2021 American College of Rheumatology guideline for the treatment of rheumatoid arthritis. Arthritis Rheumatol. 2021;73(7):1108-1123.
3. Sieper J, Braun J, Kay J, et al. Sarilumab for the treatment of ankylosing spondylitis: results of a Phase II, randomised, double-blind, placebo-controlled study (ALIGN). Ann Rheum Dis. 2015;74(6):1051-1057.
4. COVID-19 Treatment Guidelines Panel. Coronavirus Disease 2019 (COVID-19) Treatment Guidelines. National Institutes of Health. Updated January 26, 2023. Available at https://www.covid19treatmentguidelines.nih.gov/. Accessed March 7, 2023.
5. US National Institutes of Health. In: ClinicalTrials.gov [Internet]. Bethesda (MD): National Library of Medicine (US). 2000- [cited 2023 March 7]. Available from: https://clinicaltrials.gov/. Search terms: coronavirus, sarilumab.
6. Rochwerg B, Siemieniuk R, Jacobs M, et al. Therapeutics and COVID-19: living guideline. Updated January 12, 2023. Available at: https://app.magicapp.org/#/guideline/nBkO1E. Accessed on March 7, 2023.

7. Dejaco C, Singh YP, Perel P, et al. 2015 Recommendations for the management of polymyalgia rheumatica: a European League Against Rheumatism/American College of Rheumatology collaborative initiative. Ann Rheum Dis. 2015;74(10):1799-807.

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	√	√	√	--	√	√	--	--
Adalimumab products (Humira, biosimilars)	√	√	√	--	√	√	√	√
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	--	√#	--	--	--	--	--

	Rheumatology					Dermatology	Gastro-enterology
	Rheumatoid Arthritis	**Juvenile Idiopathic Arthritis**	**Ankylosing Spondylitis**	**nr-axSpA**	**Psoriatic Arthritis**	**Plaque Psoriasis**	**Ulcerative Colitis**
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.