Effective Date **6/1/2024**
Coverage Policy Number **IP0225**

Baricitinib

Table of Contents

Related Coverage Resources

COVID-19 Drug and Biologic Therapeutics

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 baricitinib (**Olumiant**®).

The use of baricitinib in the management of COVID-19 is addressed in a separate coverage policy. Please refer to the related coverage policy link above (COVID-19 Drug and Biologic Therapeutics).

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

Medical Necessity Criteria

Baricitinib (Olumiant) is considered medically necessary when ONE of the following are met:

1. **Alopecia Areata (includes alopecia universalis and alopecia totalis).** Individual meets **ALL** of the following criteria:
   A. 18 years of age or older
   B. Current episode of alopecia areata lasting for at least 6 months
   C. At least 50% scalp hair loss prior to initiating baricitinib

D. **ONE** of the following:
    i. Failure, contraindication or intolerance to **ONE** of the following:
        a. Conventional systemic therapy used for at least 3 months (for example, corticosteroids, methotrexate, cyclosporine)
        b. Prescription topical corticosteroids used for at least 28 days
        c. Intralesional corticosteroids used for at least 3 months
    ii. Already tried Litfulo (ritlecitinib capsules)
E. For Olumiant 4 mg tablet only, **ONE** of the following:
    i. Has not had adequate response to Olumiant 2 mg administered once daily and requires dose escalation to 4 mg
    ii. Has nearly complete or complete scalp hair loss, with or without substantial eyelash or eyebrow hair loss
F. Medication is prescribed by, or in consultation with, a dermatologist

2. Rheumatoid Arthritis. Individual meets **ALL** of the following criteria:
A. 18 years of age or older
B. Documentation of **ONE** of the following:
    i. Failure after 3 months to **ONE** conventional synthetic disease-modifying anti-rheumatic drug (csDMARD)
    ii. Contraindication or intolerance to **ALL** csDMARD
    iii. Already tried a biologic or targeted synthetic DMARD for rheumatoid arthritis
C. Documentation of **ONE** of the following:
    i. Failure after 3 months to **ONE** tumor necrosis factor inhibitor (TNFi)
    ii. Contraindication or intolerance to tumor necrosis factor inhibitors (TNFi)
D. Medication is being prescribed by, or in consultation with, a rheumatologist
E. 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] A. **Cimzia** [requires prior authorization] B. **Enbrel** [requires prior authorization] C. **Rinvoq** [requires prior authorization] D. **Xeljanz/XR** [requires prior authorization]

Individual and Family 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]

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 baricitinib (Olumiant) is considered medically necessary when **ONE** of the following is met:

1. **Alopecia Areata.** Individual meets **ONE** of the following criteria:
    A. For Olumiant 2 mg tablets, initial criteria are met AND beneficial response is demonstrated
    B. For Olumiant 4 mg tablets, meets **BOTH** of the following criteria:
        i. Initial criteria are met AND beneficial response is demonstrated
        ii. Has been titrated to the least effective dose to control disease

2. **Rheumatoid Arthritis.** Individual meets the following criteria:
    A. Initial criteria are met AND beneficial response is demonstrated

Authorization Duration

Initial approval duration:

- Rheumatoid Arthritis: up to 12 months
- Alopecia Areata: up to 6 months

Reauthorization approval duration:

- Rheumatoid Arthritis: up to 12 months
- Alopecia Areata: up to 6 months

Conditions Not Covered

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

1. **Causes of hair loss other than alopecia areata.** Olumiant is not indicated for the treatment of other causes of hair loss other than alopecia areata.[1]

2. **Concurrent Use with a Biologic, Targeted Synthetic DMARD or potent immunosuppressant.** The use of baricitinib is not recommended for use in combination with biologic immunomodulators, cyclosporine or other potent immunosuppressants (see Appendix for examples)[1]. 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.

3. **Concurrent Use with a Biologic Immunomodulator.** Olumiant is not recommended in combination with biologic immunomodulators (for example, Adbry [tralokinumab-ldrm subcutaneous injection], Cinqair [reslizumab intravenous], Dupixent [dupilumab subcutaneous injection], Fasenra [benralizumab subcutaneous injection], Nucala [mepolizumab subcutaneous injection], Tezspire [tezepelumab-ekko subcutaneous injection], and Xolair [omalizumab subcutaneous injection]).[1]

4. **Concurrent Use with Topical Janus Kinase Inhibitors (JAKis).** Olumiant should not be administered in combination with a topical JAKi (for example, Opzelura [ruxolitinib] cream]) used for Atopic Dermatitis. Combination therapy is generally not recommended due to a potential for a higher rate of adverse effects and lack of evidence for additive efficacy.

5. **Vitiligo.** Insufficient efficacy and safety data to support use in vitiligo. Xeljanz is not indicated for this use.[1] A small case series of 10 individuals with vitiligo were treated with JAK inhibitors. Five subjects achieved some repigmentation at sites of either sunlight exposure or low dose nbUVB light. The authors stated that JAK monotherapy does not seem to be effective, but appears to need concurrent nbUVB phototherapy or sunlight exposure. The authors concluded that prospective clinical trials are necessary to evaluate the use of JAK inhibitors in vitiligo. This study was limited by small sample size, retrospective design and no control group.[5]

Background

OVERVIEW

Olumiant, an inhibitor of the Janus kinases (JAK) pathways, is indicated for the following indications:[1]

- **Alopecia Areata,** in adults with severe disease.
- **Coronavirus Disease 2019 (COVID-19)**, for adults hospitalized requiring supplemental oxygen, non-invasive or invasive mechanical ventilation, or extracorporeal membrane oxygenation (ECMO). For COVID-19, the dose is 4 mg once daily for 14 days or until hospital discharge, whichever comes first.
- **Rheumatoid Arthritis**, in adults with moderate to severe active disease who have had an inadequate response to one or more tumor necrosis factor inhibitors. Olumiant is not recommended for use in combination with other JAK inhibitors, or in combination with biologics or potent immunosuppressants such as azathioprine or cyclosporine.

Guidelines

Olumiant is addressed in the following guidelines:

- **Alopecia Areata:** An international expert opinion on treatments for alopecia areata (2020) The American Academy of Dermatology lists JAK inhibitors among the therapies for treatment of extensive hair loss. First-line treatments for adults include topical and/or systemic corticosteroids. Steroid-sparing therapies to mitigate the risk associated with prolonged use of corticosteroids include cyclosporine, methotrexate, and azathioprine.
- **COVID-19:** The Infectious Disease Society of America (IDSA) and the National Institutes of Health (NIH) have developed treatment guidelines for the management of COVID-19 and each address the use of Olumiant.[3,4] Both the IDSA and NIH guidelines recommend Olumiant for hospitalized patients with COVID-19 for a duration of 14 days or until discharge from the hospital.
- **Rheumatoid Arthritis:** Guidelines from the American College of Rheumatology (2021) recommend addition of a biologic or a targeted synthetic disease-modifying antirheumatic drug (DMARD) for a patient taking the maximum tolerated dose of methotrexate who is not at target.[2]

References

1. Olumiant® tablets [prescribing information]. Indianapolis, IN: Lilly; June 2022.
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. COVID-19 Treatment Guidelines Panel. Coronavirus disease 2019 (COVID-19) treatment guidelines. National Institutes of Health. Available at: https://www.covid19treatmentguidelines.nih.gov/. Accessed on June 20, 2023.
4. Bhimraj A, Morgan RL, Shumaker AH, et al. Infectious Disease Society of America Guidelines on the treatment and management of patients with COVID-19. May 15, 2023. Available at: https://www.idsociety.org/COVID19guidelines. Accessed June 20, 2023.
5. Liu LY, Strassner JP, Refat MA, et al. Repigmentation in vitiligo using the janus kinase inhibitor, tofacitinib, may require concomitant light exposure. J Am Acad Dermatol. 2017 October ; 77(4): 675–682.

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	√	--	--	--	--	--	--
Opzelura	--	--	--	--	--	--	--
Rinvoq	√	--	√	√	√	--	√
Xeljanz tablets	√	√[#]	√	--	√	--	√
Xeljanz oral solution	--	√[#]	--	--	--	--	--
Xeljanz XR	√	--	√	--	√	--	√
Phosphodiesterase Type 4 Inhibitor							
Otezla	--	--	--	--	√	√	--
Sphingosine 1-Phosphate Receptor Modulator							
Zeposia	--	--	--	--	--	--	√
Tyrosine Kinase 2 Inhibitor							

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