Olumiant (baricitinib)

NOTICE

This policy contains information which is clinical in nature. The policy is not medical advice. The information in this policy is used by Wellmark to make determinations whether medical treatment is covered under the terms of a Wellmark member's health benefit plan. Physicians and other health care providers are responsible for medical advice and treatment. If you have specific health care needs, you should consult an appropriate health care professional. If you would like to request an accessible version of this document, please contact customer service at 800-524-9242.

BENEFIT APPLICATION

Benefit determinations are based on the applicable contract language in effect at the time the services were rendered. Exclusions, limitations or exceptions may apply. Benefits may vary based on contract, and individual member benefits must be verified. Wellmark determines medical necessity only if the benefit exists and no contract exclusions are applicable. This medical policy may not apply to FEP. Benefits are determined by the Federal Employee Program.

DESCRIPTION

The intent of the Olumiant drug policy is to ensure appropriate selection of patients for therapy based on product labeling, clinical guidelines and clinical studies while steering utilization to the most cost-effective medication within the therapeutic class. For this program, adalimumab-aacf, Enbrel, Cosentyx, Otezla, Rinvoq, Simponi, Skyrizi, Otulfi (ustekinumab-aauz), Tremfya, and Xeljanz/Xeljanz XR are the preferred products and will apply to members requesting treatment for an indication that is FDA-approved for the preferred product. The criteria will require the use of two of the health plan’s preferred products before the use of non-preferred products unless there are clinical circumstances that exclude the use of all the preferred products, the patient is currently receiving treatment with the non-preferred drug and experience a positive therapeutic outcome, or there is only one preferred product for an indication.

The indications below including FDA-approved indications and compendial uses are considered covered benefits provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications

1. Olumiant is indicated for the treatment of adult patients with moderately to severely active rheumatoid arthritis who have had an inadequate response to one or more tumor necrosis factor (TNF) blockers.
2. Olumiant is indicated for the treatment of coronavirus disease 2019 (COVID-19) in hospitalized adults requiring supplemental oxygen, non-invasive or invasive mechanical ventilation, or extracorporeal membrane oxygenation (ECMO).
3. Olumiant is indicated for the treatment of adult patients with severe alopecia areata.

Note: The criteria outlined in this policy is only applicable to coverage in the outpatient setting. Hospitalized members receiving Olumiant for the treatment of COVID-19 will be managed according to the member's inpatient benefit.

POLICY

Required Documentation

Submission of the following information is necessary to initiate the prior authorization review:

A. Rheumatoid Arthritis

1. For initial requests: Chart notes, medical record documentation, or claims history supporting previous medications tried, including response to therapy (if applicable).
2. For continuation requests: Chart notes or medical record documentation supporting positive clinical response.

B. Alopecia Areata

1. For initial requests:
   i. Chart notes, medical record documentation, or claims history supporting previous medications tried, including response to therapy (if applicable).
   ii. Chart notes or medical record documentation supporting more than 50% scalp hair loss (e.g., Severity of Alopecia Tool (SALT) score of 50 or higher).
2. For continuation requests: Chart notes or medical record documentation supporting positive clinical response (i.e., increased scalp hair coverage, 80% total scalp hair coverage [Severity of Alopecia Tool (SALT) score of 20 or less])

Must meet BOTH the Preferred Drug Plan Design and Criteria for Initial Approval/Continuation of Therapy when both are applicable.

Preferred Drug Plan Design

A. Rheumatoid Arthritis

Criteria for initial approval for rheumatoid arthritis will only apply when at least ONE of the following criteria are met:

1. Member has had an inadequate response to treatment or intolerable adverse event with at least TWO of the preferred products (Enbrel, adalimumab-aacf, Rinvoq, Simponi, and Xeljanz/Xeljanz XR).
2. Member has a clinical reason to avoid TNF-inhibitors (Enbrel, adalimumab-aacf, and Simponi) (See Appendix A) AND has had an inadequate response to treatment or intolerable adverse event with the preferred products, Rinvoq AND Xeljanz/Xeljanz XR.
3. Member is currently receiving treatment with the requested product through insurance (excludes obtainment as samples or via manufacturer's patient assistance programs) and experiencing a positive therapeutic outcome.

Prescriber Specialties (initial requests only)

This medication must be prescribed by or in consultation with one of the following:

A. Rheumatoid arthritis: rheumatologist
B. Alopecia areata: dermatologist

Criteria for Initial Approval

A. Moderately to severely active rheumatoid arthritis (RA)

1. Authorization of 12 months may be granted for adult members who have previously received a biologic (other than a TNF inhibitor) or targeted synthetic drug (e.g., Rinvoq, Xeljanz) indicated for moderately to severely active rheumatoid arthritis.

2. Authorization of 12 months may be granted for adult members for treatment of moderately to severely active RA when the member has experienced an inadequate response to at least one tumor necrosis factor (TNF) inhibitor.

B. Alopecia Areata

Authorization of 6 months may be granted for adult members for treatment of alopecia areata when ALL the following criteria are met:

1. Member has a diagnosis of severe alopecia (including alopecia totalis and alopecia universalis) defined as having more than 50% scalp hair loss (e.g., Severity of Alopecia Tool [SALT] score of 50 or higher).
2. Member has a current episode of alopecia areata lasting more than 6 months without spontaneous regrowth.
3. Duration of current episode of hair loss is less than 10 years.
4. Other forms of alopecia have been ruled out (e.g., androgenetic alopecia, trichotillomania, telogen effluvium, chemotherapy-induced hair loss, tinea capitis).
5. Member has had an inadequate response to corticosteroids (e.g., intralesional, oral, and/or topical depending on severity and age of the member).
6. Member has not been previously treated with another JAK inhibitor (e.g., ritlecitinib, ruxolitinib, tofacitinib) and had an inadequate response (i.e., absence of significant terminal hair growth after at least 12 weeks of treatment).
7. Member will not use requested medication in combination with other Janus kinase (JAK) inhibitors, biologic immunomodulators, cyclosporine, or other potent immunosuppressants

Continuation of Therapy

A. Moderately to severely active rheumatoid arthritis (RA)

Authorization of 12 months may be granted for all members (including new members) who are using the requested medication for moderately to severely active rheumatoid arthritis and who achieve or maintain a positive clinical response as evidenced by disease activity improvement of at least 20% from baseline in tender joint count, swollen joint count, pain, or disability.

B. Alopecia Areata

Initial continuation request: Authorization of 6 months may be granted for all members (including new members) who meet Criteria for Initial Approval above and are demonstrating a positive clinical response to therapy as evidenced by an improvement of at least 10% scalp hair coverage.

Subsequent continuation requests*: Authorization of 12 months may be granted for all members (including new members) who meet Criteria for Initial Approval above and achieve or maintain a positive clinical response as evidenced by at least 80% total scalp hair coverage (SALT score of 20 or less).

*Subsequent continuation requests criteria applies when member has received at least 12 months of Olumiant therapy.

Other

For all indications: Member has had a documented negative tuberculosis (TB) test (which can include a tuberculosis skin test [TST] or an interferon-release assay [IGRA])* within 12 months of initiating therapy for persons who are naïve to biologic drugs or targeted synthetic drugs associated with an increased risk of TB.

* If the screening testing for TB is positive, there must be further testing to confirm there is no active disease (e.g., chest x-ray). Do not administer the requested medication to members with active TB infection. If there is latent disease, TB treatment must be started before initiation of the requested medication.

For all indications: Member cannot use the requested medication concomitantly with any other biologic drug, targeted synthetic drug, or potent immunosuppressant such as azathioprine or cyclosporine.

Olumiant is considered **not medically necessary** for members who do not meet the criteria set forth above.

Non-Formulary Exception Criteria

Non-Formulary Exception criteria applies to formularies which do not include the requested product(s) on the formulary drug list. Meeting the criteria above may satisfy some, or all, portions of the Non-Formulary Exception Criteria. A medication that is non-formulary may be covered when the Criteria for Approval AND the following criteria are met:

1. The requested drug must be used for an FDA-approved indication, or an indication supported in the compendia of current literature (examples: AHFS, Micromedex, current accepted guidelines). Diagnostic testing/lab results required when applicable.
2. The prescribed dose/quantity must fall within the FDA-approved labeling or dosing guidelines found in the compendia of current literature.
3. All covered formulary alternative drugs on any tier will be ineffective, have been ineffective, would not be as effective as the non-formulary drug, or would have adverse effects. Documentation is required and must include chart note(s) or other documentation indicating prior treatment failure, severity of the adverse event (if any), and dosage and duration of the prior treatment, or contraindication to formulary alternatives.

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Dosage and Administration

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

Quantity Limits Apply

Olumiant - 30 tablets per 30 days

Appendix

Appendix A: Clinical reasons to avoid TNF-inhibitors

1. History of demyelinating disorder
2. History of congestive heart failure
3. History of hepatitis B infection
4. Autoantibody formation/lupus-like syndrome
5. Risk of lymphoma

CLINICAL RATIONALE

Olumiant received an indication for severe alopecia areata in June 2022 and was the first systemic treatment approved for that condition, although several medications have been used off-label in the past.

PROCEDURES AND BILLING CODES

To report provider services, use appropriate CPT* codes, Alpha Numeric (HCPCS level 2) codes, Revenue codes, and/or ICD diagnostic codes.

- N/A

REFERENCES

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- Smolen JS, Landewé R, Bijlsma J, et al. EULAR recommendations for the management of rheumatoid arthritis with synthetic and biological disease-modifying antirheumatic drugs: 2019 update. *Ann Rheum Dis.* 2020;79:685-699.
- Fraenkel L, Bathon JM, England BR, et al. 2021 American College of Rheumatology guideline for the treatment of rheumatoid arthritis. *Arthrit Care Res*. 2021;0:1-16.
- King B, Ohyama M, Kwon O, et al. Two phase 3 trials of baricitinib for alopecia areata. *NEJM*. 2022;386(18):1687-1699.
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*Some content reprinted from CVSHealth

POLICY HISTORY

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