Opzelura (ruxolitinib)

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 policy may not apply to FEP. Benefits are determined by the Federal Employee Program.

DESCRIPTION

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

FDA-Approved Indications

Opzelura is indicated for the topical short-term and non-continuous chronic treatment of mild to moderate atopic dermatitis in non-immunocompromised patients 2 years of age and older whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable.

Opzelura is indicated for the topical treatment of nonsegmental vitiligo in adult and pediatric patients 12 years of age and older.

Limitation of Use:

Use of Opzelura in combination with therapeutic biologics, other JAK inhibitors or potent immunosuppressants such as azathioprine or cyclosporine is not recommended.

POLICY

Criteria for Initial Approval

Atopic Dermatitis

Authorization of 3 months may be granted when the requested drug is being prescribed for topical short-term and non-continuous chronic treatment of mild to moderate atopic dermatitis in a non-immunocompromised patient when ALL of the following criteria are met:

- The requested drug is NOT being prescribed in combination with therapeutic biologics, other Janus kinase (JAK) inhibitors, or potent immunosuppressants such as azathioprine or cyclosporine
- The request is for an adult or pediatric patient 2 years of age or older.
- The patient meets ONE of the following:
    - The patient's disease is NOT adequately controlled with other topical prescription therapies (e.g., medium or higher potency topical corticosteroid, topical calcineurin inhibitor).
    - Other topical prescription therapies are NOT advisable (e.g., medium or higher potency topical corticosteroid, topical calcineurin inhibitor).
- The requested drug will NOT be applied to affected areas of greater than 20% body surface area (BSA)
- If additional quantities are being requested, then the requested drug is being prescribed to treat a body surface area that requires more than 60 grams per 28 days.

Nonsegmental Vitiligo

Authorization of 7 months may be granted when the requested drug is being prescribed for nonsegmental vitiligo when ALL of the following criteria are met:

- The requested drug is NOT being prescribed in combination with therapeutic biologics, other Janus kinase (JAK) inhibitors, or potent immunosuppressants such as azathioprine or cyclosporine
- The requested drug is for an adult or pediatric patient 12 years of age or older
- The requested drug will NOT be applied to affected areas of greater than 10% body surface area (BSA)
- If additional quantities are being requested, then the requested drug is being prescribed to treat a body surface area that requires more than 60 grams per 28 days.

Continuation of Therapy

Atopic Dermatitis

Authorization of 12 months may be granted when the requested drug is being prescribed for topical short-term and non-continuous chronic treatment of mild to moderate atopic dermatitis in a non-immunocompromised patient when ALL of the following criteria are met:

- The requested drug is NOT being prescribed in combination with therapeutic biologics, other Janus kinase (JAK) inhibitors, or potent immunosuppressants such as azathioprine or cyclosporine
- The request is for an adult or pediatric patient 2 years of age or older.
- The patient has achieved or maintained a positive clinical response as evidenced by improvement [(e.g., improvement in or resolution of any of the following signs and symptoms: erythema (redness), edema (swelling), xerosis (dry skin), erosions, excoriations (evidence of scratching), oozing and crusting, lichenification (epidermal thickening), OR pruritus (itching)].
- The requested drug will NOT be applied to affected areas of greater than 20% body surface area (BSA)
- If additional quantities are being requested, then the requested drug is being prescribed to treat a body surface area that requires more than 60 grams per 28 days.

Nonsegmental Vitiligo

Authorization of 12 months may be granted when the requested drug is being prescribed for nonsegmental vitiligo when ALL of the following criteria are met:

- The requested drug is NOT being prescribed in combination with therapeutic biologics, other Janus kinase (JAK) inhibitors, or potent immunosuppressants such as azathioprine or cyclosporine
- The request is for an adult or pediatric patient 12 years of age or older.
- The patient has achieved or maintained a positive clinical response as evidenced by improvement (e.g., meaningful repigmentation).
- The requested drug will NOT be applied to affected areas of greater than 10% body surface area (BSA).
- If additional quantities are being requested, then the requested drug is being prescribed to treat a body surface area that requires more than 60 grams per 28 days.

Dosing 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
60 gm per 21 days or 180 gm per 63 days

For larger body surface area (BSA) for Vitiligo: 180 grams per 21 days or 540 grams per 63 days.
For larger body surface area (BSA) for Atopic Dermatitis: Pediatric patients 2 to 11 years of age: 120 grams per 21 days or 360 grams per 63 days.
For larger body surface area (BSA) for Atopic Dermatitis: Patients 12 years of age and older: 240 grams per 21 days or 720 grams per 63 days.

The duration of 21 days is used for a 28-day fill period and 63 days is used for an 84-day fill period to allow time for refill processing.

The intent is for prescriptions of the requested drug to be filled one month at a time for new starts; there should be no 3-month supplies filled for new starts.

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.

- Code(s), if applicable

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POLICY HISTORY

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