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 12 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

A. Opzelura may be considered **medically necessary** when 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

AND

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- The requested drug is being prescribed for the topical treatment of nonsegmental vitiligo in an adult or pediatric patient 12 years of age or older

  AND
- The requested drug will NOT be applied to affected areas of greater than 10% body surface area (BSA)

OR

- 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 adult or pediatric patient 12 years of age or older

  AND
  - The requested drug will be used on sensitive skin areas (e.g., face, genitals, or skin folds)

    AND
  - The patient has experienced an inadequate treatment response, intolerance or contraindication to a topical calcineurin inhibitor

  OR
  - The patient has experienced an inadequate treatment response, intolerance or contraindication to a topical calcineurin inhibitor AND a medium or higher potency topical corticosteroid

  AND
- The requested drug will NOT be applied to affected areas of greater than 20% body surface area (BSA)

Approval will be for 3 months with a quantity limit not to exceed 60 gm per 30 days.

Continuation of Therapy

The continuation of Opzelura may be considered medically necessary when the following criteria are met:

- The requested drug is being prescribed for continuation of therapy for the treatment of atopic dermatitis and the patient achieved or maintained positive clinical response as evidenced by improvement [e.g., improvement in or resolution of any of the following signs and symptoms: erythema (redness), exudation (oozing and crusting), excoriation (evidence of scratching), induration (hardening)/papulation (formation of papules), lichenification (epidermal thickening), OR pruritus (itching)]

  AND
- The requested drug will NOT be applied to affected areas of greater than 20% body surface area (BSA)

OR

- The request is for continuation of therapy for the treatment of nonsegmental vitiligo and the patient achieved or maintained meaningful repigmentation

  AND
- The requested drug will NOT be applied to affected areas of greater than 10% body surface area (BSA)

AND

- 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

Approval will be for 12 months with a quantity limit not to exceed 60 gm per 30 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

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60 gm per 30 days

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

REFERENCES

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POLICY HISTORY

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