LifeWise
Health Plan of Washington

PHARMACY / MEDICAL POLICY – 5.01.641

Pharmacologic Treatment of Vitiligo

Effective Date:	Apr. 1, 2025	RELATED MEDICAL POLICIES:
Last Revised:	Mar. 11, 2025	5.01.628 Pharmacologic Treatment of Atopic Dermatitis
Replaces:	N/A	

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POLICY CRITERIA | DOCUMENTATION REQUIREMENTS | CODING
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Introduction

Vitiligo is a condition that causes skin depigmentation. Any part of the body can be affected, including skin, hair, and mucous membranes, but it usually begins on the hands, forearms, feet, and face. There are two major types of vitiligo: Nonsegmental vitiligo and segmental vitiligo. Most individuals with vitiligo have nonsegmental vitiligo. Drugs for vitiligo are excluded under many benefit plans. Therefore, use of drugs for vitiligo may not be covered. Please refer to the applicable benefit plan document to determine benefit availability and the terms, conditions, and limitations of coverage. For questions about benefit information, providers should contact customer service using the telephone number on the back of the member's identification card.

Note: The Introduction section is for your general knowledge and is not to be taken as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals. It is intended for providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider also can be a place where medical care is given, like a hospital, clinic, or lab. This policy informs them about when a service may be covered.

Policy Coverage Criteria

Drug	Medical Necessity
Opzelura (ruxolitinib)	**Opzelura (ruxolitinib) may be considered medically necessary for the topical treatment of nonsegmental vitiligo when all the following criteria are met:** • The individual is aged 12 years or older **AND** • Has nonsegmental vitiligo **AND** • Has vitiligo involvement estimated to affect ≤ 10% of the body surface area **AND** • Has had an inadequate response or intolerance to one topical corticosteroid medication ○ **Exception:** this may be granted for face or genital involvement **AND** • Has had an inadequate response or intolerance to one topical calcineurin inhibitor medication, such as pimecrolimus or tacrolimus **AND** • Opzelura (ruxolitinib) is prescribed by or in consultation with a dermatologist **AND** • Dose is limited to 60 grams per month* **Note:** Drugs for vitiligo are excluded under many benefit plans. Therefore, the use of Opzelura (ruxolitinib) for vitiligo may not be covered. Please refer to the applicable benefit plan document to determine benefit availability (see **Benefit Application** for further information). ***Note:** Dose limit is less than the maximum dose listed in the US Food and Drug Administration (FDA) prescribing information.

Drug	Investigational
As listed	**The medications listed in this policy are subject to the product's US Food and Drug Administration (FDA) dosage and administration prescribing information unless noted**

Drug	Investigational
	otherwise for the medication under the medical necessity criteria. All other uses of the drugs listed in this policy for conditions not outlined in this policy or policy 5.01.628 are considered investigational.

Drug	Not Medically Necessary
As listed	All other uses of the drugs for approved conditions listed in this policy are considered not medically necessary.

Length of Approval	
Approval	**Criteria**
Initial authorization	Non-formulary exception reviews and all other reviews for all drugs listed in this policy may be approved up to 12 months.
Re-authorization criteria	Non-formulary exception reviews and all other reviews for all drugs listed in this policy may be approved up to 12 months as long as the drug-specific coverage criteria are met, and chart notes demonstrate that the individual continues to show a positive clinical response to therapy.

Documentation Requirements
The individual's medical records submitted for review for all conditions should document that medical necessity criteria are met. The record should include the following: • Office visit notes that contain the diagnosis, relevant history, physical evaluation and medication history

Coding

Code	Description
HCPCS	

Code	Description
J3490	Unclassified drugs (use only to report Opzelura)

Note: HCPCS codes, descriptions and materials are copyrighted by Centers for Medicare Services (CMS).

Related Information

Consideration of Age

The ages stated in this policy for which Opzelura (ruxolitinib) are considered medically necessary are based on the ages approved in the FDA labeling.

Benefit Application

Many benefit plans exclude drugs for vitiligo. Please refer to the applicable benefit plan to determine benefit availability and the terms, conditions, and limitations of coverage. For questions about benefit information, providers should contact customer service using the telephone number on the back of the member's identification card.

Evidence Review

Summary of Evidence

Opzelura (ruxolitinib)

Approval for nonsegmental vitiligo (NSV) was based on data from two duplicate Phase 3 clinical trials (TRuE-V1 and TRuE-V2) evaluating Opzelura in 674 individuals aged 12 years and older with NSV. Trial participants were required to have depigmentation affecting ≥0.5% facial BSA, ≥3% non-facial BSA, and a total BSA (facial and non-facial) not exceeding 10%. At Week 24, about 30% of individuals treated with Opzelura twice a day achieved at least a 75% improvement from baseline in the facial Vitiligo Area Scoring Index (F-VASI75), the primary endpoint, compared with about 8% and 13% of those in the vehicle groups of the two trials. At

Week 52, about 50% of individuals treated with Opzelura achieved F-VASI75 and about 20% of individuals achieved a 75% reduction in the total body Vitiligo Area Scoring Index (T-VASI75).

References

1. Opzelura (ruxolitinib). Prescribing Information. Incyte Corporation. Wilmington, DE. Revised August 2024.
2. Papp K, Szepietowski JC, Sun K, et al. Efficacy and safety of ruxolitinib cream for the treatment of atopic dermatitis: results from two phase 3, randomized, double-blind studies. J Am Acad Dermatol. 2021;85:863-872. 3.
3. Kim BS, Howell MD, Sun K, et al. Treatment of atopic dermatitis with ruxolitinib cream (JAK1/JAK2 inhibitor) or triamcinolone cream. J Allergy Clin Immunol. 2020;145(2):572-582. 4. Rosmarin D, Passeron T, Pandya AG, et al. Two phase 3, randomized, controlled trials of ruxolitinib cream for vitiligo. N Engl J Med. 2022;387(16):1445-1455.
4. Seneschal J, Speekaert R, Taieb A, et al. Worldwide expert recommendations for the diagnosis and management of vitiligo: position statement from the International Vitiligo Task Force—Part 2: specific treatment recommendations. J Eur Acad Dermatol Venereol. 2023;37(11):2185-2195.
5. Olsen EA, Kornacki D, Sun K, et al. Ruxolitinib cream for the treatment of patients with alopecia areata: a 2-part, double-blind, randomized, vehicle-controlled phase 2 study. J Am Acad Dermatol. 2020;82(2):412-419.

History

Date	Comments
04/01/25	New policy, approved March 11, 2025. Added coverage criteria for Opzelura (ruxolitinib) for the treatment of vitiligo.