

Coverage of Acne Medications for Members < 21 years of age

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Includes:

Preferred medications:

Claravis®	<i>isotretinoin</i>
Myorisan®	<i>isotretinoin</i>
Zenatane®	<i>isotretinoin</i>

**All other formulations prescribed for treatment of acne will be considered non-formulary.*

** Benzoyl peroxide 2.5%, 5% or 10% gel #60 grams is a covered benefit when billed with doxycycline. Quantity limit of #180 grams per 12-months.*

Please send in prior authorization request prior to prescribing to ensure member is eligible for medication according to timeframes specified in **I-Pledge program. (If you or the member need help signing up for I-Pledge, please contact Advanced Health.)*

GUIDELINE FOR USE:

1. Is diagnosis funded by OHP or has provider submitted documentation supporting at least moderate acne and that acne has caused a profound psychological impact, contributing to low self-esteem, depression, and anxiety?
 - a. If yes, then go to #2.
 - b. If no, deny as criteria not met. Isotretinoin is FDA approved for moderate to severe acne. Off-label use is not a covered benefit under the Oregon Health Plan.
2. Is medication FDA-approved for condition and has member trialed at least 90 days of formulary alternatives, doxycycline with topical benzoyl peroxide gel, and adapalene, or has provider submitted clinical rationale for why formulary alternatives cannot be trialed or optimized?
 - a. If yes, then approve for 90 days.
 - b. If no, deny as criteria not met/non-formulary. Please trial at least 90 days of doxycycline plus topical benzoyl peroxide gel.

Renewal Criteria:

1. Has condition improved and does documentation support continued therapy?
 - a. If yes, approve for 90 days.
 - b. If no, deny as criteria not met. Please submit current chart note evaluating response to requested medication.

Rationale: To ensure there is a funded condition, treatments are used appropriately, and formulary alternatives have been utilized prior to advancing treatment for acne in member under the age of 21.

FDA Approved Indication:

Isotretinoin: Acne, severe recalcitrant nodular: Treatment of severe recalcitrant nodular acne unresponsive to conventional therapy (including systemic antibiotics).

Mechanism of Action:

Reduces sebaceous gland size and reduces sebum production in acne treatment; in neuroblastoma, decreases cell proliferation and induces differentiation.

Dosing: Acne vulgaris, severe recalcitrant nodular: Children ≥ 12 years and Adolescents:

Softgel capsule (eg, generics, Amnesteem, Claravis, Myorisan, Zenatane) or hard-gelatin capsule (Absorica):

Initial: Oral: 0.5 mg/kg/day in 2 divided doses for 4 weeks, then increase dose to 1 mg/kg/day in 2 divided doses (AAD [Zaenglein 2016]; AAP [Eichenfield 2013]); for severe extensive cases (involving trunk, nuchal region, lower back, buttocks, thighs) may require higher doses up to 2 mg/kg/day in 2 divided doses (manufacturer labeling).

Duration of therapy: Typically 15 to 20 weeks depending upon daily dose; a target cumulative dose range of 120 to 150 mg/kg has been recommended based on observed lower relapse rates with courses ≥ 120 mg/kg and the plateau effect observed with higher cumulative total doses of >150 mg/kg (AAD [Zaenglein 2016]).

Repeat course: In older adolescents who have completed skeletal growth, a second course of isotretinoin may be repeated after a period of ≥ 2 months off therapy for persistent or recurring severe nodular acne; for younger patients who have not completed skeletal growth, the optimal interval before retreatment has not been defined.

Contraindication:

Hypersensitivity to isotretinoin or any component of the formulation; sensitivity to parabens (Zenatane only) or vitamin A; pregnancy.

References:

1. Up To Date Acne vulgaris: Management of moderate to severe acne. Literature review current through: Feb 2022. This topic last updated: Feb 17, 2021. Accessed March 14, 2022.
2. Up To Date Acne vulgaris: Overview of management. Literature review current through: Feb 2022. This topic last updated: Oct 26, 2021. Accessed March 14, 2022.
3. Isotretinoin prescribing information.
4. Journal of the American Academy of Dermatology. Guidelines of care for the management of acne vulgaris. [https://www.jaad.org/article/S0190-9622\(15\)02614-6/fulltext#secsectitle0055](https://www.jaad.org/article/S0190-9622(15)02614-6/fulltext#secsectitle0055).
5. American Academy of Dermatology Association. <https://www.aad.org/member/clinical-quality/guidelines/acne>.
6. Restricted Distribution in the US: refer to www.ipledgeprogram.com for more information.