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Isotretinoin Low Dose

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Related Coverage Resources

[Multi-Source Brand Name Drugs – \(IP0011\)](#)

INSTRUCTIONS FOR USE

The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

Overview

This policy supports medical necessity review for formulary exceptions to the following non-covered products:

- Isotretinoin low dose (Absorica LD™) capsule

Receipt of sample product does not satisfy any criteria requirements for coverage.

Medical Necessity Criteria

Coverage criteria are listed for products in below table:

Employer Group Non-Covered Products and Criteria:

Non-Covered Product	Criteria
Absorica LD (isotretinoin) 8 mg, 16 mg, 20 mg, 24	Isotretinoin low dose capsule (Absorica LD) is medically necessary for the treatment of severe recalcitrant nodular acne when there is documentation of failure, contraindication or intolerance to ONE of the following: a. Amnesteem® (isotretinoin) 10 mg, 20 mg, 40 mg

Non-Covered Product	Criteria
mg, 28 mg, 32 mg capsule	b. Claravis™ (isotretinoin) 10 mg, 20 mg, 30 mg, or 40 mg capsule c. Isotretinoin 10 mg, 20 mg, 30 mg, or 40 mg capsule d. Myorisan™ (isotretinoin) 10 mg, 20 mg, 30 mg, or 40 mg capsule e. Zenatane™ (isotretinoin) 10 mg, 20 mg, 30 mg, or 40 mg capsule

When coverage is available and medically necessary, the dosage, frequency, duration of therapy, and site of care should be reasonable, clinically appropriate, and supported by evidence-based literature and adjusted based upon severity, alternative available treatments, and previous response to therapy.

Reauthorization Criteria

Isotretinoin low dose capsule is considered medically necessary for continued use when initial criteria are met AND there is documentation of beneficial response.

Authorization Duration

Initial approval duration is up to 6 months.
 Reauthorization approval duration is up to 6 months.

Conditions Not Covered

Any other use is considered not medically necessary.

Background

OVERVIEW

Isotretinoin is indicated for the treatment of severe recalcitrant nodular acne.¹⁻⁶

Table 1. Available Strengths for the Isotretinoin Products.¹⁻⁴

Product	Available Strengths/Formulations
Absorica	10 mg, 20 mg, 25 mg, 30 mg, 35 mg, 40 mg capsule
Absorica LD	8 mg, 16 mg, 24 mg, 32 mg capsule
Accutane, Claravis, Myorisan, Zenatane	10 mg, 20 mg, 30 mg, 40 mg capsule
Amnesteem	10 mg, 20 mg, 40 mg capsule
Isotretinoin (generic)	10 mg, 20 mg, 25 mg, 30 mg, 35 mg, 40 mg capsule

References

1. Amnesteem (prescribing information). Morgantown, WV: Mylan Pharmaceuticals; August 2022.
2. Claravis (prescribing information). North Wales, PA: Teva Pharmaceuticals; August 2022.
3. Myorisan (prescribing information). Lake Forest, IL: Akorn Operating Company LLC; December 2022.
4. Zenatane (prescribing information). Princeton, NJ: Dr. Reddy's Laboratories; September 2022.
5. Absorica and Absorica LD (prescribing information). Cranbury, NJ: Sun Pharmaceutical Industries; April 2022.
6. Accutane (prescribing information). Scottsdale, AZ: JG Pharma; August 2022.

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