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Step Therapy
Isotretinoin

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Product Identifier(s)

Effective 1/1/23 to 2/6/23: 107695
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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.

National Formulary Medical Necessity

Drugs Affected

- Absorica® (isotretinoin capsules, generic)
• Absorica LD™ (isotretinoin capsules)
• Accutane® (isotretinoin capsules, generic)
• Amnesteem® (isotretinoin capsules, generic)
• Claravis™ (isotretinoin capsules, generic)
• Myorisan™ (isotretinoin capsules, generic)
• Zenatane™ (isotretinoin capsules, generic)

This program has been developed to encourage the use of a Step 1 Product prior to the use of a Step 2 Product. If the Step Therapy rule is not met for a Step 2 Product at the point of service, coverage will be determined by the Step Therapy criteria below. All approvals are provided for 1 year in duration.

Step 1: Accutane, Amnesteem, Claravis, isotretinoin capsules (all true generic isotretinoin products), Myorisan, Zenatane, authorized generic to Absorica

Step 2: Absorica, Absorica LD

**Cigna covers Step 2 agents as medically necessary when the following criteria are met:**

1. If the individual has tried one Step 1 Product, approve a Step 2 Product.

Note: Absorica with DAW 9 (indicating that substitution is allowed by the prescriber but the Plan requests brand) will also count as a Step 1 Product.

## Conditions Not Covered

Any other exception is considered not medically necessary.

## Background

### Overview

Isotretinoin is indicated for the treatment of **severe recalcitrant nodular acne**.<sup>1-6</sup>

**Table 1. Available Strengths for the Isotretinoin Products.**<sup>1-6</sup>

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

## References

1. Amnesteem® [prescribing information]. Morgantown, WV: Mylan; August 2022.
2. Claravis™ [prescribing information]. North Wales, PA: Teva; April 2022.
3. Myorisan® [prescribing information]. Lake Forest, IL: Akorn; February 2022.
4. Zenatane™ [prescribing information]. Bachupally India: Dr. Reddy's; September 2022.
5. Absorica® and Absorica LD™ [prescribing information]. Cranbury, NJ: Sun; October 2019.
6. Accutane® [prescribing information]. Scottsdale, AZ: JG Pharma; April 2022.

## Revision History

Type of Revision	Summary of Changes	Approval Date
Annual Revision	No criteria changes.	01/18/2023

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