

STEP THERAPY POLICY

- POLICY:** Isotretinoin Step Therapy Policy
- Absorica® (isotretinoin capsules – Sun, generic)
 - Absorica LD™ (isotretinoin capsules – Sun)
 - Accutane® (isotretinoin capsules – JG Pharma, generic)
 - Amnesteem® (isotretinoin capsules – Mylan, generic)
 - Claravis™ (isotretinoin capsules – Teva, generic)
 - Myorisan™ (isotretinoin capsules – Akorn, generic)
 - Zenatane™ (isotretinoin capsules – Dr Reddy’s, generic)

REVIEW DATE: 01/18/2023

OVERVIEW

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

Table 1. Available Strengths for the Isotretinoin Products.¹⁻⁶

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

POLICY STATEMENT

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.

Automation: A patient with a of one Step 1 Product within the 130-day look-back period is excluded from Step Therapy.

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

Step 2: Absorica, Absorica LD

CRITERIA

1. If the patient 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.
2. No other exceptions are recommended.

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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.