

STEP THERAPY POLICY

- POLICY:** Isotretinoin Capsules Step Therapy Policy
- Absorica® (isotretinoin capsules – Sun Pharmaceuticals)
 - Absorica LD (isotretinoin capsules – Sun Pharmaceuticals)
 - Amnesteem® (isotretinoin capsules – Mylan Pharmaceuticals)
 - Claravis™ (isotretinoin capsules – Teva Pharmaceuticals)
 - Myorisan™ (isotretinoin capsules – VersaPharm)
 - Zenatane™ (isotretinoin capsules – Dr Reddy’s Laboratories)

REVIEW DATE: 03/03/2021

OVERVIEW

Isotretinoin is indicated for the treatment of **severe recalcitrant nodular acne**.¹⁻⁵ Nodules are inflammatory lesions with a diameter of 5 mm or greater and the nodules may become suppurative or hemorrhagic. “Severe”, by definition, means “many” as opposed to “few or several” nodules. Due to the significant adverse reactions associated with isotretinoin use, isotretinoin is reserved for patients with severe nodular acne who are unresponsive to conventional therapy, including systemic antibiotics.

Isotretinoin is in the FDA pregnancy category X; there is an extremely high risk that severe birth defects will result if pregnancy occurs while taking isotretinoin in any amounts, even for short periods of time.¹⁻⁶ Due to isotretinoin’s teratogenicity and to minimize fetal exposure, isotretinoin is only approved for marketing under a special restricted distribution program approved by the FDA, iPLEDGE®. Only prescribers who are registered and activated with the iPLEDGE program can prescribe isotretinoin and only pharmacies registered and activated with iPLEDGE can dispense isotretinoin to patients who are registered and meet all requirements of iPLEDGE.

Isotretinoin capsules is available as generics, marketed as Amnesteem, Claravis, Myorisan, and Zenatane; Absorica and Absorica LD are branded isotretinoin products.¹⁻⁵ Refer to Table 1 for the available strengths of each product.

Table 1. Available Strengths for the Isotretinoin Products.¹⁻⁵

Product	Available Strengths/Formulations
Isotretinoin (generic)	10 mg, 20 mg, 30 mg, 40 mg capsules
Absorica	10 mg, 20 mg, 25 mg, 30 mg, 35 mg, 40 mg,
Absorica LD	8 mg, 16 mg, 24 mg, 32 mg capsules
Amnesteem	10 mg, 20 mg, 40 mg capsules
Claravis	10 mg, 20 mg, 30 mg, 40 mg capsules
Myorisan	10 mg, 20 mg, 30 mg, 40 mg capsules
Zenatane	10 mg, 20 mg, 30 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 history of one Step 1 Product within the 130-day look-back period is excluded from Step Therapy.

Step 1: Amnesteem, Claravis, generic isotretinoin capsules, Myorisan, Zenatane

Step 2: Absorica, Absorica LD

CRITERIA

1. If the patient has tried one Step 1 Product, approve a Step 2 Product.
2. No other exceptions are recommended.

REFERENCES

1. Amnesteem[®] [prescribing information]. Morgantown, WV: Mylan Pharmaceuticals Inc.; August 2018.
2. Claravis[™] [prescribing information]. North Wales, PA: Teva Pharmaceuticals USA, Inc; April 2018.
3. Myorisan[™] [prescribing information]. Lake Forest, IL: VersaPharm Inc, an Akorn Company; August 2019.
4. Zenatane[™] [prescribing information]. Bachupally India: Dr. Reddy's Laboratories Limited; January 2019.
5. Absorica[®] and Absorica[®] LD [prescribing information]. Cranbury, NJ: Sun Pharmaceutical Industries, Inc.; October 2019.
6. iPLEDGE[®] program. Available at: <https://www.ipledgeprogram.com/iPledgeUI/home.u>. Accessed on March 2, 2021.