

New Hampshire Medicaid Fee-for-Service Program

Oral Isotretinoin Criteria

Approval Date: July 12, 2022

Pharmacology

Isotretinoin is a retinoid, which when administered in pharmacologic dosages of 0.5 to 1.0 mg/kg/day, inhibits sebaceous gland function and keratinization. The exact mechanism of action of isotretinoin is unknown.

Indication

Isotretinoin is indicated for the treatment of severe recalcitrant nodular acne. Nodules are inflammatory lesions with a diameter of 5 mm or greater. The nodules may become suppurative or hemorrhagic. Severe, by definition, means many as opposed to few or several nodules. Because of significant adverse effects associated with its use, isotretinoin should be reserved for patients with severe nodular acne who are unresponsive to conventional therapy, including systemic antibiotics.

Medications

Brand Name	Generic Name	Dosage Strengths
Absorica®/LD	isotretinoin	10 mg, 20 mg, 25 mg, 30 mg, 35 mg, 40 mg; LD: 8mg, 16mg, 24mg, 32mg
Amnesteem®	isotretinoin	20 mg
Claravis®	isotretinoin	10 mg, 20 mg, 30 mg, 40 mg
Myorisan®	isotretinoin	10 mg, 20 mg, 30 mg, 40 mg
Zenatane®	isotretinoin	10 mg, 20 mg, 30 mg, 40 mg

Criteria for Authorization

1. Diagnosis of severe recalcitrant acne-nodular; **AND**
2. Documented trials and therapy failures of at least two conventional acne treatments, one of which is a systemic antibiotic unless being treated for acne conglobata; **AND**

- Patient and provider are registered and meet all the requirements of the iPLEDGE risk management program, **INCLUDING** a confirmed negative serum pregnancy test, if appropriate, and a plan for contraception in place, if appropriate; **AND**
- A maximum day supply of 30 is dispensed at a time.

Criteria for Denial

- Failure to meet criteria for authorization.
- Treatment of mild to moderate acne.

Initial approval period: Six months

Continued approval: An additional six-month approval will be granted after one therapy failure **AND** after a minimum of two months without therapy.

References

Available upon request.

Revision History

Review	Reason for Review	Date Approved
Pharmacy and Therapeutic Committee	New	11/02/2006
Commissioner	New	11/16/2006
DUR Board	Update	10/25/2010
Commissioner	Approval	02/10/2011
DUR Board	Update	10/11/2016
Commissioner	Approval	11/22/2016
DUR Board	Update	09/27/2018
Commissioner Designee	Approval	11/27/2018
DUR Board	Update	10/28/2019
Commissioner Designee	Approval	12/03/2019
DUR Board	Update	12/15/2020
Commissioner Designee	Approval	02/24/2021
DUR Board	Revision	06/02/2022
Commissioner Designee	Approval	07/12/2022