

## Clinical Policy: Isotretinoin (Claravis, Absorica, Absorica LD, Amnesteem, Myorisan, Zenatane)

Reference Number: IL.PMN.143

Effective Date: 1.1.20

Last Review Date: 04.11.22

Line of Business: Medicaid

[Revision Log](#)

See [Important Reminder](#) at the end of this policy for important regulatory and legal information.

### Description

Isotretinoin (Claravis™, Absorica®, Absorica LD™, Myorisan™, Amnesteem™, Zenatane®) is a systemic retinoid.

### FDA Approved Indication(s)

Claravis, Absorica, Absorica LD, Myorisan, Amnesteem, and Zenatane are indicated for severe recalcitrant nodular acne. Absorica and Absorica LD are specifically indicated in patients 12 years of age and older.

Limitation(s) of use: Claravis, Absorica, Absorica LD, Myorisan, Amnesteem, and Zenatane may only be administered to patients enrolled in the iPLEDGE program.

### Policy/Criteria

*Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.*

It is the policy of health plans affiliated with Centene Corporation® that Claravis, Absorica, Absorica LD, Myorisan, Amnesteem, and Zenatane are **medically necessary** when the following criteria are met:

#### I. Initial Approval Criteria

##### A. Acne (must meet all):

1. Diagnosis of nodular acne;
2. Age  $\geq$  12 years;
3. Failure of  $\geq$  2 of the following topical agents (must be from 2 different classes listed below), unless contraindicated or clinically significant adverse effects are experienced:
  - a. Topical antibiotics: clindamycin, erythromycin;
  - b. Topical anti-infectives: benzoyl peroxide 10% gel, benzoyl peroxide 10% lotion;
  - c. Topical retinoids: tretinoin 0.025% cream and gel, tretinoin 0.05% cream and gel, tretinoin 0.1% gel;

*\*Prior authorization may be required for tretinoin for age  $\geq$  35 years*
4. At least one of the topical agents above was used concurrently with one of the following oral antibiotics for  $\geq$  60 days: doxycycline, erythromycin, minocycline,

- tetracycline, trimethoprim-sulfamethoxazole, unless contraindicated or clinically significant adverse effects are experienced to the listed antibiotic agents;
5. If request is for Absorica or Absorica LD, member has intolerance or contraindications to the excipients in Myorisan, Claravis, Amnesteem, Zenatane, and generic isotretinoin;
  6. Dose does not exceed one of the following (a or b):
    - a. Absorica, Claravis, Myorisan, Amnesteem, Zenatane: 2 mg/kg per day;
    - b. Absorica LD: 1.6 mg/kg per day

**Approval duration:**

**Medicaid** – 6 months

**B. Other diagnoses/indications**

1. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.PMN.53 for Medicaid.

**II. Continued Therapy**

**A. Acne (must meet all):**

1. Previously received medication via Centene benefit or member has previously met initial approval criteria;
2. Member is responding positively to therapy;
3. If member has received 20 consecutive weeks of treatment, an 8 week treatment-free interval must be allowed prior to reinitiating isotretinoin treatment;
4. If request is for Absorica or Absorica LD, member has intolerance or contraindications to the excipients in Myorisan, Claravis, Amnesteem, Zenatane, and generic isotretinoin;
5. Dose does not exceed one of the following (a or b):
  - c. Absorica, Claravis, Myorisan, Amnesteem, Zenatane: 2 mg/kg per day;
  - d. Absorica LD: 1.6 mg/kg per day

**6. Approval duration:**

**Medicaid** – 6 months

**B. Other diagnoses/indications (must meet 1 or 2):**

1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy.  
**Approval duration: Duration of request or 12 months (whichever is less);** or
2. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.PMN.53 for Medicaid.

**III. Diagnoses/Indications for which coverage is NOT authorized:**

- A.** Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – CP.PMN.53 for Medicaid or evidence of coverage documents.

#### **IV. Appendices/General Information**

##### *Appendix A: Abbreviation/Acronym Key*

FDA: Food and Drug Administration

##### *Appendix B: Contraindications*

- Contraindication(s): pregnancy (category X), hypersensitivity to the medication or any of its components
- Boxed warning(s): if pregnancy occurs during isotretinoin use, there is an extremely high risk for severe birth defects (iPLEDGE REMS program enrollment is required for prescribers, patients, pharmacies, and distributors)

##### *Appendix C: General Information*

- Micromedex classifies the use of isotretinoin for the non-FDA labeled indication of acne vulgaris as a Class II-a strength of recommendation.
- The American Academy of Dermatology recognizes that isotretinoin is also useful for the management of lesser degrees of acne that are treatment-resistant or for the management of acne that is producing either physical or psychological scarring.
- Micromedex classifies the use of isotretinoin for the non-FDA labeled indication of rosacea as a Class II-a strength of recommendation.
- The American Acne and Rosacea Society Consensus Recommendations recognize that isotretinoin has been shown to be effective in treating some refractory cases of papulopustular rosacea, but therapeutic benefit may require continued use. Due to the limited data on the management of refractory rosacea, isotretinoin should only be considered in select cases.
- Because of the risk of teratogenicity and to minimize fetal exposure, isotretinoin is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called iPLEDGE. Isotretinoin must only be prescribed by prescribers who are registered and activated with the iPLEDGE program. Isotretinoin must only be dispensed by a pharmacy registered and activated with iPLEDGE, and must only be dispensed to patients who are registered and meet all the requirements of iPLEDGE. Registered and activated pharmacies must receive isotretinoin only from wholesalers registered with iPLEDGE. For more information call 866-495-0654 or visit <http://www.ipledgeprogram.com>.

#### **V. Dosage and Administration**

<b>Indication</b>	<b>Dosing Regimen</b>	<b>Maximum Dose</b>
Isotretinoin (Absorica, Claravis, Myorisan, Amnesteem, Zenatane)	0.5 to 1 mg/kg/day PO given in two divided doses	2 mg/kg/day
Isotretinoin (Absorica LD)	0.4 to 0.8 mg/kg/day PO given in two divided doses	1.6 mg/kg/day

#### **VI. Product Availability**

Drug Name	Availability
Isotretinoin (Absorica)	Capsules: 10 mg, 20 mg, 25 mg, 30 mg, 35 mg, and 40 mg
Isotretinoin (Absorica LD)	Capsules: 8 mg, 16 mg, 20 mg, 24 mg, 28 mg, and 32 mg
Isotretinoin (Claravis, Myorisan, Zenatane)	Capsules: 10 mg, 20 mg, 30 mg, and 40 mg
Isotretinoin (Amnesteem)	Capsules: 10 mg, 20 mg, 40 mg

## VII. References

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2021. Available at: <http://www.clinicalpharmacology-ip.com/>. Accessed August 10, 2021.
2. Zaenglein AL, Pathy AL, Schlosser BJ, Alikhan A, Baldwin HE, Berson DS, et al. Guidelines of care for the management of acne vulgaris. J Am Acad Dermatol. 2016 Feb 15;74(5):945-973.e33. doi: 10.1016/j.jaad.2015.12.037.

### **Prescribing Information**

3. Absorica and Absorica LD Prescribing Information. Cranbury, NJ: Sun Pharmaceutical Industries, Inc.; October 2019. Available at: <http://absorica.com>. Accessed August 10, 2021.
4. Amnesteem Prescribing Information. Morgantown, WV: Mylan Pharmaceuticals Inc; April 2018. Available at: <https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=b2cb63c9-f825-4991-9a2c-6260f1bbcc2c>. Accessed August 10, 2021.
5. Claravis Prescribing Information. North Wales, PA: Teva Pharmaceuticals USA, Inc.; April 2018. Available at: <https://dailymed.nlm.nih.gov/dailymed/lookup.cfm?setid=a31fd109-d0fd-4ab9-ba98-a3d64333c18d>. Accessed August 10, 2021..
6. Myorisan Prescribing Information. Lake Forest, IL: VersaPharm Inc.; October 2018. Available at: <https://dailymed.nlm.nih.gov/dailymed/lookup.cfm?setid=51ff6346-9256-4c01-9f52-417d13f2df05>. Accessed August 10, 2021.
7. Zenatane Prescribing Information. Princeton, NJ: Dr. Reddy's Laboratories Inc.; January 2019. Available at: <https://dailymed.nlm.nih.gov/dailymed/lookup.cfm?setid=27b3cf26-f22e-5b70-1c24-009933b7c6ee>. Accessed August 10, 2021.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
New policy created, adapted CP.PMN.143 Isotretinoin policy.	12.13.19	1.7.20
4Q 2020 annual review; references reviewed and updated. RT4: added Absorica LD with required step through of other isotretinoin products (including an additional product: generic isotretinoin); references reviewed and updated.	12.15.20	
2Q 2022 annual review: Updated <i>Prior authorization may be required for tretinoin for age ≥ 35 years</i> ; added Amnesteem as preference if Absorica or Absorica LD is requested ; updated appendix B :contraindication; references reviewed and updated	4.11.22	

### **Important Reminder**

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. “Health Plan” means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan’s affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

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**Note:**

**For Medicaid members**, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

**For Health Insurance Marketplace members**, when applicable, this policy applies only when the prescribed agent is on your health plan approved formulary. Request for non-formulary drugs must be reviewed using the formulary exception policy.

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