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

Reference Number: IL.ERX.PMN.143
Effective Date: 06.01.21
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Line of Business: Illinois 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™, Zenatane®) is a systemic retinoid.

FDA Approved Indication(s)

Claravis, Absorica, Absorica LD, Myorisan, 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, 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.

Health plan approved formularies should be reviewed for all coverage determinations. Requirements to use preferred alternative agents apply only when such requirements align with the health plan approved formulary.

It is the policy of health plans affiliated with Envolve Pharmacy Solutions™ that Claravis, Absorica, Absorica LD, Myorisan, 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 ≥ 12 years;
3. Failure of ≥ 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% gel, tretinoin 0.05% cream, tretinoin 0.1% cream;
4. At least one of the topical agents above was used concurrently with one of the following oral antibiotics for ≥ 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, Zenatane, and generic isotretinoin;
6. Dose does not exceed one of the following (a or b):
   a. Absorica, Claravis, Myorisan, Zenatane: 2 mg/kg per day;
   b. Absorica LD: 1.6 mg/kg per day

Approval duration: 6 months

B. Other diagnoses/indications

1. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy

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

1. Previously received medication via a health plan affiliated with Envolve Pharmacy Solutions 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, Zenatane, and generic isotretinoin;
5. Dose does not exceed one of the following (a or b):
   a. Absorica, Claravis, Myorisan, Zenatane: 2 mg/kg per day;
   b. Absorica LD: 1.6 mg/kg per day

Approval duration: 6 months

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

1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions and documentation supports positive response to therapy.
   Approval duration: Duration of request or 12 months (whichever is less); or
2. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

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 policy – ERX.PA.01 or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
FDA: Food and Drug Administration

Appendix B: Contraindications
Not applicable

Appendix C: General Information

- Micromedex classifies the use of isotretinoin for the non-FDA labeled indication of mild-to-moderate acne vulgaris as a Class IIa 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 IIa 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.

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Isotretinoin (Absorica, Claravis, Myorisan, 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

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
Policy created	04.15.21	05.21
4Q 2021 annual review: no significant changes; references reviewed and updated.	08.09.21	11.21

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.

This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. 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.