

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

Reference Number: PA.CP.PST.06

Effective Date: 01/18

Last Review Date: 11/16

Line of Business: Medicaid

[Coding Implications](#)  
[Revision Log](#)

### Description

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

Limitation of use: Isotretinoin may only be administered to patients enrolled in the iPLEDGE program.

### FDA approved indication

Isotretinoin is indicated for severe recalcitrant nodular acne.

### Policy/Criteria

*\* Provider must submit documentation (including office chart notes and lab results) supporting that member has met all approval criteria \**

It is the policy of Pennsylvania Health and Wellness® that Claravis™, Absorica®, Myorisan™, and Zenatane® are **medically necessary** when the following criteria are met:

#### I. Initial Approval Criteria

##### A. Step Therapy for Isotretinoin (must meet all):

1. Age 12 and older;
2. Member has NOT received up to 20 consecutive weeks of treatment within the previous 8 weeks;
3. Member must meet one of the following (a or b):
  - a. Failure of  $\geq 2$  of the following topical agents each from different medication classes:
    - i. Topical antibiotics: clindamycin, erythromycin
    - ii. Topical anti-infectives: benzoyl peroxide 10% gel, benzoyl peroxide 10% lotion
    - iii. Topical retinoids: tretinoin 0.025% gel, tretinoin 0.05% cream, tretinoin 0.1% cream (Note: tretinoin requires a prior authorization  $\geq$  age 22)

##### AND

At least one of the topical agents above was used concurrently with one of the following oral antibiotics for  $\geq 60$  days: clindamycin, doxycycline, erythromycin, minocycline, tetracycline, trimethoprim-sulfamethoxazole, unless member experiences clinically significant adverse effects or has contraindication(s) to all listed antibiotic agents;

- b. Contraindications to  $\geq 2$  topical agents in criterion 3 and failure of  $\geq 60$  day trial of at least 2 of the following agents: clindamycin, doxycycline, erythromycin, minocycline, tetracycline, trimethoprim-sulfamethoxazole, unless member experiences clinically significant adverse effects or has contraindication(s) to all listed antibiotic agents.

**Isotretinoin**

4. Request does not exceed health plan approved daily quantity limit.

**Approval duration: 20 weeks**

**B. Other diagnoses/indications – Refer to PA.CP.PMN.53 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized)**

**II. Continued Therapy**

**A. Step Therapy for Isotretinoin (must meet all):**

1. Previously received medication via Pennsylvania Health and Wellness benefit or member has previously met initial approval criteria or the Continuity of Care policy (PA.LTSS.PHAR.01) applies;
2. If member has received up to 20 consecutive weeks of treatment, an 8 week treatment-free interval must be allowed prior to reinitiating isotretinoin treatment;
3. Request does not exceed health plan approved daily quantity limit.

**Approval duration: allow no more than 20 weeks of treatment per course**

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

1. Currently receiving medication via Pennsylvania Health and Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA.LTSS.PHAR.01) applies; or
2. Refer to PA.CP.PMN.53 if requested indication is NOT listed under section III (Diagnoses/Indications for which coverage is NOT authorized)

**Approval duration: allow no more than 20 weeks of treatment per course**

**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 medical necessity guideline for the off-label use of a drug policy – PA.CP.PMN.53 or evidence of coverage documents**

**IV. Appendices/General Information**

*Appendix A: Abbreviation Key*

N/A

**V. Dosage and Administration**

<b>Drug</b>	<b>Recommended Dosage</b>	<b>Maximum Dose</b>
Absorica (isotretinoin)	0.5 to 1 mg/kg/day given in two divided doses	2 mg/kg/day
Claravis (isotretinoin)		
Myorisan (isotretinoin)		
Zenatane (isotretinoin)		

**VI. Product Availability**

<b>Drug</b>	<b>Availability</b>
Absorica (isotretinoin)	10 mg, 20 mg, 25 mg, 30 mg, 35 mg, 40 mg capsule
Claravis (isotretinoin)	10 mg, 20 mg, 30 mg, 40 mg capsule

## CLINICAL POLICY

### Isotretinoin



Myorisan (isotretinoin)	
Zenatane (isotretinoin)	

#### VII. References

1. Isotretinoin Clinical Monograph. Clinical Pharmacology. Available at <http://www.clinicalpharmacology-ip.com>. Accessed October 2016.
2. Claravis Package Insert. North Wales, PA: Teva Pharmaceuticals USA, Inc., April 2016. Available at <https://dailymed.nlm.nih.gov/>. Accessed October 2016.
3. 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.
4. Absorica Package Insert. Jacksonville, FL: Ranbaxy Laboratories, Inc. September 2015. Available at <http://absorica.com>. Accessed October 2016.

Reviews, Revisions, and Approvals	Date	Approval Date