Prior Authorization Review Panel

CHC-MCO Policy Submission

A separate copy of this form must accompany each policy submitted for review.
Policies submitted without this form will not be considered for review.

Plan: PA Health & Wellness	**Submission Date: 11/01/2018**
Policy Number: PA.CP.PST.06	**Effective Date: 10/17/2018** **Revision Date: 10/17/2018**
Policy Name: Isotretinoin (Claravis, Absorica, Myorisan, Zenatane)	**HC Approval Date:**

Type of Submission – Check all that apply:

- ☐ **New Policy**
- ☐ **Revised Policy***
- ☐ **Annual Review – No Revisions**
- ☐ **Attestation of HC PARP Policy –** *This option should only be used during Readiness Review for Community HealthChoices. The policy must be identical to the PARP approved policy for the HealthChoices Program, with the exception of revisions/clarifications adding the term "Community HealthChoices" to the policy.*

***All revisions to the policy must be highlighted using track changes throughout the document.**

Please provide any changes or clarifying information for the policy below:

This policy is being retired and replaced by the following policy:

PA.CP.PMN.143 isotretinoin

Name of Authorized Individual (Please type or print): **Francis G. Grillo, MD**	**Signature of Authorized Individual:**

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 ≥ 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 ≥ age 22)

      AND

      At least one of the topical agents above was used concurrently with one of the following oral antibiotics for ≥ 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 ≥ 2 topical agents in criterion 3 and failure of ≥ 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.

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

Drug	Recommended Dosage	Maximum Dose
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

Drug	Availability

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
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