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

Reference Number: CP.PPA.26
Effective Date: 09.05.17
Last Review Date: 11.17
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®, Myorisan™, Zenatane®) is a retinoid.

FDA Approved Indication(s)
Isotretinoin is indicated for severe recalcitrant nodular acne.

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

Policy/Criteria
Provider must submit documentation (which may include office chart notes and lab results) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with Centene Corporation® that Claravis, Absorica, 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 *(Note: tretinoin requires prior authorization for ages ≥ 35 years)*;
4. 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 contraindicated or clinically significant adverse effects are experienced to all listed antibiotic agents;
5. If request is for Absorica, member has intolerance or contraindications to the excipients in Claravis, Myorisan, and Zenatane;
6. Dose does not exceed 2 mg/kg/day.

Approval duration: 20 weeks

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, member has intolerance or contraindications to the excipients in Claravis, Myorisan, and Zenatane;
5. If request is for a dose increase, new dose does not exceed 2 mg/kg/day.

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

III. Appendices/General Information

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

Appendix B: Black Box Warning – Birth Defects
Pregnancy Category X.
- Isotretinoin must not be used by female patients who are or may become pregnant.
- There is an extremely high risk that severe birth defects will result if pregnancy occurs while taking isotretinoin in any amount, even for short periods of time. Potentially any fetus exposed during pregnancy can be affected.
- There are no accurate means of determining whether an exposed fetus has been affected.
- Isotretinoin is available only through a restricted program called the iPLEDGE program. Prescribers, patients, pharmacies, and distributors must enroll in the program.

IV. Dosage and Administration

Drug	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

V. Product Availability

Drug	Availability
Isotretinoin (Absorica)	Capsules: 10 mg, 20 mg, 25 mg, 30 mg, 35 mg, and 40 mg
Isotretinoin (Claravis, Myorisan, Zenatane)	Capsules: 10 mg, 20 mg, 30 mg, and 40 mg

VI. Workflow Document

N/A

VII. References

1. Isotretinoin Clinical Monograph. Clinical Pharmacology. Available at http://www.clinicalpharmacology-ip.com. Accessed August 2017.
2. Claravis Package Insert. North Wales, PA: Teva Pharmaceuticals USA, Inc.; August 2016. Available at https://dailymed.nlm.nih.gov/. Accessed August 3, 2017.

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 August 3, 2017.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created from CP.PST.06 which was retired. Preferencing added for Claravis, Myorisan, and Zenatane due to better pricing for these agents.	09.05.17	11.17

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.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

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.