Clinical Policy Title:	isotretinoin
Policy Number:	RxA.071
Drug(s) Applied:	Claravis™, Absorica®, Absorica LD™, Myorisan®, Zenatane™, Amnesteem®
Original Policy Date:	03/06/2020
Last Review Date:	01/01/2024
Line of Business Policy Applies to:	All lines of business (except Medicare)

Criteria

I. Initial Approval Criteria

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

1. Diagnosis of severe recalcitrant nodular acne;
2. Age ≥ 12 years;
3. Prescribed by or in consultation with a dermatologist;
4. History of failure, contraindication, or intolerance to an adequate trial of two of the following conventional therapy regimens:
   a. Topical antibiotics (e.g., clindamycin, erythromycin);
   b. Topical anti-infectives (e.g., benzoyl peroxide);
   c. Topical retinoids or retinoid like agents (e.g., tretinoin, adapalene, tazoratene
   d. Oral antibiotic (e.g., minocycline, doxycycline, erythromycin)

Approval Duration

All Lines of Business (except Medicare): 12 months

II. Continued Therapy Approval

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

1. Member is currently receiving medication, excluding manufacturer samples;
2. If member has received 20 consecutive weeks of treatment, an 8-week treatment-free interval must be allowed prior to reinitiating isotretinoin treatment;

Approval Duration

All Lines of Business (except Medicare): 6 months

References

1. Zaenglein AL, Pathy AL, Schlosser BJ, Alikhan A, BaLD™win HE, Berson DS, et al. Guidelines of care for the management of acne vulgaris. J Am Acad Dermatol. 2016 May;74(5):945-973.e33. doi: 10.1016/j.jaad.2015.12.037. Available at: https://sci-hubtw.hkvisa.net/10.1016/j.jaad.2015.12.037. Accessed November 15, 2023.
2. Acne clinical guideline. Available at: https://www.aad.org/member/clinical-quality/guidelines/acne. Accessed November 15, 2023.

Review/Revision History	Review/Revision Date	P&T Approval Date
Policy was established.	2/2020	03/06/2020
Policy was reviewed:	05/2020	05/2020

1. Added dose criteria for initial and continuation of therapy for Absorica® LD™. 2. Added drug information for Absorica LD™ (new formulation).		
Policy was reviewed: 1. Clinical policy title table was updated. 2. Continued therapy criteria II.A.1 was rephrased to "Currently receiving medication that has been authorized by RxAdvance..." 3. References were updated.	02/19/2021	03/09/2021
Policy was reviewed: 1. Continued Therapy Approval Criteria II.A.1 was rephrased to "Member is currently receiving medication that has been authorized by RxAdvance...". 2. References were reviewed and updated.	12/07/2021	01/17/2022
Policy was reviewed: 1. References were reviewed and updated.	06/27/2022	07/18/2022
Policy was reviewed: 1. Initial Approval Criteria, I.A.5: Updated to remove prior concurrent therapy criteria "At least 1 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." 2. Initial Approval Criteria, I.A.6: Updated to remove prior contraindication/adverse event criteria "Member has intolerance or contraindications to the excipients in generic isotretinoin." 3. Continued Therapy Approval Criteria, II.A.4: Updated to remove prior contraindication/adverse event	04/14/2023	07/13/2023

criteria "Member has intolerance or contraindications to the excipients in generic isotretinoin." 4. References were reviewed and updated.		
Policy was reviewed. 1. Removed prior dosing criteria. 2. Added requirement to try/fail Oral antibiotic (e.g., minocycline, doxycycline, erythromycin). 3. Updated approval duration. 4. Removed reauthorization requirement for positive response to therapy. 5. References were reviewed and updated.	01/01/2024	01/01/2024