Clinical Policy Title:	isotretinoin
Policy Number:	RxA.071
Drug(s) Applied:	Amnesteem®, Claravis™, Zenatane™, isotretinoin, Accutane
Original Policy Date:	03/06/2020
Last Review Date:	06/18/2026
Line of Business Policy Applies to:	All lines of business (except Medicare)

Criteria

I. Initial Approval Criteria

A. Acne (Policy applies to patient's 25 years of age and older, must meet all):

1. Diagnosis of severe recalcitrant nodular acne;
2. Documented trial and failure of three covered formulary alternatives each from a different class, unless contraindicated or clinically significant adverse effects are experienced, supported by chart notes or claims history (a, b, c, and d)*:
   a. Topical retinoid: tretinoin, adapalene;
   b. Topical anti-infectives: clindamycin, erythromycin;
   c. Topical Keratolytic: sulfacetamide;
   d. Oral antibiotic (e.g., minocycline, doxycycline, erythromycin).

*Combination formulations will be considered as one trial or failure

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 that has been authorized by RxAdvance or the member has met initial approval criteria.

Approval Duration
All Lines of Business (except Medicare): 12 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 December 16, 2024.
2. Acne clinical guideline. Available at: https://www.aad.org/member/clinical-quality/guidelines/acne. Accessed December 16, 2024.

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

This clinical policy has been developed to authorize, modify, or determine coverage for individuals with similar conditions. Specific care and treatment may vary depending on individual need and benefits covered by the plan. This policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. This document may contain prescription brand name drugs that are trademarks of pharmaceutical manufacturers that are not affiliated with RxAdvance.

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Policy was reviewed: 1. Added dose criteria for initial and continuation of therapy for Absorica® LD™. 2. Added drug information for Absorica LD™ (new formulation).	05/2020	05/2020
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	04/14/2023	07/13/2023

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contraindication/adverse event 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
Policy was reviewed: 1. Removed Absorica, Absorica Ld and Myorisan from Drug(s) Applied. 2. Removed prescriber criteria. 3. Removed age criteria. 4. Updated trial and failure criteria. 5. Updated approval duration for continued therapy approval. 6. Updated Continued therapy approval to “Member is currently receiving medication that has been authorized..”	12/16/2024	12/05/2024
Policy was reviewed: 1. Added Accutane to policy	8/21/2025	N/A
Policy was reviewed: 1. Changed language to specify the type of documentation needed.	3/12/2026	N/A
Policy was reviewed: 1. Policy applied only to patient that are 25 years of age and older	6/18/2026	6/25/2026

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