Pharmacy Policy Bulletin: J-0695 Oral Isotretinoin Therapy – Commercial and Healthcare Reform	
Number: J-0695	**Category:** Prior Authorization
Line(s) of Business: ☒ Commercial ☒ Healthcare Reform ☐ Medicare	**Benefit(s):** **Commercial:** **Prior Authorization (1.):** **1.** Other Managed Prior Authorization = Yes w/ Prior Authorization **Healthcare Reform**: Not applicable
Region(s): ☒ All ☐ Delaware ☐ New York ☐ Pennsylvania ☐ West Virginia	**Additional Restriction(s):** None
Version: J-0695-013	**Original Date:** 11/08/2012
Effective Date: 04/25/2025	**Review Date:** 04/09/2025

Drugs Product(s):	• Absorica (isotretinoin capsules) • Absorica LD (isotretinoin capsules)
FDA-Approved Indication(s):	• Treatment of severe recalcitrant nodular acne in non-pregnant patients 12 years of age and older with multiple inflammatory nodules with a diameter of 5 mm or greater who are unresponsive to conventional therapy, including systemic antibiotics.

Background:	• Isotretinoin is a retinoid, which reduces sebaceous gland size and sebum production. Clinical improvement in nodular acne patients occurs in association with a reduction in sebum secretion. The decrease in sebum secretion is temporary and is related to the dose and duration of treatment. The exact mechanism of action of isotretinoin is unknown. • Isotretinoin capsules are indicated for the treatment of severe recalcitrant nodular acne. Nodules are solid, raised inflammatory lesions with a diameter of 5 mm or greater. Severe acne can be characterized by the following: numerous large papules and/or pustules (for example, > 50 inflammatory lesions or > 125 total lesions); multiple nodules and deep lesions (for example, > 5); associated with scarring. • The 2024 American Academy of Dermatology (AAD) guidelines make strong recommendations for benzoyl peroxide, topical retinoids, topical antibiotics, and oral doxycycline. Oral isotretinoin is strongly recommended for acne that is severe, causing psychosocial burden or scarring, or failing standard oral or topical therapy. • Isotretinoin capsules should be reserved for patients with severe nodular acne who are unresponsive to conventional therapy, including systemic antibiotics. Conventional therapy would include: ○ Systemic antibiotic therapy for acne, such as doxycycline, minocycline, and tetracycline. Although oral erythromycin and azithromycin can be effective in treating acne, their use should be limited to those who cannot use tetracyclines (specifically, pregnant women or children < 8 years of age). Erythromycin use should be restricted because of its increased risk of

	bacterial resistance. Use of systemic antibiotics, other than tetracyclines and macrolides, is discouraged because there are limited data for their use in acne. Trimethoprim-sulfamethoxazole and trimethoprim use should be restricted to patients who are unable to tolerate tetracyclines or in treatment-resistant patients. Other systemic antibiotics, including amoxicillin and cephalexin may be used but should be reserved for particular clinical situations. ○ Topical therapies, such as retinoids (e.g., adapalene, tretinoin), antibiotics (e.g., clindamycin, erythromycin), and combination products (e.g., benzoyl peroxide/clindamycin, benzoyl peroxide/erythromycin). ○ Other common systemic therapies, such as spironolactone and estrogen-containing hormonal contraceptives (females). • Prescribing Considerations: ○ Isotretinoin capsules are only indicated for non-pregnant patients because they can cause severe birth defects. Therapy with isotretinoin is monitored through the Ipledge REMS program. The medication can only be prescribed by registered practitioners, dispensed by registered pharmacies, and taken by registered patients. ○ Isotretinoin capsules have high lipophilicity, and oral absorption is enhanced when given with a high fat meal. Absorica or Absorica LD may be taken without regard to meals. ○ Absorica is not substitutable with Absorica LD because of different bioavailability and recommended dosage. ○ A single course of therapy for 15 to 20 weeks has been shown to result in complete and prolonged remission of disease in many patients. If a second course of therapy with isotretinoin is needed, the second course should not be initiated until at least 8 weeks after completion of the first course, because experience has shown that patients may continue to improve following treatment with isotretinoin. ○ Prior to prescribing Absorica perform fasting lipid profile and liver function tests. ○ Perform pregnancy tests prior to prescribing, each month during therapy, end of therapy, and one month after discontinuation. ○ The recommended dosage of Absorica is 0.5 to 1 mg/kg/day and Absorica LD is 0.4 to 0.8 mg/kg/day, given in two divided doses without regards to meals for 15 to 20 weeks. Once daily dosing is not recommended.

Approval Criteria

I. Initial Authorization

When a benefit, coverage of Absorica (isotretinoin capsules) or Absorica LD may be approved when all of the following criteria are met **(A. through E.)**:

A. The member is 12 years of age or older.

B. The member has a diagnosis of acne (ICD-10: L70.0), classified as severe nodular acne.

C. The member has experienced therapeutic failure or intolerance to one (1) generic, topical acne product from two (2) different therapeutic categories **(1. and 2.)**, or all topical acne products are contraindicated:

1. Topical retinoids: adapalene (cream or gel), adapalene-benzoyl peroxide (gel), non-micronized tretinoin (cream or gel), tazarotene (cream)

2. Topical antibiotics: clindamycin (gel, lotion, or solution), erythromycin (gel, solution, swab), clindamycin-benzoyl peroxide (1.2-2.5% or 1-5% gel), erythromycin-benzoyl peroxide (gel)

D. The member has experienced therapeutic failure or intolerance to at least one (1) oral antibiotic indicated for the treatment of acne (for example, minocycline immediate-release (IR), tetracycline, doxycycline), or all oral antibiotics are contraindicated.

E. The member has experienced therapeutic failure or intolerance to one (1) of the following plan-preferred agents **(1. through 5.)**:
   1. Amnesteem
   2. Claravis
   3. Myorisan
   4. Zenatane
   5. Accutane

II. Reauthorization

When a benefit, reauthorization of Absorica (isotretinoin capsules) or Absorica LD may be approved when all of the following criteria are met **(A. and B.)**:

A. The member has not received isotretinoin therapy for least 8 weeks after completion of the initial course.

B. The member has experienced persistent or recurring severe acne following the initial course of isotretinoin therapy.

III. An exception to some or all of the criteria above may be granted for select members and/or circumstances based on state and/or federal regulations.

Limitations of Coverage

I. Oral isotretinoin agents must not be used by female patients who are or may become pregnant.

II. Coverage of drugs addressed in this policy for disease states outside of the FDA-approved indications should be denied based on the lack of clinical data to support effectiveness and safety in other conditions.

III. For Commercial or HCR members with a closed formulary, a non-formulary product will only be approved if the member meets the criteria for a formulary exception in addition to the criteria outlined within this policy.

Authorization Duration

- Commercial and HCR plans: If approved, up to a 5 month authorization may be granted.

Automatic Approval Criteria

None.

Refer to J-374 for previous versions.

References:

1. Absorica [package insert]. Cranbury, NJ. Sun Pharmaceutical Industries, Inc.; July 2023.
2. Absorica LD [package insert]. Cranbury, NJ. Sun Pharmaceutical Industries, Inc.; July 2023.
3. Amnesteem [package insert]. Canonsburg, PA. Mylan Pharmaceuticals Inc.; October 2022.
4. Claravis [package insert]. North Wales, PA: Teva Pharmaceuticals USA Inc.; October 2022
5. Myorisan [package insert]. Lake Forest, IL: VersaPharm Incorporated; October 2022.
6. Zenatane [package insert]. Bachupally, India: Dr. Reddy's Laboratories Limited; October 2022.
7. Reynolds RV, Yeung H, Cheng CE, et al. Guidelines of care for the management of acne vulgaris. *J Am Acad Dermatol*. 2024 Jan 30:S0190-9622(23)03389-3.
8. Hauk L. Acne vulgaris: treatment guidelines from the AAD. *Am Fam Physician*. 2017;95(11):740-741.
9. Oge' LK, Broussard A, Marshall MD. Acne vulgaris: diagnosis and treatment. *Am Fam Physician*. 2019;100(8):475-484.