Pharmacy Medical Necessity Guidelines: Isotretinoin

Effective: September 15, 2026

Prior Authorization Required	√	Type of Review – Care Management	
Not Covered		Type of Review – Clinical Review	√
Pharmacy (RX) or Medical (MED) Benefit	RX	Department to Review	RXUM
These pharmacy medical necessity guidelines apply to the following: ☒ Tufts Health RITogether – A Rhode Island Medicaid Plan		**Fax Numbers:** RXUM: 617.673.0939	

Note: This guideline does not apply to Medicare Members (includes dual eligible Members).

OVERVIEW

FOOD AND DRUG ADMINISTRATION-APPROVED INDICATIONS

Isotretinoin is indicated for the 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 millimeter or greater. Due to significant adverse reactions associated with use, isotretinoin is reserved for patients with severe nodular acne who are unresponsive to convention therapy, including systemic antibiotics.

If a second course of isotretinoin therapy is needed, it is not recommended before a two-month waiting period because a patient's acne may continue to improve following the first course of therapy.

Isotretinoin may only be administered to patients enrolled in the iPLEDGE program.

COVERAGE GUIDELINES

The plan may authorize coverage of isotretinoin for Members when **ALL** of the following criteria are met:

1. The request is for a Member with one of the following conditions: severe recalcitrant nodular acne, cystic acne, acne vulgaris

   AND

   The Member had an insufficient response to a minimum of a 4-week course of therapy with an oral antibiotic

   AND

   If the request is for a brand isotretinoin product: The member had an inadequate response, intolerance or contraindication to a generic oral isotretinoin product and there is a clinical rationale why the same response is not anticipated with the brand oral isotretinoin product.

   OR

2. The request is for a Member with one of the following conditions: hidradenitis suppurativa, ichthyosis follicularis, pityriasis rubra pilaris, use as part of a chemotherapy regimen, or a CMS-recognized off-label use

   AND

   If the request is for a brand isotretinoin product: The member had an inadequate response, intolerance or contraindication to a generic oral isotretinoin product and there is a clinical rationale why the same response is not anticipated with the brand oral isotretinoin product.

LIMITATIONS

1. Approvals will be limited to 6 months for acne-related conditions, and a Member will not be approved for more than two complete courses of therapy. A second course of therapy will only be approved if the Member has been off isotretinoin therapy for a period of at least 8 weeks.
2. Approvals will be limited to 2 years for hidradenitis suppurativa, ichthyosis follicularis, pityriasis rubra pilaris, if part of a chemotherapy regimen, or if for a CMS-recognized off-label use.
3. Requests for brand-name products, which have AB-rated generics, will be reviewed according to Brand Name criteria.

CODES

None

REFERENCES

1. Absorica/Absorica LD (isotretinoin) [prescribing information]. Cranbury, NJ: Sun Pharmaceutical Industries, Inc; June 2023 .
2. Amnesteem (isotretinoin) [prescribing information] Morgantown, WV: Mylan Pharmaceuticals; August 2022.

3. Claravis (isotretinoin) [prescribing information]. North Wales, PA: Teva Pharmaceuticals, Inc; August 2022 .
4. Myorisan (isotretinoin) [prescribing information]. Lake Forest, IL: Akorn; December 2022 .
5. Zenatane (isotretinoin) [prescribing information]. Princeton, NJ: Dr. Reddy's Laboratories, Inc; May 2024.

APPROVAL HISTORY

October 11, 2022: Reviewed by Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:

1. September 12, 2023: No changes.
2. September 10, 2024: Administrative change to fax number.
3. September 9, 2025: No changes
4. September 15, 2026: No changes.

BACKGROUND, PRODUCT AND DISCLAIMER INFORMATION

Pharmacy Medical Necessity Guidelines have been developed for determining coverage for plan benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. The plan makes coverage decisions on a case-by-case basis considering the individual member's health care needs. Pharmacy Medical Necessity Guidelines are developed for selected therapeutic classes or drugs found to be safe, but proven to be effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. The plan revises and updates Pharmacy Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Pharmacy Medical Necessity Guideline and a self-insured Member's benefit document, the provisions of the benefit document will govern.

Treating providers are solely responsible for the medical advice and treatment of members. The use of this policy is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to member eligibility and benefits on the date of service, coordination of benefits, referral/authorization and utilization management guidelines when applicable, and adherence to plan policies and procedures and claims editing logic.

Provider Services