Pharmacy Medical Necessity Guidelines: Isotretinoin

Effective: February 9, 2021

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:

Commercial Products

☐ Tufts Health Plan Commercial products – large group plans
☐ Tufts Health Plan Commercial products – small group and individual plans
☐ Tufts Health Freedom Plan products – large group plans
☐ Tufts Health Freedom Plan products – small group plans
- CareLink℠ – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization

Tufts Health Public Plans Products

☐ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product)
☒ Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans
☐ Tufts Health RITogether – A Rhode Island Medicaid Plan

Fax Numbers:
RXUM: 617.673.0988

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

OVERVIEW

The recommended dosage of isotretinoin for severe recalcitrant nodular acne is 0.5 to 1 mg/kg/day orally in two divided doses for 15 to 20 weeks. Therapy may be discontinued earlier if the total cyst count decreases by 70%. A second course of isotretinoin therapy may be initiated after a period of at least two months off therapy. Isotretinoin at a dose of ≤0.5 mg/kg/day may be used to minimize initial flaring.

FOOD AND DRUG ADMINISTRATION-APPROVED INDICATIONS

Isotretinoin is indicated for the treatment of severe recalcitrant nodular acne.

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

1. 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. A quantity limit of two capsules per day applies.

4. 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 2020.
2. Amnesteem (isotretinoin) [prescribing information] Morgantown, WV: Mylan Pharmaceuticals; August 2018.
3. Claravis (isotretinoin) [prescribing information]. North Wales, PA: Teva Pharmaceuticals, Inc; April 2018.
4. Myorisan (isotretinoin) [prescribing information]. Lake Forest, IL: VersaPharm Inc.; August 2019.
5. Zenatane (isotretinoin) [prescribing information]. Princeton, NJ: Dr. Reddy's Laboratories, Inc; January 2019.

APPROVAL HISTORY

July 19, 2012: Reviewed by Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:

1. December 9, 2014: Approval will be limited to generic products.
2. April 14, 2015: Diagnosis of hidradenitis suppurativa included. For ichthyosis follicularis and pityriasis rubra pilaris the criteria was modified to not include a previous trial with an antibiotic regimen; a 2 year approval was added for non-acne conditions.
3. January 1, 2016: Administrative change to rebranded template.
4. May 10, 2016: Remove Limitations #4 "A course of therapy for an acne-related condition should not exceed a total cumulative dose of 150 mg/kg." and #5 "Requests for quantities that exceed the quantity limit will be reviewed according to the Quantity Limit criteria."
5. May 9, 2017: Administrative update, adding Tufts Health RITogether to the template
6. July 11, 2017: No changes.
7. July 10, 2018: No changes.
8. June 11, 2019: Administrative changes made to template.
9. August 13, 2019: Increased length of approval from five months to six months.
10. February 11, 2020: Updated criteria for brand name oral isotretinoin products. Added to the limitations section of the MNG that requests for brand-name products with AB-rated generics will also be reviewed according to brand-name criteria.
11. February 9, 2021: 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.