Pharmacy Medical Necessity Guidelines: Isotretinoin

Effective: July 10, 2018

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

This Pharmacy Medical Necessity Guidelines applies to the following:

**Tufts Health Plan Commercial Plans**
☐ Tufts Health Plan Commercial Plans – large group plans
☐ Tufts Health Plan Commercial Plans – small group and individual plans

**Tufts Health Public Plans**
☐ Tufts Health Direct – Health Connector
☒ Tufts Health Together – A MassHealth Plan
☐ Tufts Health RITogether – A Rite Care + Rhody Health Partners Plan

**Tufts Health Freedom Plan products**
☐ Tufts Health Freedom Plan - large group plans
☐ Tufts Health Freedom Plan - small group plans

Fax Numbers:
RXUM: 617.673.0988

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
   The request is for a generic 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
   The request is for a generic product

LIMITATIONS
1. Approvals will be limited to 5 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.

CODES
None

REFERENCES
3. Claravis (isotretinoin) [prescribing information]. North Wales, PA: Teva Pharmaceuticals, Inc; April 2016.

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

Subsequent endorsement date(s) and changes made:
- December 9, 2014: Approval will be limited to generic products.
- 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.
- January 1, 2016: Administrative change to rebranded template.
- 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.”
- May 9, 2017: Administrative update, adding Tufts Health RITogether to the template
- July 11, 2017: No changes.
- July 10, 2018: 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. They are used in conjunction with a Member’s benefit document and in coordination with the Member’s physician(s). 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.

This Pharmacy Medical Necessity Guideline does not apply to Uniformed Services Family Health Plan Members or to certain delegated service arrangements. Unless otherwise noted in the Member’s benefit document or applicable Pharmacy Medical Necessity Guideline, Pharmacy Medical Necessity Guidelines do not apply to CareLinkSM Members. For self-insured plans, drug coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a coverage guideline and a self-insured Member’s benefit document, the provisions of the benefit document will govern. Applicable state or federal mandates will take precedence.

For Tufts Health Plan Medicare Preferred, please refer to Tufts Health Plan Medicare Preferred Prior Authorization Criteria.

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.