Isotretinoin (Absorica, Amnesteem, Claravis, Myorisan, Zenatane)

Effective: 7/1/15

Clinical Documentation and Prior Authorization Required | ✓ | Type of Review – Case Management
Not Covered | ✓ | Type of Review – Clinical Review
Fax: 617-673-0988
Pharmacy (RX) or Medical (MED) Benefit | RX | Department to Review

OVERVIEW

FDA-APPROVED INDICATIONS
Isotretinoin products are indicated for the treatment of severe recalcitrant nodular acne unresponsive to conventional therapy.

The recommended dosage for severe recalcitrant nodular acne is 0.5 to 1 mg/kg/day orally in 2 divided doses for 15 to 20 weeks; therapy may be discontinued earlier if the total cyst count decreases by 70%. A second course of therapy may be initiated after a period of ≥2 months off therapy. A dose of ≤0.5 mg/kg/day may be used to minimize initial flaring.

PHARMACY COVERAGE GUIDELINES

Tufts Health Plan – Network Health may authorize coverage of isotretinoin for members when all the following criteria for a particular regimen are met and limitations do not apply:

- The request is for a member with one of the following conditions: severe recalcitrant nodular acne, cystic acne, acne vulgaris, hidradenitis suppurativa 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
- The request is for a member with one of the following conditions: ichthyosis follicularis, pityriasis rubra pilaris. part of a chemotherapy regimen or for a CMS-recognized off-label use, and
- The request is for a generic product

LIMITATIONS

- Approvals will be limited to a 5-month duration for acne-related conditions and hidradenitis suppurativa, 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.
- Approvals will be limited to 2 years for ichthyosis follicularis, pityriasis rubra pilaris, if part of a chemotherapy regimen or if for a CMS-recognized off-label use.
- A quantity limit of two capsules per day applies.
- A course of therapy for an acne-related condition should not exceed a total cumulative dose of 150 mg/kg.
- Requests for quantities that exceed the quantity limit will be reviewed according to the Quantity Limit criteria.

CODES

None

REFERENCES

1. Absorica (isotretinoin) [prescribing information]. Jacksonville, FL: Ranbaxy Laboratories Inc; August 2014.

APPROVAL HISTORY

- 04/14/15: Reviewed by the Pharmacy and Therapeutics Committee. 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.
- 12/09/14: Reviewed by the Pharmacy and Therapeutics Committee. Approval will be limited to generic products.
- 07/19/12 : Reviewed by the Pharmacy and Therapeutics Committee
BACKGROUND, PRODUCT, AND DISCLAIMER INFORMATION

Pharmacy Medical Necessity Guidelines have been developed for determining coverage for Tufts Health Plan – Network Health benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. They are used in conjunction with the applicable Member Handbook and in coordination with the member’s physician(s). 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 Tufts Health Plan – Network Health service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. Tufts Health Plan – Network Health reviews Pharmacy Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

Pharmacy Medical Necessity Guidelines apply to all fully insured Tufts Health Plan – Network Health offerings unless otherwise noted in this policy or the applicable Member Handbook. Check the applicable product formulary in the Pharmacy section of our website to determine if the drug requires you to get prior authorization.

For Tufts Health Unify (Medicare-Medicaid One Care for people ages 21 – 64), please refer to Tufts Health Unify Prior Authorization Medical Necessity Guidelines.

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.