

Commercial/Healthcare Exchange PA Criteria

Effective: February 2013

Prior Authorization: Absorica

Products Affected: Absorica (isotretinoin) capsules

Medication Description: Isotretinoin (13-cis retinoic acid, RO-43,780) is classified as a retinoid, which is a synthetic analogue of vitamin A. Its exact mechanism of action is not known. When administered in pharmacologic dosages, isotretinoin inhibits sebaceous gland function and keratinization. In nodular acne, clinical improvement is associated with a reduction in sebum secretion which is related to the dose and duration of isotretinoin treatment. Retinoids affect the keratinization process, and therefore without specificity exhibit effectiveness in all types of hyperkeratotic conditions.

Covered Uses: 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.

Exclusion Criteria:

1. Known hypersensitivity to isotretinoin (or Vitamin A, given the chemical similarity to isotretinoin)
2. Known or suspected pregnancy

Required Medical Information:

1. Diagnosis
2. Previous medications tried/failed
3. Confirmation of the use 2 effective contraception methods or continuous abstinence for 1 month prior, during, and 1 month after isotretinoin therapy

Age Restrictions: 12 years of age and older

Prescriber Restrictions: Prescribed by, or in consultation with, a dermatologist.

Coverage Duration: 5 months

Other Criteria:

- A. Patient has diagnosis of severe recalcitrant nodular acne characterized by multiple inflammatory nodules with a diameter of 5 mm or greater; AND
- B. Patient's acne is unresponsive to conventional therapy, including systemic antibiotics; AND
- C. Patient has a documented intolerance to, or treatment failure with, an adequate trial of TWO (2) generic isotretinoin preparations (Amnesteem, Claravis, Myorisan).

References:

1. Absorica full prescribing information. Ranbaxy Laboratories, Jacksonville, FL

Policy Revision history

Rev #	Type of Change	Summary of Change	Sections Affected	Date
1	New Policy	New Policy	All	02/2013
2	Update	Moved to updated template Revision History: 7/15, 8/17	All	02/05/2020