

Initial Prior Authorization

Isotretinoins (All Oral)

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Absorica	isotretinoin
Absorica LD	isotretinoin
Accutane	isotretinoin
Amnesteem	isotretinoin
Claravis	isotretinoin
Myorisan	isotretinoin
Zenatane	isotretinoin

Indications

FDA-approved Indications

Absorica, Absorica LD

Absorica and Absorica LD are 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 mm or greater. Because of significant adverse reactions associated with its use, Absorica and Absorica LD are reserved for patients with severe nodular acne who are unresponsive to conventional therapy, including systemic antibiotics.

Reference number(s)
118-A

Limitations of Use

If a second course of Absorica/Absorica LD therapy is needed, it is not recommended before a two-month waiting period because the patient's acne may continue to improve following a 15 to 20-week course of therapy.

Accutane, Amnesteem, Claravis, Myorisan, Zenatane

Isotretinoin is indicated for the treatment of severe recalcitrant nodular acne. Nodules are inflammatory lesions with a diameter of 5 mm or greater. The nodules may become suppurative or hemorrhagic. "Severe," by definition, means "many" as opposed to "few or several" nodules. Because of significant adverse effects associated with its use, isotretinoin should be reserved for patients with severe nodular acne who are unresponsive to conventional therapy, including systemic antibiotics. In addition, isotretinoin is indicated only for those patients who are not pregnant, because isotretinoin can cause life-threatening birth defects.

A single course of therapy for 15 to 20 weeks has been shown to result in complete and prolonged remission of disease in many patients. If a second course of therapy is needed, it should not be initiated until at least 8 weeks after completion of the first course, because experience has shown that patients may continue to improve while off isotretinoin. The optimal interval before retreatment has not been defined for patients who have not completed skeletal growth.

Compendial Uses

Acne – refractory⁹

Cutaneous T-Cell Lymphoma (CTCL) (e.g., mycosis fungoides, Sézary syndrome)⁷

Keratosis follicularis (Darier Disease) – severe⁹

Lamellar ichthyosis – severe skin involvement⁷

Neuroblastoma⁹

Pityriasis rubra pilaris⁷

Rosacea – severe refractory⁹

Squamous Cell Cancers – to reduce the development of precancers and skin cancers in high risk patients⁹

Transient acantholytic dermatosis (Grover's Disease) – severe⁹

Coverage Criteria

Acne Vulgaris, Rosacea

Reference number(s)
118-A

Authorization may be granted when the patient has a diagnosis of severe recalcitrant nodular acne vulgaris, refractory acne vulgaris, OR severe refractory rosacea when ALL of the following criteria are met:

- The patient has tried and had an inadequate treatment response to ANY topical acne product AND an oral antibiotic [Note: Topical products include salicylic acid, benzoyl peroxide, azelaic acid, adapalene, tretinoin, tazarotene, clindamycin, erythromycin, or metronidazole for rosacea. Oral antibiotics include minocycline, doxycycline, tetracycline, erythromycin, trimethoprim-sulfamethoxazole, trimethoprim, azithromycin.]
- Treatment will be limited to 40 weeks (2 courses) or less AND with at least 8 weeks between each course

Neuroblastoma, Cutaneous T-cell Lymphoma (CTCL), Squamous Cell Cancers, Grover's Disease, Darier Disease, Lamellar Ichthyosis, Pityriasis Rubra Pilaris

Authorization may be granted when the patient has a diagnosis of neuroblastoma, cutaneous T-cell lymphoma (CTCL) (e.g., mycosis fungoides, Sézary syndrome), is at high risk for developing skin cancer (squamous cell cancers), transient acantholytic dermatosis (Grover's Disease), keratosis follicularis (Darier Disease), lamellar ichthyosis, OR pityriasis rubra pilaris

Duration of Approval (DOA)

- 118-A: DOA 12 months

References

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