

## Oral Retinoids for Acne

### Disclaimer

*Clinical guidelines are developed and adopted to establish evidence-based clinical criteria for utilization management decisions. Clinical guidelines are applicable according to policy and plan type. The Plan may delegate utilization management decisions of certain services to third parties who may develop and adopt their own clinical criteria.*

*Coverage of services is subject to the terms, conditions, and limitations of a member's policy, as well as applicable state and federal law. Clinical guidelines are also subject to in-force criteria such as the Centers for Medicare & Medicaid Services (CMS) national coverage determination (NCD) or local coverage determination (LCD) for Medicare Advantage plans. Please refer to the member's policy documents (e.g., Certificate/Evidence of Coverage, Schedule of Benefits, Plan Formulary) or contact the Plan to confirm coverage.*

### Summary

Acne is a skin issue that arises due to a multitude of factors, such as follicular hyperkeratinization, excessive sebum production, a bacterial overgrowth (notably *Cutibacterium acnes*), and inflammation.

The approach to treating acne is largely influenced by its severity. Therapeutic options aim to address the multiple contributing factors of acne pathogenesis.

1. First-line therapy generally includes topical formulations such as benzoyl peroxide or salicylic acid, which function to prevent oil gland obstruction, and topical antibiotics to manage bacterial proliferation.
2. For moderate to severe or refractory acne, systemic treatments may be warranted. Oral antibiotics are utilized for their anti-inflammatory and antibacterial properties. Hormonal therapies, including certain oral contraceptive pills, can be particularly beneficial in female patients, where hormonal fluctuations can exacerbate the condition.
3. For recalcitrant or severe forms of acne, prescription medications such as isotretinoin may be employed. Isotretinoin acts by profoundly reducing sebum production, thus targeting a key component of acne pathogenesis.

4. Additional treatment options may include light or laser therapies and chemical peels, which help reduce bacteria and inflammation, and remove dead skin cells. For severe or hard-to-treat acne, more intense methods like injections or surgery can be used, but these are usually aimed at dealing with leftover acne scars rather than treating current acne outbreaks.

Isotretinoin, a retinoid medication, is often prescribed for severe acne when other treatments have proven ineffective. It carries serious risks, and to ensure safe use, the iPLEDGE program is in place, and has specific registration and requirements for:

- Wholesalers/distributors
- Prescribers
- Pharmacies
- Patients (members)

The iPLEDGE program can be accessed at <https://www.iPledgeprogram.com> or by calling 1-866-495-0654.

**Table 1: Oral Retinoids for Acne**

<b>Brand</b>	<b>Available generic(s) or (generic name)</b>	<b>Orange Book Therapeutic Equivalence Code*</b>	<b>Available Strengths</b>
Accutane	Amnesteem Claravis Isotretinoin Myorisan Zenatane	AB1	10mg, 20mg, 30mg, 40mg
Absorica	Isotretinoin	AB2	10mg, 20mg, 25mg, 30mg, 35mg, 40mg
Absorica LD	(Isotretinoin)	NR <sup>#</sup>	8mg, 16mg, 24mg, 32mg

\*Drugs that the FDA considers to be therapeutically equivalent to other pharmaceutically equivalent products, i.e., drugs products for which there are no known or suspected bioequivalence problems, and can be substituted for one another (e.g., AB1 can be substituted with AB1 products, but not AB2).

<sup>#</sup>NR (Not Rated), Products listed in the Orange Book that are not multi-source (i.e., no FDA-approved generic equivalents).

## Definitions

“**Acanthosis Nigricans**” is a skin condition characterized by dark, thick, velvety skin in body folds and creases.

“**Acne**” is a type of skin problem, more commonly known as pimples.

“**Carcinoma**” is another word for cancer.

“**Neoplasm**” is a word commonly used to describe fast and abnormal growth of tissues due to cells dividing too fast.

“**Neuroblastoma**” is a type of cancer that starts in early forms of nerve cells found in an embryo or fetus.

“**Psoriasis**” is a chronic skin condition that speeds up the life cycle of skin cells causing cells to build up rapidly on the surface of the skin.

“**Recalcitrant**” means hard to deal with or treat.

“**Rosacea**” is a type of skin problem that affects areas of the skin such as face, cheeks, nose, forehead and chin—causing redness or raised bumps.

“**Squamous Cell Carcinoma**” is a type of skin cancer that begins in the squamous cells.

## Medical Necessity Criteria for Authorization

The Plan considers isotretinoin medically necessary when **ONE** of the following criteria is met:

1. The member meets **BOTH** of the following criteria:
  - a. The member has **ONE** of the following diagnoses:
    - i. severe recalcitrant nodular (cystic) acne; **or**
    - ii. severe refractory rosacea; **or**
    - iii. moderate to severe acne vulgaris; **and**
  - b. The member is unable to use, or has tried and failed **BOTH** of the following conventional therapies:
    - i. topical agent (e.g., clindamycin phosphate, benzoyl peroxide); **and**
    - ii. oral antibiotics (e.g., doxycycline); **OR**
2. The medication is being requested for **ONE** of the following diagnoses or uses:

- a. acanthosis nigricans; **or**
- b. advanced squamous cell carcinoma of the skin, refractory to standard therapy; **or**
- c. cutaneous T-cell lymphoma (including mycosis fungoides and Sézary syndrome); **or**
- d. high-risk neuroblastoma; **or**
- e. keratoacanthomas; **or**
- f. keratosis follicularis (Darier's disease); **or**
- g. keratosis palmaris et plantaris; **or**
- h. lamellar ichthyosis; **or**
- i. pityriasis rubra pilaris (PRP); **or**
- j. prevention of squamous cell skin cancer for a member with high-risk; **or**
- k. psoriasis, severe or pustular; **or**
- l. squamous cell carcinoma of the lung, with inoperable neoplasms.

**If the above prior authorization criteria are met, isotretinoin will be approved for 12 months.**

#### Experimental or Investigational / Not Medically Necessary

Isotretinoin for any other indication is considered not medically necessary by the Plan, as it is deemed to be experimental, investigational, or unproven.

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#### Clinical Guideline Revision / History Information

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