UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2021 P 2157-4
Program	Prior Authorization/Medical Necessity
Medications	Absorica* (isotretinoin), Absorica LD* (isotretinoin micronized)
P&T Approval Date	12/2018, 12/2019, 5/2020, 7/2021
Effective Date	10/1/2021; Oxford only: 10/1/2021

1. Background:

Isotretinoin is indicated for the treatment of severe recalcitrant nodular acne. Nodules are inflammatory lesions with a diameter of 5 mm or more. "Severe," by definition, means "many" as opposed to "few or several" nodules. Isotretinoin should be reserved for patients with severe nodular acne who are unresponsive to conventional therapy, including systemic antibiotics. Due to its teratogenicity, isotretinoin is not indicated in females who are or may become pregnant.

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 is recommended to wait 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.

2. Coverage Criteria:

A. **Initial Authorization**

1. **Absorica* or Absorica LD*** will be approved based on **all** of the following criteria:

a. Submission of medical records documenting **one** of the following:

(1) Diagnosis of severe recalcitrant nodular acne unresponsive to conventional therapy

-OR-

(2) Diagnosis of treatment resistant acne

-AND-

b. History of failure, contraindication, or intolerance to an adequate trial of **two** of the following conventional therapy regimens:

(1) Topical retinoid or retinoid-like agent [e.g.,Retin-A/Retin-A Micro

(tretinoin),]

-OR-

(2) Oral antibiotic [e.g., Ery-Tab (erythromycin), Minocin (minocycline)]

-OR-

(3) Topical antibiotic with or without benzoyl peroxide [eg, Cleocin-T (clindamycin), erythromycin, BenzaClin (benzoyl peroxide/clindamycin), Benzamycin (benzoyl peroxide/erythromycin)]

-AND-

c. History of failure, contraindication, or intolerance to an adequate trial on **two** oral isotretinoin formulations (document duration of trial):

(1) Claravis
(2) Myorisan
(3) Zenatane
(4) Amnesteem

Authorization will be issued for 6 months.

B. **Reauthorization**

1. **Absorica or Absorica LD** will be approved for **continuation of therapy** based on submission of medical records documenting **one** of the following criterion:

a. After ≥ 2 months **off** therapy, persistent or recurring severe recalcitrant nodular acne is still present.

-OR-

b. Total cumulative dose for total duration of therapy is less than 150 mg/kg (will be approved up to a total up 150 mg/kg)

Reauthorization will be issued for 6 months.

*Absorica and Absorica LD are typically excluded from benefit coverage

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class
- Supply limits may be in place.

4. References:

1. Absorica [Package Insert] Jacksonville, FL: Ranbaxy Laboratories Inc.;June 2020.

Program	Prior Authorization/Medical Necessity – Absorica, Absorica LD
Change Control	
Date	Change
12/2018	New program
12/2019	Annual review. Updated references.
5/2020	Added Absorica LD in scope.
7/2021	Added authorized generic in scope. Updated references.