UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2018 P 1051-8
Program	Prior Authorization/Notification - Isotretinoin
Medications	Absorica* (isotretinoin), Myorisan (isotretinoin), Claravis (isotretinoin), Amnesteem (isotretinoin), Zenatane (isotretinoin)
P&T Approval Date	4/2013, 2/2014, 11/2014, 11/2015, 7/2016, 7/2017, 7/2018
Effective Date	10/1/2018; Oxford only: 10/1/2018

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. 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. Due to its severe 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, do not initiate it 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.

2. Coverage Criteria:

I. Oncology Uses (off label)

A. **Oral isotretinoin** will be approved based on the following criteria:

1. Used for oncology indication meeting NCCN or other compendia recommendations per policy

Authorization will be issued for 60 months

II. Acne

A. **Initial Authorization**

1. **Oral isotretinoin** will be approved based on **all** of the following criteria:

a. 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 on **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)]

Authorization will be issued for 6 months of therapy.

B. **Reauthorization**

1. **Oral isotretinoin** will be approved for **continuation of therapy** based on 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 of therapy.

*May be excluded from benefit coverage

3. Additional Clinical Rules:

- Supply limits may be in place.

4. References:

1. Absorica Prescribing Information. Ranbaxy Laboratories Inc. Jacksonville FL. December 2017.
2. Amnesteem Prescribing information. Mylan Pharmacetuicals Inc. Morgantown WV. April 2018.
3. Claravis Prescribing Information. Barr Laboratories Inc. Pomona, NY. April 2016
4. Myorisan Prescribing Information. VersaPharm Incorporated. Marietta, GA. September 2015.
5. Zenatane Prescribing Information. Dr. Reddy's Laboratories Limited. Bachupally, India. June 2015.

Program	Prior Authorization/Notification - Isotretinoin
Change Control	
Date	Change
2/2014	Added criteria for approval for oncology uses. Documented isotretinoin brand names.
9/2014	Administrative change - Tried/Failed exemption for State of New Jersey removed.
11/2014	Revised reauthorization criteria to add weight based dosing.
11/2015	Revised background information. Updated references.
7/2016	Removed maximum number of reauthorizations from the criteria per new clinical guidelines. Removed Accutane and Sotret as they have been discontinued from the market. Updated authorization and reauthorization period from 20 weeks to 6 months.
7/2017	Annual review. Updated references.
7/2018	Annual review. Updated references.