UnitedHealthcare Community Plan

Clinical Pharmacy Program Guidelines for Isotretinoin

Program	Prior Authorization
Medication	Myorisan (isotretinoin), Claravis (isotretinoin), Amnesteem (isotretinoin), Zenatane (isotretinoin), Absorica (isotretinoin)
Markets in Scope	Arizona, California, Florida-CHIP, Hawaii, Maryland, Nevada, New Mexico, New York, New York EPP, Ohio, Rhode Island
Issue Date	9/2009
Pharmacy and Therapeutics Approval Date	2/2018
Effective Date	4/2018

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:

A. <u>Oncology Uses (off label)</u>

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

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

Authorization will be issued for 12 months

B. <u>Acne</u>

1. **Initial Authorization**

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

      1. **One** of the following:

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

         -OR-

         (b) Diagnosis of treatment resistant acne

         -AND-

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

         (a) Topical retinoid or retinoid-like agent [eg,Retin-A/Retin-A Micro (tretinoin)]

         -OR-

         (b) Oral antibiotic [eg, Ery-Tab (erythromycin), Biaxin (clarithromycin), Minocin (minocycline)]

         -OR-

         (c) 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.

2. **Reauthorization**

   a. **Oral isotretinoin** will be approved for **continuation of therapy** based on one of the following criterion:

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

-OR-

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

Reauthorization will be issued for up to 6 months of therapy.

3. References:

1. Absorica Prescribing Information. Ranbaxy Laboratories Inc. Jacksonville FL. September 2015.
2. Amnesteem Prescribing information. Mylan Pharmacetuicals Inc. Morgantown WV. March 2015.
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 –Myorisan (isotretinoin), Claravis (isotretinoin), Amnesteem (isotretinoin), Zenatane (isotretinoin)
Change Control	
Date	Change
9/2009	Criteria were taken from a previously approved Unison policy, RX06 Accutane. Policy was reformatted.
12/2010	Annual Review, no changes.
12/2011	Annual Review, no changes.
12/2012	Annual Review, no changes.
7/2016	Clinical criteria updated to align with E&I notification policy. Updated policy to new template.
9/2016	Added Absorica and non-preferred criteria to policy
7/2017	Annual review. Updated reauthorization duration. Updated references.
9/2017	Added clarithromycin as an example of an oral antibiotic
2/2018	Removed non-preferred criteria since all products are preferred