Isotretinoin
Policy Number: C4231-C

CRITERIA EFFECTIVE DATES:

ORIGINAL EFFECTIVE DATE	LAST REVIEWED DATE	NEXT REVIEW DATE
4/1/2012	3/1/2019	3/1/2020
J CODE	**TYPE OF CRITERIA**	**LAST P&T APPROVAL**
NA	RxPA	Q2 2019

PRODUCTS AFFECTED:
Absorica, Amnesteem, Claravis, Myorisan, Zenatane , isotretinoin

DRUG CLASS:
Acne Products

ROUTE OF ADMINISTRATION:
External

PLACE OF SERVICE:
Retail Pharmacy

AVAILABLE DOSAGE FORMS:
Absorica CAPS 10MG, Absorica CAPS 20MG, Absorica CAPS 25MG, Absorica CAPS 30MG, Absorica CAPS 35MG, Absorica CAPS 40MG, Amnesteem CAPS 10MG, Amnesteem CAPS 20MG, Amnesteem CAPS 40MG, Claravis CAPS 10MG, Claravis CAPS 20MG, Claravis CAPS 30MG, Claravis CAPS 40MG, ISOtretinoin CAPS 10MG, ISOtretinoin CAPS 20MG, ISOtretinoin CAPS 30MG, ISOtretinoin CAPS 40MG, Myorisan CAPS 10MG, Myorisan CAPS 20MG, Myorisan CAPS 30MG, Myorisan CAPS 40MG, Zenatane CAPS 10MG, Zenatane CAPS 20MG, Zenatane CAPS 30MG, Zenatane CAPS 40MG

FDA-APPROVED USES: Isotretinoin is indicated for the treatment of severe recalcitrant nodular acne.

COMPENDIAL APPROVED OFF-LABELED USES: None

COVERAGE CRITERIA: INITIAL AUTHORIZATION

DIAGNOSIS: severe recalcitrant nodular acne.

REQUIRED MEDICAL INFORMATION:

A. SEVERE NODULAR ACNE:
   1. Diagnosis of severe recalcitrant nodular acne
      AND
   2. Documentation member had a trial period of 6 months(with at least 3 consistant months of combination therapy- oral and topical) and had an inadequate treatment response to TWO of the following therapy regimens: Topical retinoid or retinoid-like agent OR Oral antibiotic OR Topical antibiotic with or without benzoyl peroxide
      AND
   3. Documentation patient is enrolled in the iPLEDGE REMS program
      AND

4. Documentation of trial (3 months) and inadequate response to Myorisan, isotretinoin (generic), Amnesteem, and Zenatane PRIOR to access to Claravis or Absorica

B. ONCOLOGY INDICATION: SEE STANDARD ONCOLOGY CRITERIA

DURATION OF APPROVAL: Initial authorization: 20 weeks, Continuation of therapy: 20 weeks

QUANTITY: 60 capsules/ 30 days

PRESCRIBER REQUIREMENTS: None

AGE RESTRICTIONS: 12 years of age and older

GENDER:
Male and female

CONTINUATION OF THERAPY:
A. SEVERE NODULAR ACNE:
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) *** A second course of isotretinoin therapy may be initiated after a period of at least two months off therapy. Isotretinoin at a dose of ≤0.5 mg/kg/day may be used to minimize initial flaring.

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION: All other uses of Isotretinoin are considered experimental/investigational and therefore, will follow Molina's Off-Label policy. Isotretinoin is absolutely contraindicated in pregnancy

OTHER SPECIAL CONSIDERATIONS: Black boxed warnings include but may not be limited to risk of birth defects. Isotretinoin may only be administered to patients enrolled in the iPLEDGE program.

BACKGROUND:
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 female patients who are not pregnant, because isotretinoin can cause severe 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.

APPENDIX: None

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