Effective Date: 1/2019
Reviewed: 2/2019, 2/2020, 6/2021, 4/2022, 4/2023 Scope: Medicaid

NON-ONCOLOGY POLICY
isotretinoin capsules

For oncology indications, please refer to NHPRI Oncology Policy

FDA-APPROVED INDICATIONS

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.

Compendial Uses
Acne – refractory[7]
Keratosis follicularis (Darier Disease) – severe[7]
Lamellar ichthyosis – severe skin involvement[6]
Pityriasis rubra pilaris[6]
Rosacea – severe refractory[7]
Transient acantholytic dermatosis (Grover's Disease) – severe[7]

COVERAGE CRITERIA

The requested drug will be covered for 12 months with prior authorization when the following criteria are met:

- The patient has any of the following diagnoses: A) severe recalcitrant nodular acne vulgaris, B) refractory acne vulgaris, C) severe refractory rosacea
  AND
- The patient has tried and had inadequate treatment responses to any topical acne product AND an oral antibiotic
  AND
- Treatment will be limited to 40 weeks (2 courses) or less AND with at least 8 weeks between each course
  OR
- The patient has any of the following diagnoses:
  A) Transient acantholytic dermatosis (Grover's Disease)
  B) Keratosis follicularis (Darier Disease)
  C) Lamellar ichthyosis
  D) Pityriasis rubra pilaris

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