Authorization guidelines
For patients who have the following:
- Documentation of trial, failure or contraindication of at least one oral antibiotic prescribed for the treatment of acne.

Authorization and Limitations
Initial Approval: 5 months for severe recalcitrant nodular acne.
Extended Approval:
- For severe recalcitrant nodular acne
  An additional 5 month approval may be granted after one failure of isotretinoin (or generics) and a 2 month “holiday” from the first.
  OR
- If after 5 months of treatment a minimum of 120mg/kg cumulative dose has not been reached then an extension may be granted to reach this minimum target.

Note: No extensions are granted if the 20 week course produces a cumulative dose greater than 150mg/kg. (0.8mg/kg daily for 5 months produces the 120mg/kg target)

Quantity Limit: 2 capsules/day for all strengths and generic equivalents.

Additional Information:
Isotretinoin is NOT covered for members with the following criteria:
- Use not approved by the FDA; AND
- The use is unapproved and not supported by the literature or evidence as an accepted off-label use.

Special prescribing requirements: Because of isotretinoin’s teratogenicity and to minimize fetal exposure, isotretinoin is approved for marketing only under a special restricted distribution program approved by the Food and Drug Administration. This program is called iPLEDGE. Isotretinoin must only be prescribed by prescribers who are registered and activated with the iPLEDGE program. Isotretinoin must only be dispensed by a pharmacy registered and activated with iPLEDGE, and must only be dispensed to patients who are registered and meet all the requirements of iPLEDGE.
**DOSE**

*Severe recalcitrant nodular acne:* The recommended dose range for isotretinoin is 0.5 to 1 mg/kg given in 2 divided doses with food daily for 15 to 20 weeks. The cumulative target dose is 120 to 150 mg/kg. Adult patients whose disease is very severe with scarring or is primarily manifested on the trunk may require dose adjustments up to 2 mg/kg/day, as tolerated.

**Medically Necessary** — A service or benefit is Medically Necessary if it is compensable under the MA Program and if it meets any one of the following standards:

- The service or benefit will, or is reasonably expected to, prevent the onset of an illness, condition or disability.
- The service or benefit will, or is reasonably expected to, reduce or ameliorate the physical, mental or developmental effects of an illness, condition, injury or disability.
- The service or benefit will assist the Member to achieve or maintain maximum functional capacity in performing daily activities, taking into account both the functional capacity of the Member and those functional capacities that are appropriate for Members of the same age.

Determination of Medical Necessity for covered care and services, whether made on a Prior Authorization, Concurrent Review, Retrospective Review, or exception basis, must be documented in writing.

The determination is based on medical information provided by the Member, the Member’s family/caretaker and the Primary Care Practitioner, as well as any other Providers, programs, agencies that have evaluated the Member.

All such determinations must be made by qualified and trained Health Care Providers. A Health Care Provider who makes such determinations of Medical Necessity is not considered to be providing a health care service under this Agreement.

**References:**