

Reference number(s)
1175-A

Medical Necessity Criteria New to Market Drugs

Coverage Criteria

Authorization may be granted for the requested drug when ALL of the following criteria are met:

- The patient meets ONE of the following:
 - The patient had an inadequate treatment response or intolerance to the required number of formulary alternatives for the given diagnosis. (Requirement: 3 in a class with 3 or more alternatives, 2 in a class with 2 alternatives, or 1 in a class with only 1 alternative.)
 - The patient has a contraindication to ALL formulary alternatives.
 - This is the only FDA-approved product to treat the patient's diagnosis.
- The requested product is being used for an FDA-approved indication OR an indication supported in the compendia of current literature (examples: AHFS, Micromedex, current accepted guidelines).
- The prescribed dose and quantity fall within the FDA-approved labeling or within dosing guidelines found in the compendia of current literature.

Duration of Approval (DOA)

- 1175-A: DOA: 12 months

References

N/A