



Part B Prior Authorization Criteria - Medicare Part B

FDA APPROVED INDICATIONS AND DOSAGE

Please reference individual agent product labeling.

CLINICAL RATIONALE

For the purposes of the Part B Prior Authorization (PA) criteria, indications deemed appropriate are those approved in FDA labeling and/or supported by CMS approved compendium.

Document History

Original Medicare Part B PA criteria, approved by P&T UM Committee 12/2018
Annual Review Medicare Part B criteria, with changes, approved by P&T UM Committee 12/2019
Annual Review Medicare Part B criteria, with changes to criteria, approved by P&T UM Committee 12/2020
Annual Review Medicare Part B criteria, criteria maintained, approved by P&T UM Committee 12/2021

Part B Prior Authorization – Medicare Part B

OBJECTIVE

The intent of the Part B Prior Authorization (PA) program is to determine appropriate Medicare Part B coverage based on Food and Drug Administration (FDA) product labeling and/or clinical practice guidelines and according to dosing recommended in product labeling or CMS approved compendia dosing for the requested indication. Requests will be reviewed when patient-specific documentation has been provided.

TARGET AGENT(S)

To be determined by clients.

PRIOR AUTHORIZATION CRITERIA FOR APPROVAL

Initial Evaluation

The target agent will be approved when ALL of the following are met:

1. ONE of the following:
 - a. The patient has an FDA labeled indication for the requested agent

OR

 - b. The patient has an indication that is supported in CMS approved compendia for the requested agent
 2. The patient does NOT have any FDA labeled contraindications to the requested agent
- AND**
3. The requested dose is within the FDA labeled or CMS approved compendia dosing for the requested indication

Length of Approval: 12 months

Renewal Evaluation

The target agent will be approved when ALL of the following are met:

1. The patient has been previously approved for the requested agent through the plan's Prior Authorization criteria
- AND**
2. ONE of the following:
 - a. The patient has an FDA labeled indication for the requested agent

OR

 - b. The patient has an indication that is supported in CMS approved compendia for the requested agent
 3. The patient has had clinical benefit with the requested agent
- AND**
4. The patient does NOT have any FDA labeled contraindications to the requested agent
- AND**
5. The requested dose is within the FDA labeled or CMS approved compendia dosing for the requested indication

Length of Approval: 12 months