

SPECIALTY GUIDELINE MANAGEMENT

Global Criteria

PROGRAM RATIONALE: The Specialty Global Criteria ensure appropriate utilization of Specialty medications and confirm that selection elements established in the FDA-approved product labeling are followed. These global criteria for approval apply to medications not otherwise managed through a product-specific Specialty Guideline Management (SGM) program. The criteria may be applied in situations where specific criteria are pending development.

These global criteria confirm the medication is prescribed for an FDA-approved indication and that the participant has no contraindications to therapy as described in the FDA-approved product labeling.

For participants who meet the global criteria, the duration of approval for the requested product is 3 months.

SPECIALTY GLOBAL CRITERIA FOR APPROVAL:

1. What is the patient's diagnosis?
2. Is the requested medication prescribed for an FDA-approved indication?
3. Does the patient have a contraindication to the use of the requested medication as listed in the medication's prescribing information?