

STANDARD MEDICARE PART B MANAGEMENT

UNIVERSAL CRITERIA FOR MEDICARE PART B

POLICY

I. PROGRAM SUMMARY

The Universal Criteria for Medicare Part B ensure appropriate utilization of medications eligible for reimbursement under Medicare Part B and confirm that selection elements established in the FDA-approved product labeling and Medicare-approved compendia are followed. These universal criteria for approval apply to medications not otherwise managed through a product-specific Medicare Part B program. The criteria may be applied in situations where specific criteria are pending development.

These universal criteria confirm the medication is prescribed for an FDA-approved indication or compendial use and that the member has no contraindications to therapy as described in the FDA-approved product labeling.

II. CRITERIA FOR APPROVAL

Authorization of 3 months may be granted for a requested medication when both of the following criteria are met:

- A. The medication is being prescribed for one of the below indications:
 1. The medication is prescribed for an FDA-approved indication.
 2. The medication is prescribed for anticancer chemotherapy and the indication is supported by the one of the compendia and level of evidence below:
 - i. NCCN with NCCN Category of 1, 2A, 2B
 - ii. DrugDex I, IIa, or IIb
 - iii. AHFS DI with “supportive” text
 - iv. Clinical Pharmacology with “supportive” narrative text
 - v. Lexi-Drugs with “use: off-label” and Evidence Level A
 - vi. Applicable professional journals or articles
 3. The medication is prescribed for a use other than anticancer chemotherapy and the indication is supported by one of the following:
 - i. DrugDex I, IIa, or IIb
 - ii. AHFS DI with “supportive” text
 - iii. Lexi-Drugs with “use: off-label” and Evidence Level A
 - iv. Applicable professional guidelines
- B. The member does not have contraindications to therapy as described in the prescribing information.

III. REFERENCES

1. Centers for Medicare and Medicaid Services: CMS Benefit Policy Manual Chapter 15- Covered Medical and Other Health Services.

Reference number(s)
5606-A

<https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c15.pdf> Accessed February 23, 2023.