# 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.
  - 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**

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

MedB Universal Criteria 5606-A P2023.docx

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Reference number(s)

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

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