JURISDICTION SPECIFIC MEDICARE PART B

CAMCEVI (leuprolide mesylate)

POLICY

I. COVERED USES

The indications below are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

A. The FDA-labeled indications and recognized compendia (off-label) uses are listed below:

Prostate cancer

B. Compendial Uses- ICD-10 codes supported by the Medicare Administrative Contractor The list of covered ICD-10 codes is prohibitively long to include within this policy. A complete list can be found at: https://www.cms.gov/medicare-coverage-database/indexes/national-and-local-indexes.aspx

All other indications will be assessed on an individual basis. Submissions for indications other than those enumerated in this policy should be accompanied by supporting evidence from Medicare approved compendia.

II. CRITERIA FOR INITIAL APPROVAL

A. Prostate Cancer

Authorization of 12 months may be granted for treatment of prostate cancer.

B. All Other Indications

Authorization of 12 months may be granted for treatment of all other approvable indications listed in LCA A52453.

III. DOSAGE AND ADMINISTRATION

Approvals may be subject to administration and dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

IV. REFERENCES

 Drugs and Biologicals LCD (L33394) Version R15. Available at: https://www.cms.gov/medicare-coverage-database/indexes/national-and-local-indexes.aspx. Accessed February 1, 2023.

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- Billing and Coding: LHRH Analogs (A52453) Version R11. Available at: https://www.cms.gov/medicare-coverage-database/indexes/national-and-local-indexes.aspx. Accessed February 1, 2023
- Billing and Coding: Drugs and Biologicals (A52855) Version R8. Available at: https://www.cms.gov/medicare-coverage-database/indexes/national-and-local-indexes.aspx. Accessed February 1, 2023.
- 4. Camcevi [package insert]. Durham, NC: Accord BioPharma Inc.; May 2021.
- 5. The NCCN Drugs & Biologics Compendium[®] © 2023 National Comprehensive Cancer Network, Inc. Available at: https://www.nccn.org. Accessed February 1, 2023

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