Reference number(s)
4764-A

Standard Medicare Part B Management Camcevi

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Camcevi ETM	leuprolide mesylate
Camcevi Kit	leuprolide mesylate

Indications

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

FDA-approved Indication[1,2]

Camcevi is indicated for the treatment of adult patients with advanced prostate cancer.

Compendial Uses[3]

- Prostate Cancer
- Salivary Gland Tumor

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

Coverage Criteria

Prostate Cancer[1-3]

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

Salivary Gland Tumor[3]

Authorization of 12 months may be granted for treatment of recurrent, unresectable, or metastatic salivary gland tumor as a single agent or in combination with abiraterone and prednisone when the tumor is androgen receptor positive.

Continuation of Therapy

Prostate Cancer

All members (including new members) requesting authorization for continuation of therapy must be currently receiving therapy with the requested agent.

Authorization of 12 months may be granted when all of the following criteria are met:

- The member is currently receiving therapy with the requested medication.
- The requested medication is being used to treat prostate cancer.
- The member is receiving benefit from therapy (e.g., serum testosterone less than 50 ng/dL) and has not experienced an unacceptable toxicity.

Salivary Gland Tumor

All members (including new members) requesting authorization for continuation of therapy must be currently receiving therapy with the requested agent.

Authorization of 12 months may be granted when all of the following criteria are met:

- The member is currently receiving therapy with the requested medication.
- The requested medication is being used to treat salivary gland tumor.
- The member is receiving benefit from therapy. Benefit is defined as:
    - No evidence of unacceptable toxicity while on the current regimen AND
    - No evidence of disease progression while on the current regimen.

Summary of Evidence

The contents of this policy were created after examining the following resources:

- The prescribing information for Camcevi and Camcevi ETM.
- The available compendium
    - National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium
    - Micromedex DrugDex
    - American Hospital Formulary Service- Drug Information (AHFS-DI)
    - Lexi-Drugs

    - Clinical Pharmacology
- NCCN Guideline: Prostate cancer
- NCCN Guideline: Head and neck cancers

After reviewing the information in the above resources, the FDA-approved indications listed in the prescribing information for Camcevi and Camcevi ETM are covered in addition to salivary gland tumor and several other treatment settings for prostate cancer.

Explanation of Rationale

Support for FDA-approved indications can be found in the manufacturer's prescribing information.

Support for using Camcevi for treating salivary gland tumor and prostate cancer, including the FDA-approved indication of advanced prostate cancer, can be found in the NCCN Drugs and Biologics Compendium. Use of information in the NCCN Drugs and Biologics Compendium for off-label use of drugs and biologicals in an anti-cancer chemotherapeutic regimen is supported by the Medicare Benefit Policy Manual, Chapter 15, section 50.4.5 (Off-Label Use of Drugs and Biologicals in an Anti-Cancer Chemotherapeutic Regimen).

References

1. Camcevi [package insert]. Raleigh, NC: Accord BioPharma Inc.; February 2025.
2. Camcevi ETM [package insert]. Idron, France: Fareva Pau; August 2025.
3. The NCCN Drugs & Biologics Compendium® © 2025 National Comprehensive Cancer Network, Inc. http://www.nccn.org. Accessed February 4, 2025.