Clinical Policy Title:	Leuprolide mesylate
Policy Number:	RxA.693
Drug(s) Applied:	Camcevi™
Original Policy Date:	08/17/2021
Last Review Date:	09/14/2021
Line of Business Policy Applies to:	All line of business

Background

leuprolide (Camcevi™) is a gonadotropin-releasing hormone (GnRH) agonist indicated for the treatment of adult patients with advanced prostate cancer.

Dosing Information

Drug Name	Indication	Dosing Regimen	Maximum Dose
leuprolide (Camcevi™)	Prostate cancer	42 mg subcutaneously every 6 months.	42 mg subcutaneously every 6 months.

Dosage Forms

- Injectable emulsion: 42 mg

Clinical Policy

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria. The provision of provider samples does not guarantee coverage under the terms of the pharmacy benefit administered by RxAdvance. All criteria for initial approval must be met in order to obtain coverage.

I. Initial Approval Criteria

A. Prostate Cancer (must meet all):

1. Diagnosis of advanced prostate cancer;
2. Prescribed by or in consultation with an oncologist or urologist;
3. Age ≥ 18 years;
4. Requested dose does not exceed 42 mg subcutaneously every 6 months.

Approval Duration

Commercial: 6 months

Medicaid: 6 months

II. Continued Therapy Approval

A. Prostate Cancer (must meet all):

1. Member is currently receiving medication that has been authorized by RxAdvance or member has previously met initial approval criteria listed in this policy;
2. Member is responding positively to therapy;
3. Requested dose does not exceed 42 mg subcutaneously every 6 months.

Approval Duration
Commercial: 12 months
Medicaid: 12 months

III. Appendices

APPENDIX A: Abbreviation/Acronym Key
GnRH: gonadotropin-releasing hormone

APPENDIX B: Therapeutic Alternatives
Not applicable.

APPENDIX C: Contraindications/Boxed Warnings

- Contraindication(s):
  - Hypersensitivity to GnRH, GnRH agonist analogs, or any of the components of Camcevi™.

- Boxed Warning(s):
  - None reported.

APPENDIX D: General Information

- Camcevi™, like other GnRH agonists, causes a transient increase in serum levels of testosterone during the first week of treatment, declining thereafter to baseline levels or below by the end of the second week of treatment. Transient worsening of symptoms, or the occurrence of additional signs and symptoms of prostate cancer, may develop during the first few weeks of Camcevi™ treatment. Patients treated with Camcevi™ may experience a temporary increase in bone pain, which can be managed symptomatically. As with other GnRH agonists, cases of ureteral obstruction and spinal cord compression have been observed, which may contribute to paralysis with or without fatal complications. Patients with metastatic vertebral lesions and/or with urinary tract obstruction should be closely observed during the first few weeks of therapy.
- Hyperglycemia and an increased risk of developing diabetes have been reported in men receiving GnRH agonists. Hyperglycemia may represent the development of diabetes mellitus or worsening of glycemic control in patients with diabetes. Monitor blood glucose and/or glycosylated hemoglobin (HbA1c) periodically in patients receiving a GnRH agonist and manage with current practice for treatment of hyperglycemia or diabetes.
- Increased risk of developing myocardial infarction, sudden cardiac death, and stroke has been reported in association with use of GnRH agonists in men. The risk appears low based on the reported odds ratios and should be evaluated carefully along with cardiovascular risk factors when determining a treatment for patients with prostate cancer. Patients receiving a GnRH agonist should be monitored for symptoms and signs suggestive of development of cardiovascular disease and be managed according to current clinical practice.
- Androgen deprivation therapy may prolong the QT/QTc interval. Providers should consider whether the benefits of androgen deprivation therapy outweigh the potential risks in patients with congenital long QT syndrome, congestive heart failure, frequent electrolyte abnormalities, and in patients taking drugs known to prolong the QT interval. Electrolyte abnormalities should be corrected. Consider periodic monitoring of electrocardiograms and electrolytes.

- Convulsions have been reported in patients receiving GnRH agonists, like Camcevi™. Manage patients receiving a GnRH agonist who experience convulsions according to current clinical practice.
- Based on findings in animal studies and mechanism of action, Camcevi™ can cause fetal harm when administered to a pregnant woman. In animal developmental and reproductive toxicology studies, administration of a monthly formulation of leuprolide on day 6 of pregnancy (sustained exposure was expected throughout the period of organogenesis) caused adverse embryo-fetal toxicity in animals at doses less than the human dose based on body surface area using an estimated daily dose. Advise pregnant patients and females of reproductive potential of the potential risk to the fetus.

References

1. Camcevi™ [prescribing information]. Taipei City, Taiwan: Foresee Pharmaceuticals Co; May 2021. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/211488s000lbl.pdf. Accessed August 17, 2021.
2. Clinical Pharmacology [database online] powered by Clinical Key. Tampa, FL: Elsevier, 2020. Available at: https://www.clinicalkey.com/pharmacology/. Accessed August 17, 2021.

Review/Revision History	Review/Revision Date	P&T Approval Date
Policy established.	08/17/2021	09/14/2021