Canada's Drug Agency
L'Agence des médicaments du Canada

CDA-AMC REIMBURSEMENT REVIEW

Patient and Clinician Group Input

leuprolide mesylate (Camcevi)

(Accord Healthcare Inc.)

Indication: Camcevi (leuprolide mesylate) is indicated for the treatment of adult patients with advanced prostate cancer.

December 6, 2024

This document compiles the input submitted by patient groups and clinician groups for the file under review. The information is used by CDA-AMC in all phases of the review, including the appraisal of evidence and interpretation of the results. The input submitted for each review is also included in the briefing materials that are sent to expert committee members prior to committee meetings. **If your group has submitted input that is not reflected within this document, please contact Formulary-Support@cda-amc.ca.**

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No Patient Group Input was received for this review.

CADTH

CADTH Reimbursement Review

Clinician Group Input

CADTH Project Number: PC0370
Generic Drug Name (Brand Name): Leuprolide-mesylate (Camcevi)
Indication: Camcevi (leuprolide mesylate) is indicated for the treatment of advanced prostate cancer
Name of Clinician Group: Ontario Health (Cancer Care Ontario) Genitourinary Cancers Drug Advisory Committee ("GU DAC")
Author of Submission: Dr. Girish Kulkarni and Chris Morash

1. About Your Clinician Group

OH(CCO)'s Drug Advisory Committees provide timely evidence-based clinical and health system guidance on drug-related issues in support of CCO's mandate, including the Provincial Drug Reimbursement Programs (PDRP) and the Systemic Treatment Program.

2. Information Gathering

Discussed jointly via email

3. Current Treatments and Treatment Goals

Currently in Canada we have several approved and commonly used drugs with these indications. The active ingredient in Camcevi is leuprolide. Leuprolide is the active ingredient in Eligard, Lupron and Zeulide. What distinguishes these agents is the mode of injection and the delivery system to create the long acting release to suppress testosterone over 1-6 months. Camcevi is a 6-month depot injection. The only currently available 6-month depot injection is Eligard so Camcevi offers an alternative for patients who may benefit from this dosing schedule. The evidence indicates that all the currently available LHRH agonists suppress testosterone sufficiently and provide similar or equal effect in prostate cancer treatments. There are other agents available in the LHRH agonist class which have different active drugs, including Zoladex (goserelin) and Trelstar (triptorelin). Neither of these have a 6-month depot preparation.

The goals of therapy vary with the indication. In hormone dependent advanced prostate cancer, the goal is improved survival, delay in disease progression, reduction in cancer related complications such as skeletal related events with reduced need for palliative radiotherapy, spinal cord compression, urinary obstruction, need for palliative procedures such as TURP. Al of these things can improve quality of life, maintain independence, and reduce burden on caregivers.

In high risk localized and locally advanced hormone dependent prostate cancer, these drugs are commonly utilized with radiotherapy. The goals of therapy in this setting are very similar to those listed above and the combination with radiotherapy is known to improve survival significantly compared to radiotherapy alone in this setting.

4. Treatment Gaps (unmet needs)

4.1. Considering the treatment goals in Section 3, please describe goals (needs) that are not being met by currently available treatments.

Unmet needs in these patients include methods of suppressing testosterone with reduced side effects. Also, lower cost is desirable. For men without private insurance who are less than 65 years of age, these agents cost approximately $800-1200 Canadian every 3 months. This can be a substantial burden.

Patients do ultimately become resistant to available LHRH agonists, but the evidence supports continuing the LHRH agonist indefinitely through the next lines of therapy.

Due to lifestyle, location of residence, ability to travel to get treatment and travel for vacations or work can make a 6-month depot formulation to improve convenience. As stated above, there is one other approved 6-month depot formulation on the market in Canada (Eligard), perhaps an alternative option could be useful if tolerance of the injection site reactions we see with Eligard are a difficult side effect for the patient. The 6-month formulation would not be used in all or perhaps even most patients. Many prescribers and patients prefer the 3- or 4-month injections. This drug would be useful for the subpopulation described.

5. Place in Therapy

5.1. How would the drug under review fit into the current treatment paradigm?

This drug would not change current therapy other than provide an alternative to the 6-month Eligard product.

This drug would fit in to first line therapy in selected patients. Starting with a 6-month depot preparation is appropriate.

Current best evidence supports continuation of the LHRH agonist therapy indefinitely even while undergoing subsequent additional lines of therapy. Examples include chemotherapy or novel hormonal agents added on top of the androgen deprivation provided by the LHRH agonist. In some cases, we use shorter courses of LHRH agonist therapy including intermittent therapy which most commonly involves 9-month courses treatment so a 6-month depot may not be ideal for this niche.

5.2. Which patients would be best suited for treatment with the drug under review? Which patients would be least suitable for treatment with the drug under review?

Any of the patients who require LHRH agonist therapy for prostate cancer would be candidates for this drug. The selection of this agent versus other available agents would be based mostly on the prescriber and patient preference for a longer, 6-month injection interval.

Patients who need some customization of their LHRH agonist treatment interval may not be candidates, but this is a very small proportion. Example: intermittent therapy patients needing 9 months of treatment.

5.3 What outcomes are used to determine whether a patient is responding to treatment in clinical practice? How often should treatment response be assessed?

We look at testosterone levels, PSA response and radiographic response if applicable. These are standard in both clinical practice as well as clinical trials.

A common standard follow up would be a PSA level with testosterone every 3 months and interval imaging depending on the scenario.

For patients with symptoms related to either locally advanced disease or metastatic disease, a clinically meaningful response is reduction or resolution of urinary tract obstruction or pain from bone metastases. The magnitude of response is standard across prescribers and should not depend on agent chosen if the testosterone level is suppressed adequately.

5.4 What factors should be considered when deciding to discontinue treatment with the drug under review?

In metastatic prostate cancer, the evidence supports continuing the LHRH agonist indefinitely through the next lines of therapy, even with disease progression. When combined with radiotherapy, there are evidence-based finite intervals of therapy. For example, in unfavorable intermediate risk disease, typically the patient would get 6 months of concomitant and adjuvant androgen deprivation therapy while in high-risk disease patients would get 18-24 months of concomitant and adjuvant androgen deprivation therapy. On occasions, LHRH agonist therapy will be discontinued for severe intolerance or adverse side effects that interfere with quality of life significantly.

5.5 What settings are appropriate for treatment with [drug under review]? Is a specialist required to diagnose, treat, and monitor patients who might receive [drug under review]?

All settings are appropriate for this class of drug, community, academic, outpatient, hospital.

6. Additional Information

Since there are existing agents currently in practice which perform very similarly to this agent, cost should be strongly considered. It would be good to have one alternative for a patient who wants a 6-month depot.

7. Conflict of Interest Declarations

To maintain the objectivity and credibility of the CADTH drug review programs, all participants in the drug review processes must disclose any real, potential, or perceived conflicts of interest. This conflict of interest declaration is required for participation. Declarations made do not negate or preclude the use of the clinician group input. CADTH may contact your group with further questions, as needed. Please see the *Procedures for CADTH Drug Reimbursement Reviews* (section 6.3) for further details.

1. Did you receive help from outside your clinician group to complete this submission? If yes, please detail the help and who provided it.

   OH-CCO provided secretariat support to the DAC in completing this input.

2. Did you receive help from outside your clinician group to collect or analyze any information used in this submission? If yes, please detail the help and who provided it.

   No

3. List any companies or organizations that have provided your group with financial payment over the past two years AND who may have direct or indirect interest in the drug under review. **Please note that this is required for each clinician who contributed to the input — please add more tables as needed (copy and paste). It is preferred for all declarations to be included in a single document.**

Declaration for Clinician 1

Name: Dr. Girish Kulkarni
Position: Lead, OH-CCO Genitourinary Cancers Drug Advisory Committee

Date: 2-Dec-2024

☒ **I hereby certify** that I have the authority to disclose all relevant information with respect to any matter involving this clinician or clinician group with a company, organization, or entity that may place this clinician or clinician group in a real, potential, or perceived conflict of interest situation.

Table 1: Conflict of Interest Declaration for Clinician 1

	Check appropriate dollar range*			
Company	**$0 to $5,000**	**$5,001 to $10,000**	**$10,001 to $50,000**	**In excess of $50,000**

* Place an X in the appropriate dollar range cells for each company.

Declaration for Clinician 2

Name: Dr. Chris Morash
Position: Member, OH-CCO Genitourinary Cancers Drug Advisory Committee
Date: 2-Dec-2024

☒ I hereby certify that I have the authority to disclose all relevant information with respect to any matter involving this clinician or clinician group with a company, organization, or entity that may place this clinician or clinician group in a real, potential, or perceived conflict of interest situation.

Table 2: Conflict of Interest Declaration for Clinician 2

	Check appropriate dollar range*			
Company	**$0 to $5,000**	**$5,001 to $10,000**	**$10,001 to $50,000**	**In excess of $50,000**

* Place an X in the appropriate dollar range cells for each company.