Reimbursement Review

Implementation Advice: Proposed Scope

Therapeutic area: Prostate-specific membrane antigen-positive metastatic castration-resistant prostate cancer

Background

On March 3, 2023, CADTH issued a recommendation for reimbursement with clinical criteria and/or conditions for Pluvicto (lutetium vipivotide tetraxetan) for the treatment of adult patients with prostate-specific membrane antigen–positive metastatic castration-resistant prostate cancer who have received at least 1 androgen receptor pathway inhibitor and taxane-based chemotherapy. At the request of the drug programs that participate in the CADTH reimbursement review processes, CADTH is convening an implementation advice panel to advise the drug programs on radiopharmaceuticals that can be used to identify patients eligible for treatment with Pluvicto for prostate cancer. This document outlines a draft scope for the panel discussions, including which drugs are under consideration and questions to be addressed by the panel.

Consultation Process and Objectives

The implementation advice panel will comprise experts working in Canada in the area of nuclear medicine and theranostics. In addition to the clinical panellists and CADTH staff, representatives from public drug programs, the pan-Canadian Pharmaceutical Alliance, and the Canadian Association of Provincial Cancer Agencies may participate in the discussion and provide input in advance of the meeting on the topics for discussion. For more information on the implementation advice process, please refer to *CADTH Procedures for Medical Imaging Implementation Advice*.

The CADTH Provincial Advisory Group and Formulary Working Group raised the following issues to be addressed by the implementation advice panel.

- In addition to gallium gozetotide, what other prostate-specific membrane antigen–PET radiopharmaceuticals could be used in clinical practice to identify patients who could be candidates for treatment with lutetium vipivotide tetraxetan?

Opportunities for Stakeholder Input

CADTH welcomes input from patient and clinician groups as well as manufacturers whose product(s) may be impacted by the implementation advice. Stakeholders are invited to provide comments and/or complementary information using the comments on implementation advice request template. This input will be considered by CADTH and the implementation advice panel in their deliberations.

Opportunities for Feedback on Draft Advice

When ready, a draft of the implementation advice will be posted for stakeholder feedback on the CADTH website. Eligible stakeholders are welcome to provide feedback on the draft advice using the *CADTH Feedback on Draft Implementation Advice Report* template.

Drugs

Table 1: List of Drugs Under Consideration

Generic name (brand name)	Approval status and manufacturer	Indication(s)
Gallium Ga-68 gozetotide (Illuccix [kit for the preparation of gallium (^{68}Ga) gozetotide injection])	Approved in Canada (2022), the US (2021), and Australia (2021). Telix Pharmaceuticals Limited (US) Isotope can be sourced from cyclotron or Ge-68 generator.	(Canada label, 10/2022) Illuccix [kit for the preparation of gallium (^{68}Ga) gozetotide injection] is indicated for use with positron emission tomography (PET) of prostate specific membrane antigen (PSMA) positive lesions in men with prostate cancer: • with suspected metastasis who are suitable for initial definitive therapy • with suspected recurrence with elevated serum prostate specific antigen (PSA) level.
Gallium Ga-68 gozetotide (Locametz [kit for the preparation of gallium (^{68}Ga) gozetotide injection])	Approved in Canada (2023), the US (2022), and the EU (2022). Novartis Pharmaceuticals Isotope can be sourced from cyclotron or Ge-68 generator.	(Canada label, 4/2023) Locametz [kit for the preparation of gallium (^{68}Ga) gozetotide injection], after radiolabeling with gallium-68, is a radioactive diagnostic agent indicated for positron emission tomography (PET) of prostate-specific membrane antigen (PSMA)-positive lesions in men with prostate cancer: • with suspected metastasis who are candidates for initial definitive therapy • with suspected recurrence based on elevated serum prostate-specific antigen (PSA) level • for selection of patients with metastatic prostate cancer (mCRPC), for whom PSMA-directed therapy is indicated.
^{18}F PSMA-1007	Not currently approved as a commercial product in Canada. Licensed for development in Canada by CPDC from ABX GmbH, Germany. Isotope sourced from cyclotron.	In phase III development in Canada by CPDC. In use in Canadian clinical trials (NCT03525288 and NCT04557501) of clinical utility.
Fluorine ^{18}F piflufolastat (^{18}F-DCFPyL) (Pylarify)	Not currently approved in Canada. Approved in the US (2021). Lantheus Holdings, Inc. (Original approval given to Progenics Pharmaceuticals) Isotope sourced from cyclotron.	(US label, 5/2021) Pylarify is a radioactive diagnostic agent indicated for positron emission tomography (PET) of prostate-specific membrane antigen (PSMA) positive lesions in men with prostate cancer: • with suspected metastasis who are candidates for initial definitive therapy • with suspected recurrence based on elevated serum prostate-specific antigen (PSA) level Listed as investigational by CPDC. In use in Canadian registries (PREP registry, Ontario NCT03718260) and clinical trials (NCT03525288 and NCT04557501) of clinical utility.

^{18}F PSMA-1007 = fluorine-18 prostate-specific membrane antigen; ^{18}F-DCFPyL = fluorine-18 piflufolastat; ^{68}Ga PSMA-11 = gallium gozetotide; CPDC = Centre for Probe Development and Commercialization; EU = European Union; PREP = PSMA-PET for recurrent prostate cancer; PSMA = prostate-specific membrane antigen.