



Canada's Drug Agency
L'Agence des médicaments du Canada
Drugs. Health Technologies and Systems. Médicaments, technologies de la santé et systèmes.

Proposed Project Scope

Trabectedin with doxorubicin for advanced unresectable or metastatic uterine or soft-tissue leiomyosarcoma

Date: January 2025

Background and Rationale

CDA-AMC received a request from public drug programs for a Non-Sponsored Reimbursement Review of trabectedin with doxorubicin for advanced unresectable or metastatic uterine or soft-tissue leiomyosarcoma.

Table I: Policy Questions

Item	Policy Question
1	Should trabectedin be publicly reimbursed with doxorubicin for advanced unresectable or metastatic uterine or soft-tissue leiomyosarcoma?

Table II: Products Available in Canada

Product	Manufacturer
Trabectedin	Valeo Pharma inc.

Project Description

Table III: Project Scope

Criteria	Description
Population	Patients with advanced unresectable or metastatic uterine or soft-tissue leiomyosarcoma
Intervention(s)	Trabectedin with doxorubicin
Comparators	Doxorubicin monotherapy Docetaxel/gemcitabine
Outcomes	Progression-free survival Disease control Response Response duration Overall survival Safety Second progression-free survival

Table IV: Research Questions

Item	Policy Question
1	What is the effectiveness of trabectedin with doxorubicin for advanced unresectable or metastatic uterine or soft-tissue leiomyosarcoma?
2	What are the harms associated with trabectedin with doxorubicin for advanced unresectable or metastatic uterine or soft-tissue leiomyosarcoma?
3	What is the expected cost of trabectedin with doxorubicin for advanced unresectable or metastatic uterine or soft-tissue leiomyosarcoma vs. other reimbursed regimes?

Key Project and Protocol Components

This project will follow the [Procedures for Non-Sponsored Reimbursement Reviews](#).

Status of the Document

This proposed project scope is being posted for information.