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

Dabrafenib-trametinib for pediatric and young adult patients for 1st line or greater therapy in low grade gliomas with residual disease and with known BRAF V600 mutations

Date: October 2024

Background and Rationale

CDA-AMC received a request from public drug programs for a Non-Sponsored Reimbursement Review of dabrafenib-trametinib for pediatric and young adult patients for 1st line or greater therapy in low grade gliomas with residual disease and with known BRAF V600 mutations

Table I: Policy Questions

Item	Policy Question
1	Should Dabrafenib-Trametinib be publicly reimbursed for pediatric and young adult patients for 1st line or greater therapy in low grade gliomas with residual disease and with known BRAF V600 mutations?

Table II: Products Available in Canada

Product	Manufacturer
Dabrafenib	Novartis
Trametinib	Novartis

Project Description

Table III: Project Scope

Criteria	Description
Population	Pediatric and young adult patients for 1st line or greater therapy in low grade gliomas with residual disease and with known BRAF V600 mutations
Intervention(s)	Dabrafenib-trametinib
Comparators	Standard chemotherapy (carboplatin plus vincristine)
Outcomes	Overall response Investigator-assessed response Duration of response Time to response Clinical benefit Progression-free survival Overall survival Patient-reported outcomes Adverse events

Table IV: Research Questions

Item	Policy Question
1	What is the effectiveness of dabrafenib-trametinib for pediatric and young adult patients for 1st line or greater therapy in low grade gliomas with residual disease and with known BRAF V600 mutations?
2	What are the harms associated with dabrafenib-trametinib for pediatric and young adult patients for 1st line or greater therapy in low grade gliomas with residual disease and with known BRAF V600 mutations?
3	What is the expected cost of dabrafenib-trametinib for pediatric and young adult patients for 1st line or greater therapy in low grade gliomas with residual disease and with known BRAF V600 mutations 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.