CADTH

Proposed Project Scope

Everolimus for subependymal giant cell astrocytoma (SEGA) associated with tuberous sclerosis complex (TSC).

Date: December 2023

Classification: Protected A

CADTH

Background and Rationale

CADTH received a request from public drug programs for a Non-Sponsored Reimbursement Review of Everolimus for subependymal giant cell astrocytoma (SEGA) associated with tuberous sclerosis complex (TSC).

Table I: Policy Questions

Item	Policy Question
1	Should everolimus be publicly reimbursed for subependymal giant cell astrocytoma (SEGA) associated with tuberous sclerosis complex (TSC)?

Table II: Products Available in Canada

Product	Manufacturer
Everolimus (Afinitor)	Novartis Pharmaceuticals Canada Inc

Project Description

Table III: Project Scope

Criteria	Description
Population	Patients with tuberous sclerosis complex (TSC) Patients with subependymal giant cell astrocytoma (SEGA) Subpopulations: Pediatric patients (<18 years of age) Adult patients (≥18 years of age)
Intervention(s)	Everolimus
Comparators	Placebo; Sirolimus (off label)
Outcomes	SEGA response rate, median time to response, best overall SEGA Response, time to SEGA progression, reduction from baseline in primary SEGA volume, change in primary SEGA volume, changes in tuber and subependymal nodule (SEN) volumes, skin lesion response rate, renal angiomyolipoma response, angiofibroma, seizure frequency, rates of behavioral and psychiatric disorders, avoidance of surgery, adverse events, and quality of life

Table IV: Research Questions

Item	Policy Question
1	What is the effectiveness of everolimus for SEGA associated with TSC?
2	What are the harms associated with everolimus for SEGA associated with TSC?
3	What is the expected cost of everolimus for SEGA associated with TSC 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.

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