CADTH

Proposed Project Scope

Teriflunomide for Radiologically Isolated Syndrome (RIS)

Date: July 2024

CADTH

Background and Rationale

We received a request from public drug programs for a Non-Sponsored Reimbursement Review of teriflunomide for Radiologically Isolated Syndrome (RIS).

Table I: Policy Question

Item	Policy Question
1	Should teriflunomide be publicly reimbursed for radiologically isolated syndrome (RIS)?

Table II: Products Available in Canada

Product	Manufacturer
Teriflunomide	multiple

Project Description

Table III: Project Scope

Criteria	Description
Population	Patients with radiologically isolated syndrome (RIS)
Intervention(s)	Teriflunomide
Comparators	Placebo Interferon beta Glatiramer acetate
Outcomes	Time to first acute or progressive (non-acute) neurological event from CNS demyelination Time to progression MRI changes Number of new and/or enlarging lesions (T2-weighted hyperintense, gadolinium-enhancing (Gd+), changes in lesion volumes, brain atrophy etc.) Health Related Quality of Life (HRQoL) Harms (i.e., adverse events)

Table IV: Research Questions

Item	Policy Question
1	What is the clinical effectiveness of teriflunomide for RIS?
2	What are the harms associated with teriflunomide for RIS?
3	What is the expected cost of teriflunomide for RIS?

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.