Canada's Drug Agency
L'Agence des médicaments du Canada

CDA-AMC REIMBURSEMENT REVIEW

Stakeholder Feedback on Draft Recommendation

dimethyl fumarate

(non-sponsored review)

Indication: Radiologically Isolated Syndrome (RIS).

Jan 3, 2025

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CDA-AMC Feedback on Draft Recommendation: Dimethyl Fumarate in RIS

Project number: SX0751-000

Generic Name: Dimethyl Fumarate (DMF)

Indication(s): radiologically isolated syndrome (RIS)

Group Name: Canadian Network of MS Clinics (CNMSC)

Primary contact: Dr. Sarah Morrow

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Comments from CNMSC

a) General comments
- Overall, CNMSC is aligned with the draft recommendation for the use of DMF in RIS.
- We have flagged a few areas below where we believe it is important for FMEC to modify the recommendation to ensure clarity of the advice being provided to participating jurisdictions and other stakeholders.
- We appreciate CDA's collaboration on this initiative and hope that CNMSC's input has been useful.

b) Therapeutic Landscape
- The report acknowledges that there are no publicly funded treatments for RIS in Canada.
- As noted in CNMSC's input into the project scoping document, neither interferon nor glatiramer acetate are relevant comparators as there are no randomized controlled studies specific to their use in RIS based on the 2023 diagnostic criteria.
- The draft recommendation also cites comments from expert reviewers re: the lack of utility of these products in RIS.
- Thus, reference to interferon beta and glatiramer acetate being off-label treatment options should be removed and/or the dearth of evidence supporting their off-label use should be emphasized more clearly in this statement.

c) Table 1: Summary of Deliberation
- CNMSC appreciates FMEC's acknowledgement of the unmet need for this patient population, as well as the value of delaying disease onset, slowing disability, and their meaningful impacts to patients.
- CNMSC believes that it is important for FMEC to clarify some of the comments made under the Impacts on Health System category, as the current verbiage may create confusion regarding the diagnosis and management of RIS.
    - There are no "routine screening" programs for RIS as, by definition, RIS is discovered inadvertently in the process of assessing the patient for an unrelated issue.
        - BY DEFINITION, RIS is identified on the basis findings on an MRI that is carried out for a reason other than detection of RIS/MS.

- Funding of DMF for RIS would not be expected to result in increased MRIs as, by definition, MRIs are not being done for purposes of finding RIS.
- Funding of DMF would simply provide an evidence-based treatment option to delay onset of MS after RIS has been serendipitously identified via an MRI.

d) Table 2: Conditions, Reasons, and Guidance
   - CNMSC agrees with the proposed criteria for use and conditions for reimbursement.

CADTH Reimbursement Review

Feedback on Draft Recommendation

Stakeholder information	
CADTH project number	SX0752
Name of the drug and Indication(s)	teriflunomide
Organization Providing Feedback	FWG

1. Recommendation revisions Please indicate if the stakeholder requires the expert review committee to reconsider or clarify its recommendation.		
Request for Reconsideration	**Major revisions:** A change in recommendation **category** or patient **population** is requested	☐
	Minor revisions: A change in reimbursement **conditions** is requested	☐
No Request for Reconsideration	**Editorial revisions:** Clarifications in recommendation **text** are requested	X
	No requested revisions	☐

2. Change in recommendation category or conditions Complete this section if major or minor revisions are requested
Please identify the specific text from the recommendation and provide a rationale for requesting a change in recommendation.

3. Clarity of the recommendation Complete this section if editorial revisions are requested for the following elements
a) Recommendation rationale
Please provide details regarding the information that requires clarification. Clarification on the wording around unmet need, the effectiveness comparison between oral and injectable treatments, and the availability of evidence to support the claims of clinical value and cost-effectiveness for the drug under review.
b) Reimbursement conditions and related reasons
Please provide details regarding the information that requires clarification. Suggestion additional language for clarity, on teriflunomide discontinuation if the patient progresses to MS, the terminology regarding "DMTs for RIS," and the need for a cost-effectiveness analysis. Expansion on the discussion around details on patient eligibility and the funding status of similar treatments in various jurisdictions were also requested.
c) Implementation guidance

Please provide high-level details regarding the information that requires clarification. You can provide specific comments in the draft recommendation found in the next section. Additional implementation questions can be raised here. Clarification was requested regarding the specific wording for the discontinuation of treatment and the use of teriflunomide as monotherapy, as well as the alignment of terminology between reimbursement conditions and implementation guidance sections.

Outstanding Implementation Issues

In the event of a positive draft recommendation, drug programs can request further implementation support from CADTH on topics that cannot be addressed in the reimbursement review (e.g., concerning other drugs, without sufficient evidence to support a recommendation, etc.). Note that outstanding implementation questions can also be posed to the expert committee in Feedback section 4c.

Algorithm and implementation questions
1. Please specify sequencing questions or issues that should be addressed by CADTH (oncology only)
1. 2.
2. Please specify other implementation questions or issues that should be addressed by CADTH
1. 2.
Support strategy
3. Do you have any preferences or suggestions on how CADTH should address these issues?
May include implementation advice panel, evidence review, provisional algorithm (oncology), etc.