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

March 2025

Drugs Health Technologies Health Systems

Updated Reimbursement Recommendations

Cladribine and Natalizumab for Relapsing-Remitting Multiple Sclerosis

Streamlined Review

Summary

On January 30, 2025, the Formulary Management Expert Committee (FMEC) deliberated on a streamlined review for cladribine and natalizumab for relapsing-remitting multiple sclerosis.

Rationale for Updates to Previous Reimbursement Recommendations

Based on the overall evidence on efficacy, safety, and costs, FMEC voted in favour of the following reimbursement recommendations.

Recommendation 1

With a vote of 8 to 0, FMEC recommends that cladribine, for the first-line monotherapy of relapsing-remitting multiple sclerosis, be reimbursed if certain conditions are met.

Recommendation 2

With a vote of 8 to 0, FMEC recommends that natalizumab, for the first-line monotherapy of relapsing-remitting multiple sclerosis, be reimbursed if certain conditions are met.

As described in the Procedures for Reimbursement Reviews, FMEC may provide updates to previous Reimbursement Recommendations, which can include amendments to the recommendation status, criteria, and/or conditions, as appropriate.

FMEC has updated the previous criteria and/or conditions set out by the Canadian Expert Drug Advisory Committee (CEDAC) or the Canadian Drug Expert Committee (CDEC) for therapeutics in relapsing-remitting multiple sclerosis based on the scope of the streamlined drug review.

Note that only relevant reviews with positive recommendations will be updated. Recommendations that were out of scope for the review were not updated.

Updates to Previous Reimbursement Recommendations

The CDA-AMC recommendations in this document now supersede the previously published recommendations for the following relevant therapeutics.

Refer to Table 1 (summary of revisions) for the updated CDA-AMC reimbursement recommendations for these drugs, which includes the previous final recommendations (from CEDAC or CDEC) and updates by FMEC.

Table 1: Summary of Revisions to Previous Reimbursement Recommendations

Generic name (brand name)	Date of final recommendation (CDEC) issued	Final recommendation (CEDAC or CDEC)	Revision to CDA-AMC recommendation by FMEC
Cladribine (Mavenclad) (SR0546)	October 26, 2018	The CADTH Canadian Drug Expert Committee recommends that cladribine be reimbursed as monotherapy for the treatment of adult patients with relapsing-remitting multiple sclerosis (RRMS) to reduce the frequency of clinical exacerbations and delay the progression of disability, if the following conditions are met: • For use in patients who have had an inadequate response to, or are unable to tolerate, 1 previous therapy for RRMS, and who have had at least 1 relapse within the previous 12 months. • The patient is under the care of a specialist who has experience in the diagnosis and management of RRMS. There is a price reduction.	FMEC affirms that cladribine should be reimbursed with criteria or conditions. The following amendment to conditions for reimbursement will now apply. 1. Patients must have the following characteristics at the time of initiating treatment with cladribine: 1.1. a diagnosis of RRMS established according to current clinical criteria including the MRI evidence. 2. Patients must be under the care of a specialist with experience in the diagnosis and management of MS. 3. Cladribine should be priced so that it does not exceed the total drug program cost of treatment with the least costly high-efficacy DMT available for the first-line treatment of RRMS.
Natalizumab (Tysabri) (SR0133)	February 25, 2009	The Canadian Expert Drug Advisory Committee recommends that natalizumab be listed as monotherapy for patients with a diagnosis of MS established according to current clinical criteria and MRI evidence. Patients must also meet all the following criteria: 1. Failure to respond to full and adequate courses of	FMEC affirms that natalizumab should be reimbursed with criteria or conditions. The following amendment to conditions for reimbursement will now apply. 1. Patients must have the following characteristics at the time of initiating treatment with natalizumab: 1.1. a diagnosis of RRMS

Generic name (brand name)	Date of final recommendation (CDEC) issued	Final recommendation (CEDAC or CDEC)	Revision to CDA-AMC recommendation by FMEC
		treatment with at least 2 disease-modifying therapies or have contraindications to, or be intolerant of, these therapies. 2. Significant increase in T2 lesion load compared to a previous MRI or at least 1 gadolinium-enhancing lesions. 3. Two or more disabling relapses in the previous years.	established according to current clinical criteria including the MRI evidence. 2. Patients must be under the care of a specialist with experience in the diagnosis and management of MS. 3. Natalizumab should be priced so that it does not exceed the total drug program cost of treatment with the least costly high-efficacy DMT available for the first-line treatment of RRMS.

CDEC = Canadian Drug Expert Committee; CEDAC = Canadian Expert Drug Advisory Committee; DMT = disease-modifying therapy; FMEC = Formulary Management Expert Committee; RRMS = relapsing-remitting multiple sclerosis.

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Questions or requests for information about this report can be directed to Requests@CDA-AMC.ca