

CADTH Reimbursement Review

Feedback on Draft Recommendation

Stakeholder information	
CADTH project number	SR0727-000
Brand name (generic)	Radicava (edaravone)
Indication(s)	For the treatment of patients with amyotrophic lateral sclerosis (ALS)
Organization	The ALS Society of Canada
Contact information	<div style="background-color: black; width: 100px; height: 15px; margin-bottom: 5px;"></div> <div style="background-color: black; width: 450px; height: 15px; margin-bottom: 5px;"></div> <div style="background-color: black; width: 150px; height: 15px; margin-bottom: 5px;"></div> <div style="background-color: black; width: 60px; height: 15px;"></div>
Stakeholder agreement with the draft recommendation	
1. Does the stakeholder agree with the committee's recommendation.	Yes <input checked="" type="checkbox"/>
	No <input type="checkbox"/>
<p>The ALS Society of Canada agrees with the committee's draft recommendation to reimburse edaravone oral suspension and understands the rationale for aligning the reimbursement conditions for oral edaravone with current Canadian public drug plan reimbursement criteria for IV edaravone.</p> <p>However, we are concerned the initiation criteria for IV edaravone may no longer reflect the reality of care and treatment of ALS in Canada, especially the use of the ALS Functional Rating Scale – Revised (ALSFRRS-R) as a measure.</p> <p>ALS is a heterogeneous disease, meaning the disease varies from person to person, including where symptoms first appear in the body, age of onset and rate of disease progression. It can affect different areas of the body at different rates, meaning that someone with ALS may have significant paralysis in one body part while maintaining function in another.</p> <p>As our understanding of ALS has evolved, so has the clinical approach to diagnosis, treatment and care. As such, the ALS community, including clinicians, has been vocal about the ALSFRS-R not being an ideal way to measure disease progression due to the heterogeneity of the disease.</p> <p>Equitable access to innovative therapies is a critical issue for people and families affected by ALS across Canada. Therefore, we ask that CADTH consider an editorial change to update the edaravone oral suspension initiation criteria to remove any sub-score criteria.</p>	
Expert committee consideration of the stakeholder input	
2. Does the recommendation demonstrate that the committee has considered the stakeholder input that your organization provided to CADTH?	Yes <input checked="" type="checkbox"/>
	No <input type="checkbox"/>
It is our opinion that the committee considered the initial input provided to CADTH by the ALS Society of Canada when drafting the recommendation.	
Clarity of the draft recommendation	
3. Are the reasons for the recommendation clearly stated?	Yes <input checked="" type="checkbox"/>
	No <input type="checkbox"/>
Yes, we believe the reasons for the recommendation are clearly stated.	

4. Have the implementation issues been clearly articulated and adequately addressed in the recommendation?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
The implementation issues have been clearly articulated and adequately addressed.		
5. If applicable, are the reimbursement conditions clearly stated and the rationale for the conditions provided in the recommendation?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
The reimbursement conditions are clearly stated and the rationale for the conditions are provided in the recommendation		

^a CADTH may contact this person if comments require clarification.

Appendix 1. Conflict of Interest Declarations for Patient Groups

- To maintain the objectivity and credibility of the CADTH drug review programs, all participants in the drug review processes must disclose any real, potential, or perceived conflicts of interest.
- This conflict of interest declaration is required for participation. Declarations made do not negate or preclude the use of the feedback from patient groups and clinician groups.
- CADTH may contact your group with further questions, as needed.
- Please see the [Procedures for CADTH Drug Reimbursement Reviews](#) for further details.

A. Patient Group Information				
Name	Lauren Poplak			
Position	Senior Manager, Advocacy and Stakeholder Relations			
Date	08-12-2022			
<input checked="" type="checkbox"/>	I hereby certify that I have the authority to disclose all relevant information with respect to any matter involving this patient group with a company, organization, or entity that may place this patient group in a real, potential, or perceived conflict of interest situation.			
B. Assistance with Providing Feedback				
1. Did you receive help from outside your patient group to complete your feedback?			No	<input checked="" type="checkbox"/>
			Yes	<input type="checkbox"/>
If yes, please detail the help and who provided it.				
2. Did you receive help from outside your patient group to collect or analyze any information used in your feedback?			No	<input checked="" type="checkbox"/>
			Yes	<input type="checkbox"/>
N/A				
C. Previously Disclosed Conflict of Interest				
1. Were conflict of interest declarations provided in patient group input that was submitted at the outset of the CADTH review and have those declarations remained unchanged? If no, please complete section D below.			No	<input type="checkbox"/>
			Yes	<input checked="" type="checkbox"/>
D. New or Updated Conflict of Interest Declaration				
3. List any companies or organizations that have provided your group with financial payment over the past two years AND who may have direct or indirect interest in the drug under review.				
Company	Check Appropriate Dollar Range			
	\$0 to 5,000	\$5,001 to 10,000	\$10,001 to 50,000	In Excess of \$50,000
Add company name	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Add company name	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Add or remove rows as required	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>