



Feedback on Draft Recommendation

Interested party information	
Project number	SR0883-000
Brand name (generic)	Qalsody (tofersen)
Indication(s)	The treatment of adults with amyotrophic lateral sclerosis (ALS) associated with a mutation in the superoxide dismutase 1 (SOD1) gene.
Organization	ALS Society of Canada
Interested party agreement with the draft recommendation	
1. Does the interested party 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 recommendations to reimburse tofersen with conditions and appreciates the recognition of significant unmet need faced by people living with ALS, including people living with SOD1-ALS.</p> <p>However, we are concerned that the prescribing criterion 4 (tofersen should not be reimbursed when used in combination with edaravone) is not aligned with the evidence base and best practices in patient care.</p> <p>In the VALOR trial and its open-label extension, patients were permitted to receive edaravone alongside tofersen, with no evidence to suggest that concomitant use diminishes benefit or poses safety concerns.</p> <p>It is critical that decisions about treatments, including whether to use tofersen in combination with edaravone, are made collaboratively between the patient and their clinician, guided by clinical judgement and patient preferences. Given that there is no evidence of harm from the concomitant use of tofersen and edaravone, this criterion imposes a restriction on the shared decision-making of patients and clinicians.</p> <p>Additionally, as more ALS treatments are developed and approved, it is important that a reimbursement condition like this one does not set a precedent where access to one treatment automatically excludes access to another.</p> <p>Therefore, we ask that CDA consider removing prescribing criterion 4 to ensure that the recommendations support patient and clinician autonomy and avoid setting an exclusionary precedent.</p>	
Expert committee consideration of the input	
2. Does the recommendation demonstrate that the committee has considered the input that your organization provided?	Yes <input checked="" type="checkbox"/>
	No <input type="checkbox"/>

It is our opinion that the committee considered the input provided by the ALS Society of Canada to CDA 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"/>
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 CDA-AMC may contact this person if comments require clarification.