Consultation Questions & Answers for the Proposed Alignment of the CADTH Drug Reimbursement Review Processes

By: ALS Society of Canada

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393 University Avenue, Suite 1701, Toronto, ON M5G 1E6 T 416-497-2267 | F 416-497-8545 | TF 1-800-267-4257

The following are the responses that the ALS Society of Canada submitted for the 2020 CADTH Drug Reimbursement Review Processes Consultation Survey.

COMMUNICATIONS FOR DRUG REIMBURSEMENT REVIEWS

Does your organization agree with the proposal to streamline communications for CADTH's drug reimbursement reviews?

YES

Do you or your organization have any suggestions for improving CADTH's drug reimbursement reviews communications?

NO

CADTH REPORTS AND RECOMMENDATIONS

Does your organization have any suggestions for improving the clarity and consistency of CADTH clinical and pharmacoeconomic reports?

NO

Does your organization have any suggestions for improving the clarity and consistency of CADTH recommendations?

NO

How could the final recommendation document be improved? Is there content that should be added, removed, or presented in a different way?

N/A

HANDLING OF CONFIDENTIAL INFORMATION

Does your organization support increased transparency in CADTH's reports and recommendations?

YES

Does your organization have any comments or concerns related to CADTH's proposal for information that would be considered disclosable by CADTH?

N/A

Does your organization have any comments or concerns related to CADTH's proposed process for redacting confidential information from CADTH documents?

N/A

PROCEDURAL REVIEW

Are there any areas within the proposed procedural review process for drug reimbursement reviews that CADTH should address in order to strengthen the proposal?

N/A

Please identify and comment on any ambiguities in the proposed procedural review process steps and conditions.

N/A

ELIGIBILITY FOR DRUG REIMBURSEMENT REVIEW PROGRAMS

Does your organization have any comments related to the proposed alignment of eligibility criteria for CADTH's drug reimbursement review processes?

N/A

Does your organization have any comments or suggested improvements related to CADTH's processes for determining the eligibility of resubmissions and reassessments?

N/A

Does your organization have any comments or suggested improvements related to CADTH's processes for communicating situations where a manufacturer declines to file a submission with CADTH for an eligible drug?

N/A

PRE-SUBMISSION MEETINGS

Does your organization have any suggestions for improving pre-submission meetings with CADTH?

N/A

ADVANCE NOTIFICATION PROCEDURE

Does your organization have any comments or concerns related to CADTH's proposal to align the timing of advance notification to a minimum of 30 business days?

N/A

Does your organization have any comments related to the type of information required by CADTH when providing advance notification?

N/A

Do you or your organization have any comments or concerns related to the new Proposed Place in Therapy template?

N/A

APPLICATION AND SCREENING PROCEDURES

Does your organization have any suggested improvements for the application filing process?

N/A

Does your organization have any suggested improvements related to CADTH's processes for screening applications for the drug reimbursement review process?

N/A

SUBMISSION REQUIREMENTS (NON-ECONOMIC)

Does your organization have any comments or concerns related to the proposed alignment of required documentation for CADTH drug reimbursement reviews?

N/A

Do you or your organization have any suggestions for improving CADTH's procedural instructions for required documentation? Please focus on non-economic requirements in this section.

N/A

If your organization has experience with CADTH's drug reimbursement review process, did you find that CADTH's procedures were clear when describing the documentation that is required in order to accept a file for review through the drug reimbursement review processes? Please focus on non-economic requirements in this section.

N/A

The proposed templates for required documentation have been provided in the appendices of the consultation document. Please provide any commentary and/or suggested improvements for these templates.

N/A

SUBMISSION REQUIREMENTS (ECONOMIC)

If your organization has experience with CADTH's drug reimbursement review process, do you find that the CADTH's pharmacoeconomic requirements are clear when describing the information that is required in order to accept a file for review?

N/A

Do you or your organization have any suggestions for improving the clarity of CADTH's pharmacoeconomic requirements?

N/A

Do you or your organization agree with CADTH's proposal to accept cost-minimization analyses for certain drugs?

N/A

Do you or your organization agree with CADTH's proposed eligibility criteria for accepting cost-minimization analyses?

N/A

INDUSTRY ENGAGEMENT

Does your organization agree with the proposal to allow the sponsor to review and comment on the draft CADTH reports before the expert review committee meeting?

N/A

If your organization has experience with CADTH's Common Drug Review process, do you have any suggestions for improving the process under which the sponsor can review and comment on the draft reports?

N/A

Please provide other commentary regarding your organization's perspective on engagement with the sponsor through out the review process.

N/A

PATIENT ENGAGEMENT

As a patient group, is it useful to have the opportunity to review CADTH's summary of patient group input?

YES

Do you or your organization have any suggested improvements for CADTH's patient engagement processes?

We recommend that CADTH give a minimum of 50 business days for patient groups to develop patient input submissions. In our experience, as a small organization with limited internal capacity and a patient community of about 3,000 Canadians, the current timeline of 35 business days is challenging to be able to meaningfully consult with the community, analyze feedback, and prepare a comprehensive and detailed submission.

We also suggest that the summary of patient input be four pages in length, as opposed to the current maximum of approx. two pages. Two pages does not provide enough space to share all of the pertinent information and perspective. The patient input submission justifies more than two pages because patients will be the primary beneficiaries of medicines undergoing a review. While we understand and support the need for drug reviews to be completed in a more timely fashion, the impact on patients is of absolute crucial importance and the voice of Canadians living with specific diseases and disorders, especially within the rare disease space, should be a priority within the drug review reports.

CLINICIAN ENGAGEMENT

Is the rationale behind CADTH transitioning to clinician group input as opposed to open clinician input clear?

YES

Do you or your organization have any suggested improvements for the proposed template for clinician group input?

In our capacity as a patient group, we do not have the subject matter expertise to provide meaningful feedback on the proposed template.

Nevertheless, clinician input is key to provide a comprehensive evaluation of the effectiveness and impact of a new medicine on the patient population. For a terminal disease like ALS, the perspectives of the ALS clinicians are vital to understanding the real day-to-day experiences of trying to manage the symptoms of this devastating disease. From our experience with Radicava (edaravone), clinician input was not an option available while the drug was under review and key pieces of clincial information relevant to living with ALS were not reflected in the recommendations. In the end some ALS clinicians independently elected to bring forward clinical considerations once a first draft of the reimbursement recommendations was available in order to help make sure the recommendations reflected the reality of the disease.

DRUG PROGRAM ENGAGEMENT

Do you or your organization agree with CADTH's proposal to align the processes for obtaining and communicating input from the drug programs?

N/A

REVIEW PROCEDURES

Do you or your organization have any suggestions for improving CADTH's processes for reviewing clinical evidence?

N/A

Do you or your organization have any suggestions for improving CADTH's processes for reviewing economic evidence?

N/A

Do you or your organization have any suggestions for improving CADTH's processes for reviewing ethical considerations?

DELIBERATIVE PROCESS AND FRAMEWORK

Are the criteria used in the deliberative frameworks for CADTH's pharmaceutical review committees (the Canadian Drug Expert Committee [CDEC] and the pan-Canadian Oncology Drug Review Expert Review Committee [pERC]) transparent and explicit?

N/A

Are you or your organization familiar with any criteria used in deliberative frameworks in other jurisdictions that you think CDEC and pERC should consider adopting?

NO

Are there aspects of the deliberative processes of CDEC and pERC meetings that you would like to understand in greater detail?

N/A

Are you or your organization familiar with any deliberative processes used in other jurisdictions that you think CADTH committees should consider adopting?

NO

DRAFT RECOMMENDATIONS

Do you or your organization have any comments related to the proposal to post all draft recommendations for stakeholder feedback?

Yes.

We are pleased to see that patient and clinician groups for all types of drug reviews will have the opportunity to comment on draft recommendations. However, ten days is not sufficient time for stakeholders, particularly patient groups, to appropriately review and submit comments on the draft recommendations. We instead suggest providing all stakeholders, although especially patient groups, a minimum of 20 days to submit comments on the draft recommendations. This will give patient groups enough time to fully review, analyse, and put forward meaningful improvements that can better inform the Expert Review Committees and their recommendations. It will provide for a more accurate analysis of the draft recommendations from a patient perspective and will outline improvements that can be made to the lives of patients and their families.

Do you or your organization have any comments or concerns related to the proposed process for requesting the redaction of confidential information from the draft recommendation document?

NO

Do you or your organization have any suggested improvements for the proposed stakeholder feedback form?

NO

RECONSIDERATION PROCESS

Do you or your organization support CADTH's proposal to reduce the number of reviews that undergo reconsideration following issuance of the initial recommendation?

YES

Do you or your organization support CADTH's proposal to introduce greater flexibility to the reconsideration process (i.e., requests for major revisions, minor revisions, or editorial revisions)?

YES

Do you or your organization have any suggested improvements for the reconsideration process?

Yes.

We support the proposal to allow patient groups and clinician groups that responded to the call for input to review the draft recommendations to provide stakeholder feedback. People living with the disease – and those that care for them in both a clincial and non-clinical capacity – are best able to express how a new treatment could impact their lives. Having the opportunity to review the draft recommendations will help ensure any eligibility criteria put forward is realistic for patients. This is especially true for complex diseases like ALS where an eligibility condition that may seem insignificant to an expert review committee, could be very meaningful for a person living the disease.

The ALS community's experience with CADTH's common drug review of Radicava (edaravone) is a prime example of this. An initial recommendation on the Radicava Common Drug Review report included reimbursement recommendations with eligibility conditions attached. These conditions included wheelchair and assistive device use, which for a population like ALS where ALS progression affects each individual differently, is an unrealistic and inaccurate factor to determine if a person should be eligible for drug reimbursement. As such, patient group feedback on the recommendations is to ensure that Canadians will be able to access the therapies they need.

FINAL RECOMMENDATIONS

Do you or your organization have any comments or concerns related to CADTH's proposed timelines for issuing and posting final recommendation documents?

Yes.

We recommend that CADTH shorten and improve the overall timelines associated with completing and issuing common drug review recommendations for drugs that treat or cure rare terminal diseases, such as ALS. We recognize that CADTH has already taken steps to shorten overall timelines, such as beginning your review while a drug is undergoing Health Canada approval, but more must be done.

People living with ALS cannot wait the six months to one year that it takes to complete a common drug review. Approximately 500 – 1,000 Canadians living with ALS will die in that time frame. This was our community's experience with Radicava (edaravone), where it took almost a whole year for the final review report to be published and recommendations to be made to provincial drug plans. Moreover, what's more heart wrenching for the ALS community is to watch and wait for drug reimbursement recommendations all while knowing that there is a drug under review that could improve quality of life and/or add months or years to the prognosis.

Because 80% of people living with ALS die within 2-5 years of diagnosis, the need to access any new and innovative treatments is absolutely paramount. Canadians living with ALS have limited treatment options and any new therapy could mean more time with their loved ones. CADTH's reimbursement recommendations are a critical step in improving access to therapies and we encourage CADTH to shorten the timeline in any way they can.

<u>TEMPORARY SUSPENSION AND WITHDRAWAL PROCEDURES</u>

Does your organization have any comments or concerns related to CADTH's existing processes for temporarily suspending files due to incomplete information?

N/A

Does your organization have any comments or concerns related to CADTH's proposal to establish a firm cut-off point for voluntary withdrawal from the drug reimbursement review processes?

N/A

IMPLEMENTATION ADVICE ON REIMBURSEMENT RECOMMENDATIONS

Do you or your organization have any comments or suggested improvements related to CADTH's processes for issuing implementation advice reports after final recommendations have been issued?

Yes.

We suggest that patient and clinician groups be involved in any plan for CADTH to issue implementation advice reports. Clinicians and patients will be the operational end users of any reimbursement recommendation and implementation plan for new drugs and therapies and therefore must be a part of the conversation as to how the reimbursement recommendations will be implemented.

PROVISIONAL ALGORITHM

Do you or your organization have any comments or suggested improvements related to CADTH's proposal to revise the provisional algorithm process?

NO

Do you or your organization have any suggestions on how patient groups and clinician groups could provide input into provisional algorithm process?

NO