June 2020

PDCI | MARKET ACCESS

REQUEST FOR RECONSIDERATION TO CADTH

*CADTH currently provides a **Request for Reconsideration** procedure within the Common Drug Review process. While optional and only appropriate in select circumstances, manufacturers should not overlook this potential opportunity to further demonstrate their product's value in the HTA process, and perhaps even change a negative recommendation into a positive one.*

A **Request for Reconsideration** may be made by a manufacturer, during the embargo period, based on one or both of the following grounds:

- The CDEC recommendation is not supported by the evidence that had been submitted or identified in the CADTH review report(s), *and/or*
- CADTH and/or CDEC failed to act fairly and in accordance with its procedures in conducting the review

DID YOU KNOW?

In 2019, a request for reconsideration was filed for **14 of 34** products that received a final recommendation from CADTH. Of the **14, 5** products received a "*do not reimburse*" and the remaining **9** received a "*reimburse with conditions*".

BEST PRACTICES

REVIEW the CADTH reasons for recommendation and identify key critiques:

- ***Prioritize*** issues to address based on the impact each has on the recommendation and availability of evidence to support an effective response
- ***Develop*** an outline for the request for reconsideration; the document is limited to 10 pages so be concise and focused on the issues best positioned to successfully change the recommendation.

ASSESS previous CADTH and INESSS recommendations for products in a similar category or indication as well as international HTA reviews of the product of interest:

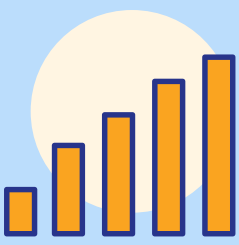
- ***Note*** whether CADTH and other HTA bodies had similar critiques and consider their relevance to your request for reconsideration
- ***Evaluate*** for inconsistencies between the CADTH embargoed recommendation, previous CADTH recommendations and other HTA recommendations

ALIGN with key stakeholders (e.g. Medical, Global) and seek consultation with external sources if appropriate (e.g. KOLs, patients, patient associations):

- ***Consider*** if KOL or patient association insight is relevant and appropriate while keeping in mind the confidential embargoed nature of the recommendation
- ***Ensure*** alignment among relevant stakeholders through constant and regular communication
- ***Ensure*** that relevant stakeholders are available to provide input and
- insights during the reconsideration period

ANALYZE draft CADTH Review Reports and your responses to these reports:

- ***Refresh*** on the evidence that was considered and arguments provided earlier in the review process
- ***Identify*** any inconsistencies between the draft review reports, manufacturer comments, the CADTH recommendation, relevant literature, KOL opinion(s), and/or clinical practice information



EVALUATE the materials that were submitted to CADTH and how these queries and comments had been addressed:

- ***Note*** where the evidence may not have been understood as intended and emphasize this in the reconsideration
- ***Determine*** if the existing data should be presented in a different way

BONUS TIP

Take advantage of the one-hour teleconference with CADTH reviewers!

- This is an ***opportunity to ensure clarity*** around the key issues raised in the request for reconsideration and to expand or include additional perspectives
- Based on needs, ***identify*** relevant presenters (e.g. Medical, KOLs, patients) provided these individuals have agreed to maintain confidentiality of the proceedings, CADTH reports and the embargoed recommendation
- Presentation slides (suggested maximum: 30) will both ***facilitate*** the meeting and be included in the briefing package provided to CDEC members and drug plans (10 business days before scheduled meeting at which the RfR will be considered)

Acronyms: CADTH = Canadian Agency for Drugs and Technologies in Health; RfR = Request for Reconsideration; KOL = Key Opinion Leader; HTA = Health Technology Assessment; CDEC = Canadian Drug Expert Committee