CADTH

CADTH REIMBURSEMENT REVIEW

Stakeholder Feedback on Draft Recommendation

Insulin icodec (Awiqli)

(Novo Nordisk Canada Inc.)

Indication: The once-weekly treatment of adults with diabetes mellitus to improve glycemic control.

May 3, 2024

CADTH Reimbursement Review

Feedback on Draft Recommendation

Stakeholder information	
CADTH project number	SR0790
Name of the drug and Indication(s)	Insulin Icodec (Awiqli) for the once-weekly treatment of adults with diabetes mellitus to improve glycemic control
Organization Providing Feedback	FWG

1. Recommendation revisions Please indicate if the stakeholder requires the expert review committee to reconsider or clarify its recommendation.		
Request for Reconsideration	**Major revisions:** A change in recommendation **category** or patient **population** is requested	☐
	Minor revisions: A change in reimbursement **conditions** is requested	☐
No Request for Reconsideration	**Editorial revisions:** Clarifications in recommendation **text** are requested	X
	No requested revisions	☐

2. Change in recommendation category or conditions Complete this section if major or minor revisions are requested
Please identify the specific text from the recommendation and provide a rationale for requesting a change in recommendation.

3. Clarity of the recommendation Complete this section if editorial revisions are requested for the following elements
a) Recommendation rationale
Please provide details regarding the information that requires clarification.
b) Reimbursement conditions and related reasons
Please provide details regarding the information that requires clarification.
c) Implementation guidance
Clarify glycemic target (i.e., A1c) outlined in initiation implementation guidance for basal insulin.

Outstanding Implementation Issues

CADTH

CADTH Reimbursement Review
Feedback on Draft Recommendation

Stakeholder information	
CADTH project number	SR0790
Brand name (generic)	Awiqli® (insulin icodec)
Indication(s)	the once-weekly treatment of adults with diabetes mellitus to improve glycemic control.
Organization	Novo Nordisk Canada Inc.
Contact information[a]	[redacted]

Stakeholder agreement with the draft recommendation		
1. Does the stakeholder agree with the committee's recommendation.	Yes	☒
	No	☐

NNCI is pleased with the Awiqli® draft recommendation as it brings Canadian patients one step closer to accessing an innovative and first once weekly basal insulin. NNCI further agrees that Awiqli® has similar efficacy and safety compared to currently available basal insulins and should be used in the same place of therapy as other basal insulins.

NNCI applauds CDEC's acknowledgement of the paradigm shift being introduced with the world's first once weekly basal insulin Awiqli® and its potential impact on reduction in treatment burden for Canadian patients with T2D.

- A once weekly basal insulin treatment option that enables patients either reluctant to initiate or non-compliant on a once daily insulin to reduce their burden of treatment will bring patients one step closer to achieving better glycemic control and reducing the risk of long-term complications.
- While not directly addressed in the recommendation wording, NNCI thus agrees with CDEC in that Awiqli® may lead to "an unknown proportion of patients with T2D who are not currently on insulin for glycemic control to start once weekly insulin injections given the improved dosing convenience" (page 5).
- Though CDEC noted uncertainty in the ability to interpret available PRO data, evidence provided through relevant PROs assessing the impact of Awiqli® on treatment compliance, convenience, satisfaction, and flexibility, support the notion that Awiqli® will lead to reduced burden of treatment compared to daily basal analogues.
- The availability of a basal insulin with reduced treatment burden is also in alignment with patient input which indicated "that living with T2D was preoccupying, inconvenient, and burdensome, with constant management requiring foresight and planning" (page 6)
- Furthermore, input from the CADTH clinical expert noted that treatment goals for a patient with T2D include "reducing risk of long-term complications through control of glycemia" (page 7) among other goals.
- Lastly, while CDEC highlighted various limitations in the CE analysis submitted by NNCI, CDEC acknowledges that "a price premium may be warranted due to the lower administration burden associated with insulin icodec (once weekly), although evidence to inform the degree of this premium is highly uncertain" (page 27).

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	☐
	No	☐

NA

Clarity of the draft recommendation		
3. Are the reasons for the recommendation clearly stated?	Yes	☒
	No	☐
NNCI considers that the reasons for the recommendation are clearly stated.		
4. Have the implementation issues been clearly articulated and adequately addressed in the recommendation?	Yes	☒
	No	☐
5. If applicable, are the reimbursement conditions clearly stated and the rationale for the conditions provided in the recommendation?	Yes	☒
	No	☐

NNCI considers that the reimbursement conditions and rationale are clearly stated. We would suggest a few editorial changes for consideration if they are deemed as providing greater clarity to the reasons provided.

1. Please ensure the wording "(A1C ≤ 7.0%)" in the implementation guidance section of criteria 1 is not interpreted to mean that having A1C ≤ 7.0% is the definition of not meeting glycemic targets and that this definition is made only in reference to clinical practice guidelines. "Based on clinical expert input, therapy with basal insulin is typically initiated in patients who are not meeting glycemic targets (A1C ≤ 7.0%) despite lifestyle modification and the use of, or…"
2. To fully capture CDEC guidance on considerations to be made for the pricing of Awiqli®, we suggest the following editorial revisions to criteria #2: "Insufficient evidence was provided to demonstrate improved treatment efficacy with insulin Icodec versus other long-acting basal insulin analogues. As such, **based on currently available clinical trial evidence,** there is insufficient evidence to justify a cost premium for insulin icodec over the least costly long-acting basal insulin analogue reimbursed for the treatment of patients with T2D who require insulin for glycemic control. **A price premium may be warranted due to the lower administration burden associated with insulin icodec (once weekly), although evidence to inform the degree of this premium is highly uncertain.**" This statement was included by CDEC on page 26 of the recommendation, and overall, the review from CADTH/CDEC acknowledges that insulin icodec may address patient needs related to burden from frequent insulin injections.
3. To capture the assumption that has the largest impact on the BIA estimates, NNCI suggests the following editorial addition: "At the submitted price, the magnitude of uncertainty in the budget impact must be addressed to ensure the feasibility of adoption, given the difference between the sponsor's estimate and CADTH's estimate. **The largest impact on the BIA is the assumption related to the market share of Awiqli® which CADTH expects to be higher than the sponsor's estimate due to an unknown proportion of patients with T2D who are not currently on insulin for glycemic control to start once weekly insulin injections given the improved dosing convenience.**"

[a] CADTH may contact this person if comments require clarification.