CADTH

CADTH REIMBURSEMENT REVIEW

Stakeholder Feedback on Draft Recommendation

dupilumab (Dupixent)

(Sanofi Genzyme, a division of sanofi-aventis Canada Inc.)

Indication: atopic dermatitis

January 6, 2023

CADTH Reimbursement Review

Feedback on Draft Recommendation

Stakeholder information	
CADTH project number	SF0754
Name of the drug and Indication(s)	Dupilumab (Dupixent) for moderate-to-severe atopic dermatitis
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	☐
	No requested revisions	X☐

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
Please provide high-level details regarding the information that requires clarification. You can provide specific comments in the draft recommendation found in the next section. Additional implementation questions can be raised here.

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CADTH Reimbursement Review
Feedback on Draft Recommendation

Stakeholder information	
CADTH project number	SF0754-000
Brand name (generic)	Dupixent (dupilumab)
Indication(s)	Atopic Dermatitis
Organization	Sanofi Aventis Canada Inc
Contact information[a]	[redacted]

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

It is Sanofi's position that the reimbursement conditions for dupilumab (DUPIXENT) should reflect the Health Canada-approved indication and evidence from the dupilumab AD phase III clinical trial program. While dupilumab, upadacitinib (RINVOQ), and abrocitinib (CIBINQO) are all indicated for the treatment of atopic dermatitis (AD), their indications, posology, and evidence supporting their use in the most appropriate treatment population differs. Therefore, while the reimbursement conditions for these agents may be aligned, they should not be identical because it is important to acknowledge the evidence and important differences between them. DUPIXENT is approved as a first line systemic agent, whereas RINVOQ and CINIBQO are approved only as a second line systemic agent.

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	☒

It is Sanofi's position that the reimbursement conditions for dupilumab should reflect the Health Canada-approved indication and evidence from the dupilumab AD phase III clinical trial program. Reimbursement conditions must also take into consideration current Canadian clinical practice, input from clinical experts who treat AD and from patients who are living with AD and reflect the greatest unmet medical need which is the AD patient uncontrolled on topical therapy. The draft recommendation failed to adequately include the following:

- The difference in **Dupixent's place in therapy** was not adequately acknowledged. According to the Health Canada indication, dupilumab's place in therapy is in patients whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable. In contrast, upadacitinib's, and abrocitinib's place in therapy is where the disease is uncontrolled with a systemic treatment (e.g., steroid or biologic). As such, the approved indication of dupilumab supports an earlier place in therapy than upadacitinib and abrocitinib, which can only be used after failure on a systemic therapy.
- Considering the numerous warnings regarding the Janus Kinase (JAK) inhibitors from regulatory agencies worldwide, including Health Canada, alignment of the criteria should also take into consideration the **comparative safety of dupilumab and upadacitinib/abrocitinib**. As a result of numerous safety reviews conducted by Health Canada, an announcement that

the Canadian labelling for all JAK inhibitors will be updated to include the risks of serious heart-related problems, fatal blood clots and cancer. There are no such warnings or precautions with Dupixent and this difference in safety profile was not adequately acknowledged.

- Since the clinical and economic evidence included in the draft recommendation was limited to 2020 recommendation, it fails to recognize or acknowledge the existence of **additional follow-up data**, **longer-term extension trials, registries and real-world studies** that have been completed since the time of the recommendation. As stated in our input submission, Dupixent has demonstrated long-term safety and tolerability in patients as young as 6 years with moderate-to-severe AD, supported by data from clinical trials (up to 4 years) and real-world evidence (up to 2 years). Longer-term safety data were provided but were not considered by CDEC.

As more experience in this setting is gained, and new efficacy and safety evidence become available, it is important to revisit the reimbursement conditions for dupilumab in this context. To that end, while dupilumab, upadacitinib, and abrocitinib are all indicated for the treatment of AD, their indications, posology, and evidence supporting their use in the most appropriate treatment population differs. Therefore, while the reimbursement conditions for these agents may be aligned, they should not be identical. The draft recommendation fails to acknowledge the current evidence and important differences between these agents.

Clarity of the draft recommendation

3. Are the reasons for the recommendation clearly stated?	Yes	☒
	No	☐
If not, please provide details regarding the information that requires clarification.		
4. Have the implementation issues been clearly articulated and adequately addressed in the recommendation?	Yes	☒
	No	☐
If not, please provide details regarding the information that requires clarification.		
5. If applicable, are the reimbursement conditions clearly stated and the rationale for the conditions provided in the recommendation?	Yes	☒
	No	☐
If not, please provide details regarding the information that requires clarification.		

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