CADTH

CADTH REIMBURSEMENT REVIEW

Stakeholder Feedback on Draft Recommendation

dupilumab (Dupixent Peds)

(Sanofi-aventis Inc.)

Indication: For the treatment of patients aged 6 months and older with moderate-to-severe atopic dermatitis whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable. Dupilumab can be used with or without topical corticosteroids.

September 28, 2023

CADTH Reimbursement Review

Feedback on Draft Recommendation

Stakeholder information	
CADTH project number	SR0774
Name of the drug and Indication(s)	Dupilumab (Dupixent)
Organization Providing Feedback	Patients aged 6 months and older with moderate-to-severe atopic dermatitis

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
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	SR0774
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	☐

Please explain why the stakeholder agrees or disagrees with the draft recommendation. Whenever possible, please identify the specific text from the recommendation and rationale.

Editorial Changes:
Table 1, Reimbursement condition 7: As per Health Canada Product Monograph, JAKs are classified as Selective immunosuppressants, not immunomodulatory drugs, and should not be grouped with biologics. Sanofi requests the following editorial change. "Dupilumab should not be used in combination with phototherapy, any immunomodulatory drugs (including biologics) or a JAK inhibitor treatment) for moderate-to-severe AD"

Page 7, paragraph 2: For clarification, the Health Canada indication was expanded twice for atopic dermatitis since the previous recommendation for 12 years and older. The NOC was extended to 6 years and older in February 2021, and to 6 months and older in April 2023.

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	☒

If not, what aspects are missing from the draft recommendation?

Table 1, Reimbursement condition 1, Implementation: In addition to the information Sanofi provided on the treatment of special areas with Dupixent, experts suggested on page 14 that "..in practice, a patient with moderate atopic dermatitis and an EASI score lower than 16 may be eligible for dupilumab if, for example, they have severe lesions, but low percent body surface area (BSA) affected or have lesions localized to special areas (e.g., hands, feet, scalp). This is supported by the literature showing that patients with moderate atopic dermatitis can have an EASI score as low as 6." Sanofi requests for this to be included under Implementation Guidance.

Clarity of the draft recommendation		
3. Are the reasons for the recommendation clearly stated?	Yes	☒
	No	☐
	Yes	☐

4. Have the implementation issues been clearly articulated and adequately addressed in the recommendation?	No	☒

Table 1, Reimbursement condition 6: For additional clarity, Sanofi requests CDEC describe what qualifies as a "community with limited access to specialists" in terms of location and/or wait times or other criteria.

Table 1, Reimbursement condition 5: In Table 2, CDEC noted that if a patient were to stop dupilumab before the age of 12, and experience residual and persistent disease after stopping, it is recommended that the patient restarts dupilumab. They expand to state that "…patients who stop dupilumab before 12 years of age should not be required to meet the initiation criteria (including not having to try phototherapy or systemic immunosuppressants) before restarting treatment after 12 years of age." Sanofi requests that this be included in the implementation guidance.

5. If applicable, are the reimbursement conditions clearly stated and the rationale for the conditions provided in the recommendation?	Yes	☒
	No	☐

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