CADTH

CADTH REIMBURSEMENT REVIEW

Stakeholder Feedback on Draft Recommendation

dupilumab (Dupixent)

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

Indication: Add-on maintenance treatment in patients aged 12 years an older with severe asthma with a Type 2/eosinophilic phenotype or oral corticosteroid-dependent asthma.

May 28, 2021

CADTH Reimbursement Review

Feedback on Draft Recommendation

Stakeholder information	
CADTH project number	SR0667
Name of the drug and Indication(s)	Dupilumab (Dupixent) Indication: Severe Eosinophilic Asthma
Organization Providing Feedback	FWG

Reconsideration of the draft recommendation		
1. Please indicate if the stakeholder requires the expert review committee to reconsider its recommendation.		
Request for major revisions: A change in recommendation category or patient population is requested		☐
Request for minor revisions: A change in reimbursement conditions is requested		☐
Clarity of the draft recommendation		
2. Is the rationale for the draft recommendation clearly stated in the draft recommendation?	Yes	☒
	No	☐
3. Are the reimbursement conditions clearly stated and the rationale for the conditions provided in the draft recommendation?	Yes	☐
	No	☒
	N/A	☐
Reimbursement condition 2, can we get clarification on specifics of eosinophils testing with regards to date of test in proximity to application for coverage, and would only one test of EOS >/= 150 from one point in time be sufficient, or should the EOS remain elevated over a certain time period, to qualify?		
4. Have the implementation issues been clearly articulated and adequately addressed in the draft recommendation?	Yes	☒
	No	☐
	N/A	☐

CADTH

CADTH Reimbursement Review
Feedback on Draft Recommendation

Stakeholder information	
CADTH project number	SR0667
Brand name (generic)	Dupixent (dupilumab)
Indication(s)	Add-on maintenance treatment in patients aged 12 years an older with severe asthma with a Type 2/eosinophilic phenotype or oral corticosteroid-dependent asthma
Organization	Sanofi Genzyme, a division of 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	x
	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.

We agree with CADTH's CDEC recommendation that dupilumab should be reimbursed as add-on maintenance treatment in patients aged 12 years and older with severe asthma with a type 2 eosinophilic phenotype or oral corticosteroid dependent asthma. This recommendation is aligned with the approved Health Canada indication. For clarity we request CADTH use similar and consistent wording throughout the recommendation:

- Page 2, Therapeutic Area: replace "severe eosinophilic asthma" with "Severe Type 2/eosinophilic phenotype and oral corticosteroid-dependent asthma",
- Page 2, Recommendation, line 2: replace "type 2 eosinophilic phenotype" with "type 2/eosinophilic phenotype"
- Page 2, Rationale for the Recommendation, paragraph 2, line 4: replace "type 2 eosinophilic asthma" with "type 2/eosinophilic asthma"
- Page 4, Discussion Points, bullet 1, line 1 and 2: type 2 eosinophilic asthma" with "type 2/eosinophilic asthma"

The QUEST, VENTURE and DRI12544 studies enrolled patients based on the severity of their asthma, moderate to severe, regardless of biomarker levels. For clarity, we request CADTH correct the description of the included trials:

- Page 2, Rationale for the Recommendation, paragraph 1, line 3: replace type 2 eosinophilic asthma with "moderate to severe asthma"
- Page 5, Summary of Evidence, bullet 1: replace "a systematic review of three double-blind clinical studies in patients with type 2 eosinophilic asthma" with "a systematic review of three double-blind clinical studies in patients with moderate to severe asthma".

Lastly, we request CADTH provide clarity in the limitations of the pharmacoeconomic analysis:

- Page 7, Cost and Cost-Effectiveness, last bullet: replace "The cost-effectiveness of the 300mg strength of dupilumab is uncertain, as the sponsor's submitted analysis incorporated

data based solely on the 200mg arm of the QUEST trial." with " The cost-effectiveness of the 300 mg strength of dupilumab is uncertain, as the sponsor's submitted analysis incorporated data from the 200 mg arm of the QUEST trial and 300 mg arm of the VENTURE trial."

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?

Sanofi Genzyme's (SGZ) reimbursement ask requested CADTH consider the full Type 2 definition of severe asthma which is defined in GINA guidelines. In addition to the recommended population, the definition of Type 2 severe asthma also includes patients FeNO ≥25 ppb and patients with clinically allergen-driven asthma. These groups were not specifically included in the reimbursement conditions and represents an unmet need for patients.

SGZ requested CADTH consider respirologists, ENTs, allergists, dermatologists, and family physicians with expertise as prescribers of DUPIXENT, aligned with the clinician group input.

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.

SZG requests CADTH make minor changes to the Reasons for the Pricing recommendation to improve the interpretation of the reason:

- Page 4, Pricing: reverse the order of the reasons such that the sentence regarding the lack of comparative evidence is first, so that it leads to the CADTH reanalysis and provides rationale for the reanalysis to be based on a comparison with SOC
- Page 4, Pricing: request "Based on the CADTH base case reanalysis" be revised to "Based on the CADTH base case reanalysis comparing dupilumab to SOC"
- Page 4, Pricing: Request the list prices of the competitors be included to address the last sentence on page two regarding pricing.

SGZ requests CADTH include the following corrections regarding the VENTURE study:

- Page 6, Efficacy section, paragraph 2, line 6: >50% reduction in OCS at w24 is 79.6% in 300mg group (not 81%)
- Page 6, Efficacy section, paragraph 2, line 8: OCS reduction <5mg/day at w24 is 71.8% in 300mg group (not 72.9%)

[a] CADTH may contact this person if comments require clarification. Contact information will not be included in any public posting of this document by CADTH.