CADTH

CADTH REIMBURSEMENT REVIEW

Stakeholder Feedback on Draft Recommendation

DUPILUMAB (DUPIXENT)

(Sanofi-aventis Canada Inc.)

Indication: As an add-on maintenance treatment in patients aged 6 years and older with severe asthma with a type 2/eosinophilic phenotype or oral corticosteroid-dependent asthma.

January 06, 2023

CADTH Reimbursement Review

Feedback on Draft Recommendation

Stakeholder information	
CADTH project number	SR0745
Name of the drug and Indication(s)	Dupilumab (Dupixent) for asthma
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
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. • In 1.1, patients whose symptoms are not controlled with use of high-dose inhaled corticosteroids (ICS) alone are included. However, the clinical experts noted they would use high dose ICS with a LABA. Further clarification in the implementation guidance

section, or perhaps a discussion bullet, explaining that use of high dose ICS alone is unlikely to occur frequently in clinical practice could be helpful. A definition for what high dose inhaled corticosteroids (ICS) is in children. (A definition for adults was defined as greater than or equal to fluticasone propionate 500mcg or equivalent daily.)

Outstanding Implementation Issues

In the event of a positive draft recommendation, drug programs can request further implementation support from CADTH on topics that cannot be addressed in the reimbursement review (e.g., concerning other drugs, without sufficient evidence to support a recommendation, etc.). Note that outstanding implementation questions can also be posed to the expert committee in Feedback section 4c.

Algorithm and implementation questions
1. Please specify sequencing questions or issues that should be addressed by CADTH (oncology only)
1. 2.
2. Please specify other implementation questions or issues that should be addressed by CADTH
1. 2.
Support strategy
3. Do you have any preferences or suggestions on how CADTH should address these issues?
May include implementation advice panel, evidence review, provisional algorithm (oncology), etc.

CADTH Reimbursement Review
Feedback on Draft Recommendation

Stakeholder information	
CADTH project number	SR0745
Brand name (generic)	Dupixent (dupilumab)
Indication(s)	Asthma
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.

Sanofi agrees with the Reimbursement Conditions for Initiation, Renewals, and Prescribing. The recommended population reflects the patients included in the Voyage clinical trial, aligns somewhat with the existing reimbursement criteria recommended for patients 12 years and older with notable differences and accommodations made for children (i.e., medium-dose ICS and treatment with systemic corticosteroids).

Sanofi has additional feedback on the Reimbursement Conditions for Pricing. While CADTH may not agree with the assumptions included in the submitted model, it is unreasonable to remove all benefits associated to hospitalization for the child population, mortality with severe exacerbation, and 52-week response. CADTH's reanalysis is extreme and does not reflect the cost-effectiveness of dupilumab for the treatment of asthma in children.

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 appreciates the acknowledgment of the differences between the pediatric and adult patient populations in the initiation criteria (i.e., inclusion of medium-dose ICS, maintenance OCS vs short courses). While Sanofi understands that the recommendation is for the 6 to 11-year-old patient population, as part of Drug Program Input, several questions were asked regarding the implementation of the criteria and how patients will qualify for dupilumab when they "age into the 12 year and older criteria". Sanofi acknowledged the drug program concern and suggested that once a patient receiving dupilumab reaches the age of 12, they should continue therapy as per the renewal criteria of the 12 years of age and older recommendation. Since the renewal criteria are aligned, the patient should continue on therapy if they continue to demonstrate value. Sanofi suggests that CADTH add these details to support stakeholders.

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. Not applicable		
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. As indicated in question 2, guidance on the continuation of dupilumab treatment upon turning 12 years can be further elaborated. It is reasonable to expect that a patient who is treated effectively with dupilumab and meets the renewal criteria should continue therapy. A patient should not be required to meet the initiation criteria for 12 years and older asthma, since the patients would have already demonstrated improvement from dupilumab treatment.		
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. Not applicable		

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