CADTH

CADTH REIMBURSEMENT REVIEW

Stakeholder Feedback on Draft Recommendation

lebrikizumab (Ebglyss)

(Eli Lilly Canada, Inc.)

Indication: For the treatment of moderate-to-severe atopic dermatitis in adults and adolescents 12 years of age and older with a body weight of at least 40 kg, whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable.

August 1, 2024

CADTH Reimbursement Review
Feedback on Draft Recommendation

Stakeholder information	
CADTH project number	SR0819-000
Brand name (generic)	**Ebglyss (Lebrikizumab)**
Indication(s)	For the treatment of adult and adolescent patients 12 years of age 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. Lebrikizumab injection can be used with or without topical corticosteroids.
Organization	Eczema Society of Canada
Contact information[a]	Name: Amanda Cresswell-Melville, Executive Director

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

Eczema Society of Canada (ESC) disagrees with the draft recommendation to not reimburse Lebrikizumab. We thank CDEC for recognizing the significant burden of living with atopic dermatitis (AD) as per our patient input submission, and we thank CDA/CADTH for the opportunity to provide this feedback on the draft recommendation.

AD is a challenging disease to managed, with itch, pain, and skin symptoms negatively impacting patient lives. Physicians need safe and effective treatment options for their AD patients and need to be able to make clinical judgement as to the best treatment for each individual patient. The profound impact of severe itch, sleep, self-esteem, and mental health highlights the urgency for new AD treatments for our patient community.

As illustrated in our original CADTH submission, AD is a multifactor disease that is complicated to treat and additionally, not all treatments work for all patients. It is essential that AD patients have multiple treatment options, and the clinical trial data on Lebrikizumab shows that it offers both a safe and effective option for treating this patient population. Patients are also seeking long term solutions to their AD as a chronic disease. Patients who have used Lebrikizumab have had their lives changed, and their suffering ended because of this medication. Lebrikizumab's four-week dose regimen also offers patients half the injections per year which is helpful for patient lifestyle as well as for those fearful of needles.

Excerpt from ESC CADTH submission - page 6, section 6, paragraph 1:

- Lebrikizumab offers a new biologic option to treat moderate to severe AD and has been shown to be effective at clearing the skin, reducing itch, and improving quality of life
- Systemic treatments for AD offer an important option for patients in need
- Lebrikizumab was reported to be an excellent treatment to break the chronic flare cycle of AD
- AD is a heterogenous disease and requires a variety of treatments to be available to fill gaps in therapeutic options
- Lebrikizumab was also reported as well-tolerated

"I experienced such a noticeable improvement [during the clinical trial for Lebrikizumab] that I knew I was likely in the treatment arm."

"While taking Lebrikizumab, I remember thinking, 'Wow, my skin hasn't ever felt so clear and normal."

- Having additional systemic treatment options for AD patients gives the patient community a better chance to manage this burdensome and debilitating disease

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	☒

ESC's input demonstrates the unmet needs in this patient population, and Lebrikizumab would offer another biologic option, including for those who fail other systemic treatments. Multiple treatments are not only important for this heterogeneous disease, but patients need multiple options in a class of medication in case of drug shortages or recalls.

Excerpt from ESC CADTH submission – page 6, section 8, paragraph 1

- AD can be an unrelenting, painful, and frustrating disease to live with and to manage, and there remains a gap in treatment for some patients
- For some patients, access to new treatments like lebrikizumab can be life changing
- Patients with moderate or severe AD suffer greatly due to constant itch, and skin symptoms such as rash, lesions, sores, blisters, scaling, crusting, and infections
- Many patients have diligently exhausted all treatment options, and are still in need, failing to achieve management of their disease
- New treatments offer great hope to patients, but patients' needs access to these potentially life changing treatments
- AD is a heterogeneous disease. No single treatment option will be able to meet the needs of all patients.

"Canadians deserve equitable access to therapies that are shown to be safe and effective."

"I would like for doctors and politicians to realize the painful effects of severe AD are debilitating and chronic, but with the help of new drugs and therapies for people suffering with AD life can be great."

"I wish a better system could support patients in managing their treatments."

"It would be wonderful if everyone in Canada had the same access to treatment."

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.
ESC remains unclear as to why the drug will not be reimbursed given the positive clinical trial data and safety profile of the drug.

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.

N/A		
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. N/A		

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

Appendix 1. Conflict of Interest Declarations for Patient Groups

- To maintain the objectivity and credibility of the CADTH drug review programs, all participants in the drug review processes must disclose any real, potential, or perceived conflicts of interest.
- This conflict of interest declaration is required for participation. Declarations made do not negate or preclude the use of the feedback from patient groups and clinician groups.
- CADTH may contact your group with further questions, as needed.
- Please see the *Procedures for CADTH Drug Reimbursement Reviews* for further details.

A. Patient Group Information	
Name	Amanda Cresswell-Melville
Position	Executive Director, Eczema Society of Canada
Date	July 30th, 2024
☒	I hereby certify that I have the authority to disclose all relevant information with respect to any matter involving this patient group with a company, organization, or entity that may place this patient group in a real, potential, or perceived conflict of interest situation.

B. Assistance with Providing Feedback		
1. Did you receive help from outside your patient group to complete your feedback?	No	☒
	Yes	☐
If yes, please detail the help and who provided it.		
2. Did you receive help from outside your patient group to collect or analyze any information used in your feedback?	No	☒
	Yes	☐
If yes, please detail the help and who provided it.		

C. Previously Disclosed Conflict of Interest		
1. Were conflict of interest declarations provided in patient group input that was submitted at the outset of the CADTH review and have those declarations remained unchanged? If no, please complete section D below.	No	☐
	Yes	☒

D. New or Updated Conflict of Interest Declaration

3. List any companies or organizations that have provided your group with financial payment over the past two years AND who may have direct or indirect interest in the drug under review.

Company	**Check Appropriate Dollar Range**			
	$0 to 5,000	**$5,001 to 10,000**	**$10,001 to 50,000**	**In Excess of $50,000**
Add company name	☐	☐	☐	☐
Add company name	☐	☐	☐	☐
Add or remove rows as required	☐	☐	☐	☐

CADTH Reimbursement Review
Feedback on Draft Recommendation

Stakeholder information	
CADTH project number	SR0819-000
Brand name (generic)	Lebrikizumab
Indication(s)	Moderate to severe Atopic dermatitis
Organization	Atlantic Dermatologists
Contact information[a]	Name: Kerri Purdy

Stakeholder agreement with the draft recommendation		
1. Does the stakeholder agree with the committee's recommendation.	Yes	☐
	No	☒
The stakeholders feel that Lebrikizumab should be considered a first line treatment option for moderate to severe atopic dermatitis.		

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	☒
n/a as we did not submit input for the draft, assuming that Lebrikizumab would receive a positive recommendation given the clinical data that exists from pivotal clinical trials.		

Clarity of the draft recommendation		
3. Are the reasons for the recommendation clearly stated?	Yes	☐
	No	☒
1. They are stated clearly, however the stakeholders disagree that there is not role for another first line treatment option despite there being no head to head. Also, the stakeholders do not feel that comparing biologics to JAKi for atopic dermatitis makes sense as there are very different adverse effect profiles for these classes. The MOA of JAKis determined their faster onset, which is apparent in short-term efficacy but are not sustained in the long-term to fulfill the need for moderate-to-severe AD management. Lebrikizumab's unique MOA of high binding affinity for IL-13 and slow disassociation rate makes it a unique asset for moderate-to-severe AD patients with long-term data up to 2 years to support it.		
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	☒
Again, the stakeholders do not feel that lebrikizumab needs to be directly compared to Dupiliumab to be given a positive recommendation by CADTH. Given the heterogeneity in disease presentation of moderate to severe AD and patient response, relying on public reimbursement of only one biologic is not sufficient for the intended to treat population		

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

Appendix 2. Conflict of Interest Declarations for Clinician Groups

- To maintain the objectivity and credibility of the CADTH drug review programs, all participants in the drug review processes must disclose any real, potential, or perceived conflicts of interest.
- This conflict of interest declaration is required for participation. Declarations made do not negate or preclude the use of the feedback from patient groups and clinician groups.
- CADTH may contact your group with further questions, as needed.
- Please see the *Procedures for CADTH Drug Reimbursement Reviews* for further details.
- For conflict of interest declarations:
  - Please list any companies or organizations that have provided your group with financial payment over the past two years AND who may have direct or indirect interest in the drug under review.
  - Please note that declarations are required for each clinician that contributed to the input.
  - If your clinician group provided input at the outset of the review, only conflict of interest declarations that are new or require updating need to be reported in this form. For all others, please list the clinicians who provided input are unchanged
  - Please add more tables as needed (copy and paste).
  - All new and updated declarations must be included in a single document.

A. Assistance with Providing the Feedback		
2. Did you receive help from outside your clinician group to complete this submission?	No	☒
	Yes	☐
If yes, please detail the help and who provided it.		
3. Did you receive help from outside your clinician group to collect or analyze any information used in this submission?	No	☒
	Yes	☐
If yes, please detail the help and who provided it.		
B. Previously Disclosed Conflict of Interest		
4. Were conflict of interest declarations provided in clinician group input that was submitted at the outset of the CADTH review and have those declarations remained unchanged? If no, please complete section C below.	No	☐
	Yes	☐
If yes, please list the clinicians who contributed input and whose declarations have not changed: • Clinician 1 • Clinician 2 • *Add additional (as required)*		

C. New or Updated Conflict of Interest Declarations

New or Updated Declaration for Clinician 1	
Name	*Kerri Purdy*
Position	*Division Head, Dermatology Dalhousie University*
Date	*August 1, 2024*
☒	**I hereby certify** that I have the authority to disclose all relevant information with respect to any matter involving this clinician or clinician group with a company, organization, or entity that may place this clinician or clinician group in a real, potential, or perceived conflict of interest situation.
Conflict of Interest Declaration	

List any companies or organizations that have provided your group with financial payment over the past two years AND who may have direct or indirect interest in the drug under review.				
Company	**Check Appropriate Dollar Range**			
	$0 to 5,000	**$5,001 to 10,000**	**$10,001 to 50,000**	**In Excess of $50,000**
Eli-Lilly	☐	☒	☐	☐
Sanofi-Genzyme	☐	☐	☒	☐
Abbvie	☐	☒	☐	☐
Pfizer		X		
Galderma	X			
Leo Pharma		X		

New or Updated Declaration for Clinician 2	
Name	*Irina Turchin*
Position	*Dermatologist, Fredericton NB*
Date	*August 1, 2024*
☒	**I hereby certify** that I have the authority to disclose all relevant information with respect to any matter involving this clinician or clinician group with a company, organization, or entity that may place this clinician or clinician group in a real, potential, or perceived conflict of interest situation.

Conflict of Interest Declaration

List any companies or organizations that have provided your group with financial payment over the past two years AND who may have direct or indirect interest in the drug under review.				
Company	**Check Appropriate Dollar Range**			
	$0 to 5,000	**$5,001 to 10,000**	**$10,001 to 50,000**	**In Excess of $50,000**
Abbvie	☐	☐	☒	☐
Eli-Lilly	☐	☒	☐	☐
Galderma	☐	☒	☐	☐
Leo Pharma			X	
Pfizer	X			
Sanofi Genzyme			X	

New or Updated Declaration for Clinician 3	
Name	*Alana McEvoy*
Position	*Dermatologist, Dalhousie University*
Date	*August 1, 2024*
☒	**I hereby certify** that I have the authority to disclose all relevant information with respect to any matter involving this clinician or clinician group with a company, organization, or entity that may place this clinician or clinician group in a real, potential, or perceived conflict of interest situation.

Conflict of Interest Declaration

List any companies or organizations that have provided your group with financial payment over the past two years AND who may have direct or indirect interest in the drug under review.				
Company	**Check Appropriate Dollar Range**			
	$0 to 5,000	**$5,001 to 10,000**	**$10,001 to 50,000**	**In Excess of $50,000**
Abbvie	☐	☒	☐	☐
Sanofi Genzyme	☒	☐	☐	☐
Eli Lilly	☐	☒	☐	☐
Leo Pharma		X		

New or Updated Declaration for Clinician 4	
Name	*Please state full name*
Position	*Please state currently held position*
Date	*Please add the date form was completed (DD-MM-YYYY)*
☐	**I hereby certify** that I have the authority to disclose all relevant information with respect to any matter involving this clinician or clinician group with a company, organization, or entity that may place this clinician or clinician group in a real, potential, or perceived conflict of interest situation.

Conflict of Interest Declaration				
List any companies or organizations that have provided your group with financial payment over the past two years AND who may have direct or indirect interest in the drug under review.				
Company	**Check Appropriate Dollar Range**			
	$0 to 5,000	**$5,001 to 10,000**	**$10,001 to 50,000**	**In Excess of $50,000**
Add company name	☐	☐	☐	☐
Add company name	☐	☐	☐	☐
Add or remove rows as required	☐	☐	☐	☐

New or Updated Declaration for Clinician 5	
Name	*Please state full name*
Position	*Please state currently held position*
Date	*Please add the date form was completed (DD-MM-YYYY)*
☐	**I hereby certify** that I have the authority to disclose all relevant information with respect to any matter involving this clinician or clinician group with a company, organization, or entity that may place this clinician or clinician group in a real, potential, or perceived conflict of interest situation.

Conflict of Interest Declaration				
List any companies or organizations that have provided your group with financial payment over the past two years AND who may have direct or indirect interest in the drug under review.				
Company	**Check Appropriate Dollar Range**			
	$0 to 5,000	**$5,001 to 10,000**	**$10,001 to 50,000**	**In Excess of $50,000**
Add company name	☐	☐	☐	☐

Add company name	☐	☐	☐	☐
Add or remove rows as required	☐	☐	☐	☐

CADTH

CADTH Reimbursement Review
Feedback on Draft Recommendation

Stakeholder information	
CADTH project number	SR0819-000
Brand name (generic)	Ebglyss (lebrikizumab)
Indication(s)	Atopic dermatitis
Organization	Dermatology Association of Ontario
Contact information[a]	Name: David Adam

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. (our comments are all made regarding sections on page 3 of the report. Relevant text is copied and pasted below)

We disagree with the draft recommendation. Currently only one biologic is recommended by CADTH. It would be relevant to note that CADTH's initial decision of dupilumab was also a negative opinion. The management of atopic dermatitis is complex in nature and patients often require multiple options as therapies can fail over time due to lack of efficacy or side effects. JAK inhibitors have a side effect profile that make them inappropriate for many patients. Only having one biologic approved when there are three available places patients on public plans in an inequitable position compared to patients with private plans. Furthermore, many of the points put forward by the committee are completely at odds with the clinical opinions of physicians who are on the front lines of managing these patients. It should be noted that our submission to CADTH represented the opinions of 11 physicians. We are also aware that a submission by the Canadian Dermatology Association was similarly supportive. It is interesting to us that CADTH chose to listen to the one dissenting voice (their clinical expert) rather than a multitude of clinical experts who came to a different conclusion.

"CDEC acknowledged the need for additional treatment options that effectively reduce the severity and symptoms of AD; however, based on the submitted evidence, CDEC could not determine whether lebrikizumab would adequately meet this need due to the lack of comparative evidence as well as uncertainty about the place in therapy."

Comparative evidence is almost never available for novel therapies. CDEC uses this rationale to refuse multiple novel therapies and thus deprives patients of much needed other options. Direct comparative evidence is not required to conclusively state that lebrikizumab is safe and effective. Comparative therapy is also not required to demonstrate that a drug that has a different mechanism of action from what is available currently will be a viable option for patients that have failed such therapies.

"There was insufficient evidence to suggest a benefit with lebrikizumab relative to dupilumab and abrocitinib, with most estimates affected by serious imprecision."

This argument does not address any relevant clinical question. If a patient has failed or is contraindicated to dupilumab or abrocitinib they still require a viable treatment option. CDEC is essentially denying these patients access to a drug that is proven to be effective in atopic dermatitis and is fundamentally different then the other therapies. The question is not whether lebrikizumab is

"better" than dupilumab or abrocitinib, rather the point is that it is effective and most importantly different.

"The NMA did not assess any safety endpoints thus the comparative safety of lebrikizumab is unknown."

This statement is untrue. One does not need a network meta-analysis to conclusively state that lebrikizumab is a safer drug than any JAK inhibitor.

"The longer-term safety and efficacy of lebrikizumab from the RCTs and extension study is uncertain due to limitations with the data which included an enriched population and carry-over effects for the 52-week data in the pivotal trials, and the lack of comparator group for the extension study."

There is no question in the mind of the clinical experts that contributed to this comment that the long-term safety and efficacy of lebrikizumab is well established from the robust clinical data collected in the studies. Once again, options are needed for our patients that are different in terms of mechanism of action. Demonstrating superiority over existing therapies is using the wrong metric to judge the relative value of a novel molecule for a difficult to treat disease state.

"Based on the evidence reviewed, CDEC could not determine whether lebrikizumab would adequately meet this need due to the uncertainty around the benefit of lebrikizumab versus appropriate comparators and in patients who received prior dupilumab or JAK inhibitor treatment."

Once again the benefit of lebrikizumab versus appropriate comparators is not relevant. Its uniqueness in mechanism of action is the key point that CDEC is not recognizing. This is particularly highlighted by the dire need for a drug in patients who are contraindicated to JAK inhibitors and are contraindicated or have failed dupilumab.

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?

The draft recommendation asks for data that is never produced in the drug development process. The draft recommendation misses the point that clinicians need different approaches to manage complex patients with life altering skin disease. Our present options of JAK inhibitors and dupilumab leave an entire emerging class of therapy outside the reach of our public patients. The importance of unique mechanisms of actions needs to be considered by CDEC rather than asking for data that is not available and not relevant. As clinicians we ask the CDEC members to put themselves in front of a patient who has failed off label therapy with methotrexate/cyclosporine, failed dupilumab and is contraindicated to JAK inhibitors. What does the committee suggest we offer this patient? How does the committee suggest we explain why this patient would have more options if they were privately covered? How is this equitable?

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.

A. Assistance with Providing the Feedback		
1. Did you receive help from outside your clinician group to complete this submission?	No	☒
	Yes	☐
If yes, please detail the help and who provided it.		
2. Did you receive help from outside your clinician group to collect or analyze any information used in this submission?	No	☒
	Yes	☐
If yes, please detail the help and who provided it.		
B. Previously Disclosed Conflict of Interest		
3. Were conflict of interest declarations provided in clinician group input that was submitted at the outset of the CADTH review and have those declarations remained unchanged? If no, please complete section C below.	No	☐
	Yes	☒
If yes, please list the clinicians who contributed input and whose declarations have not changed: • Dr. David Adam • Dr. Lyne Giroux • Dr. Fiona Lovegrove • Dr. Thanashan Rajakulendran • Dr. Jane Wu • Dr. Mohammed Bawazir • Dr. David Croitoru • Dr. Perla Lansang • Dr. Geeta Yadav		

C. New or Updated Conflict of Interest Declarations

none

CADTH

CADTH Reimbursement Review
Feedback on Draft Recommendation

Stakeholder information	
CADTH project number	SR0819-000 Stakeholder Feedback on Draft Recommendation
Brand name (generic)	Ebglyss (lebrikizumab)
Indication(s)	Atopic Dermatitis
Organization	Eli Lilly
Contact information[a]	Name: Ottawa Division of Dermatology

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

Lebrikizumab is a safe biologic option for patients with atopic dermatitis. There are a few things to consider:

- Anti-IL-13 therapies (ie tralokinumab) have been shown to be effective in some patients failing Anti-IL-4/13 therapy (ie dupilumab) - PMID: 38857764, 38834396, 36660960 – I expect that lebrikizumab, which is more effective than tralokinumab, will serve as an important treatment for patients who fail dupilumab.
- Publicly reimbursed patients deserve a second biologic option for AD, Dupilumab does not satisfy 100 % of patient needs
- Competition is key to improving access – prior to the JAK inhibitors being approved in Canada, Sanofi (Dupilumab) did not work well with clinicians or patient groups to increase access to their treatment. They were extremely stubborn throughout their negotiation processes. Only after the JAK inhibitors were on the horizon and approved did they work to get improve access status to their treatment.
- The lower dosing interval of q4 weeks is important, particularly in communities where drug delivery and access are difficult. This represents a 50 % reduction in shipping, biomedical waste and potential for error to limit access to the drug.

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	☐

This is N/A at this time.

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	☒

I disagree with the sequencing issues raised by the committee. Given the safety profile of a biologic and the decreased dosing frequency, lebrikizumab would be used in patients who have dermatitis without other atopic comorbidities as first line.

	Yes	☐

5. If applicable, are the reimbursement conditions clearly stated and the rationale for the conditions provided in the recommendation?	No	☐
I don't think this question applies.		

Appendix 2. Conflict of Interest Declarations for Clinician Groups

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A. Assistance with Providing the Feedback		
1. Did you receive help from outside your clinician group to complete this submission?	No	☒
	Yes	☐
If yes, please detail the help and who provided it.		
2. Did you receive help from outside your clinician group to collect or analyze any information used in this submission?	No	☒
	Yes	☐
If yes, please detail the help and who provided it.		
B. Previously Disclosed Conflict of Interest		
3. Were conflict of interest declarations provided in clinician group input that was submitted at the outset of the CADTH review and have those declarations remained unchanged? If no, please complete section C below.	No	☐
	Yes	☒
If yes, please list the clinicians who contributed input and whose declarations have not changed: • Mark Kirchhof		

C. New or Updated Conflict of Interest Declarations

New or Updated Declaration for Clinician 1	
Name	*Mark Kirchhof*
Position	*Head of Dermatology - Ottawa*
Date	*July 31, 2024*

☒	**I hereby certify** that I have the authority to disclose all relevant information with respect to any matter involving this clinician or clinician group with a company, organization, or entity that may place this clinician or clinician group in a real, potential, or perceived conflict of interest situation.

Conflict of Interest Declaration

List any companies or organizations that have provided your group with financial payment over the past two years AND who may have direct or indirect interest in the drug under review.

Company	Check Appropriate Dollar Range			
	$0 to 5,000	$5,001 to 10,000	$10,001 to 50,000	In Excess of $50,000
Abbvie	☐	☐	☐	☒
Amgen	☒	☐	☐	☐
Arcutis	☒	☐	☐	☐
Baush	☒	☐	☐	☐
Boehringer Ingelheim	☒	☐	☐	☐
Eli Lilly	☒	☐	☐	☐
Galderma	☒	☐	☐	☐
Novartis	☐	☒	☐	☐
Pfizer	☐	☐	☒	☐
Sanofi-Genzyme	☐	☐	☒	☐
UCB Biopharma	☐	☒	☐	☐

CADTH Reimbursement Review
Feedback on Draft Recommendation

Stakeholder information	
CADTH project number	SR0819-000
Brand name (generic)	lebrikizumab
Indication(s)	Atopic dermatitis
Organization	Fraser Health Dermatology Group
Contact information[a]	Name: Name: Gurbir Dhadwal Title: Dermatologist [redacted]

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

We do not agree with the recommendation of to not reimburse based on lack of comparative evidence and uncertainty about the place in therapy.

Regarding lack of comparative data, you cite a network meta-analysis (NMA) which provides indirect comparative data showing similar efficacy to currently available atopic dermatitis therapies. NMA are more commonly used today, and we do not see the need for a direct head to head comparison. CADTH's decision to recommend reimbursement for Abrocitinib for AD without a direct head to head vs Upadactinib would point to a similar precedent within CADTH. The NMA you cite shows lebrikizumab has a similar efficacy to our other options. Regarding lack of comparative safety data the numbers needed to treat to power a study that would show a statistically significant difference in safety outcomes is so large that those studies are going to be impractical. Looking at the safety data of lebrikizumab regarding conjunctivitis we expect the rates of conjunctivitis to be lower with lebrikizumab than dupilumab. When the dupilumab studies in AD were originally done, conjunctivitis was an unexpected adverse outcome and thus was not being watched for during the study and was likely under reported. This is supported by later studies with dupilumab showing higher rates of conjunctivitis of around 20% which mirrors what we see in clinical practice. The studies with lebrikizumab were done when clinical trialists were already primed to look for conjunctivitis and the rates are ~5-7%. This is the reason why we believe that lebrikizumab has a favorable safety profile and will be chosen by some physicians as an alternative first line biologic. Also those of us with experience using lebrikizumab, we feel the rates are significantly less than with dupilumab based on clinical experience. Regarding place in therapy; Upadactinib and Abrocitinib both received positive CADTH recommendations as first line although Abrocitinib, based on metanalysis, has a lower efficacy. In this case lebrikizumab has a similar efficacy to dupilumab and could be used as an alternative first line therapy. Having multiple medications drives competition which we would hope lower the cost to the system. From a clinical perspective, competition has helped drive competition to improve patient support programs, where some companies are now offering more services to patients free of charge such as dietician services, counselling services, and coverage for the vaccinations needed to start their medications. In the psoriasis world we have multiple medications in the same class with positive CADTH recommendations that can all be used first line. Here it would make sense to have another biologic as an alternative to dupilumab to drive price competition, competition of the patient support programs, and in our opinion with a

different safety profile. Also regarding comparison versus jak inhibitors, the biologic medications do not have the drug interactions of jak inhibitors and the concerns of cardiovascular events for our elderly patients (as labelled on the health Canada label for JAK inhibitors. Furthermore the biologic medications do not have the same monitoring requirement as the jak inhibitors and the associated lab costs, and physician follow up costs.

As a last point. We are based in British Columbia. BC Pharmacare never approved coverage for dupilumab. So without access to lebrikizumab we will not have access to any biologic option for our patients with atopic dermatitis.

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	☐
N/A we did not provide input in the original submission		

Clarity of the draft recommendation		
3. Are the reasons for the recommendation clearly stated?	Yes	☐
	No	☒
It is not clear why lack of comparative data is cited as a concern in this case, when similar data, or lack of data has not been a concern for many of the psoriasis biologics, and for comparisons between the two jak inhibitors		
4. Have the implementation issues been clearly articulated and adequately addressed in the recommendation?	Yes	☐
	No	☐
N/A		
5. If applicable, are the reimbursement conditions clearly stated and the rationale for the conditions provided in the recommendation?	Yes	☐
	No	☐
N/A		

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

Appendix 2. Conflict of Interest Declarations for Clinician Groups

- To maintain the objectivity and credibility of the CADTH drug review programs, all participants in the drug review processes must disclose any real, potential, or perceived conflicts of interest.
- This conflict of interest declaration is required for participation. Declarations made do not negate or preclude the use of the feedback from patient groups and clinician groups.
- CADTH may contact your group with further questions, as needed.
- Please see the *Procedures for CADTH Drug Reimbursement Reviews* for further details.
- For conflict of interest declarations:
  - Please list any companies or organizations that have provided your group with financial payment over the past two years AND who may have direct or indirect interest in the drug under review.
  - Please note that declarations are required for each clinician that contributed to the input.
  - If your clinician group provided input at the outset of the review, only conflict of interest declarations that are new or require updating need to be reported in this form. For all others, please list the clinicians who provided input are unchanged
  - Please add more tables as needed (copy and paste).
  - All new and updated declarations must be included in a single document.

A. Assistance with Providing the Feedback		
2. Did you receive help from outside your clinician group to complete this submission?	No	☒
	Yes	☐
If yes, please detail the help and who provided it.		
3. Did you receive help from outside your clinician group to collect or analyze any information used in this submission?	No	☒
	Yes	☐
If yes, please detail the help and who provided it.		
B. Previously Disclosed Conflict of Interest		
4. Were conflict of interest declarations provided in clinician group input that was submitted at the outset of the CADTH review and have those declarations remained unchanged? If no, please complete section C below.	No	☒
	Yes	☐
If yes, please list the clinicians who contributed input and whose declarations have not changed: • Clinician 1 • Clinician 2 • *Add additional (as required)*		

C. New or Updated Conflict of Interest Declarations

New or Updated Declaration for Clinician 1	
Name	*Gurbir Dhadwal*
Position	*Dermatologist*
Date	*Please add the date form was completed (01-08-2024)*
☒	**I hereby certify** that I have the authority to disclose all relevant information with respect to any matter involving this clinician or clinician group with a company, organization, or entity that may place this clinician or clinician group in a real, potential, or perceived conflict of interest situation.
Conflict of Interest Declaration	

List any companies or organizations that have provided your group with financial payment over the past two years AND who may have direct or indirect interest in the drug under review.				
Company	**Check Appropriate Dollar Range**			
	$0 to 5,000	**$5,001 to 10,000**	**$10,001 to 50,000**	**In Excess of $50,000**
Eli Lilly	☐	☒	☐	☐
Abbvie	☐	☐	☒	☐
Sanofi	☐	☐	☒	☐
Pfizer	☐	☐	☒	☐

New or Updated Declaration for Clinician 2	
Name	*Se Mang Wong*
Position	*Dermatologist*
Date	*Please add the date form was completed (01-08-2024)*
☒	**I hereby certify** that I have the authority to disclose all relevant information with respect to any matter involving this clinician or clinician group with a company, organization, or entity that may place this clinician or clinician group in a real, potential, or perceived conflict of interest situation.

Conflict of Interest Declaration

List any companies or organizations that have provided your group with financial payment over the past two years AND who may have direct or indirect interest in the drug under review.				
Company	**Check Appropriate Dollar Range**			
	$0 to 5,000	**$5,001 to 10,000**	**$10,001 to 50,000**	**In Excess of $50,000**
Eli lilly	☒	☐	☐	☐
Abbvie	☒	☐	☐	☐
Pfizer	☒	☐	☐	☐
	☐	☐	☐	☐

New or Updated Declaration for Clinician 3	
Name	*Aaron Wong*
Position	*Dermatologist*
Date	*Please add the date form was completed (01-08-2024)*
☒	**I hereby certify** that I have the authority to disclose all relevant information with respect to any matter involving this clinician or clinician group with a company, organization, or entity that may place this clinician or clinician group in a real, potential, or perceived conflict of interest situation.

Conflict of Interest Declaration

List any companies or organizations that have provided your group with financial payment over the past two years AND who may have direct or indirect interest in the drug under review.				
Company	**Check Appropriate Dollar Range**			
	$0 to 5,000	**$5,001 to 10,000**	**$10,001 to 50,000**	**In Excess of $50,000**
Eli Lilly	☒	☐	☐	☐

Abbvie	☒	☐	☐	☐
Sanofi	☒	☐	☐	☐
Pfizer	☒	☐	☐	☐
Johnson and Johnson	☒	☐	☐	☐

New or Updated Declaration for Clinician 4	
Name	*Chih-ho Hong*
Position	*Dermatologist*
Date	*Please add the date form was completed (01-08-2024)*
☒	**I hereby certify** that I have the authority to disclose all relevant information with respect to any matter involving this clinician or clinician group with a company, organization, or entity that may place this clinician or clinician group in a real, potential, or perceived conflict of interest situation.

Conflict of Interest Declaration

List any companies or organizations that have provided your group with financial payment over the past two years AND who may have direct or indirect interest in the drug under review.

Company	**Check Appropriate Dollar Range**			
	$0 to 5,000	**$5,001 to 10,000**	**$10,001 to 50,000**	**In Excess of $50,000**
Eli Lilly	☐	☐	☒	☐
Abbvie	☐	☐	☐	☒
Sanofi	☐	☐	☒	☐
Pfizer	☐	☐	☒	☐

New or Updated Declaration for Clinician 5	
Name	*Please state full name*
Position	*Please state currently held position*
Date	*Please add the date form was completed (DD-MM-YYYY)*
☐	**I hereby certify** that I have the authority to disclose all relevant information with respect to any matter involving this clinician or clinician group with a company, organization, or entity that may place this clinician or clinician group in a real, potential, or perceived conflict of interest situation.

Conflict of Interest Declaration

List any companies or organizations that have provided your group with financial payment over the past two years AND who may have direct or indirect interest in the drug under review.

Company	**Check Appropriate Dollar Range**			
	$0 to 5,000	**$5,001 to 10,000**	**$10,001 to 50,000**	**In Excess of $50,000**
Add company name	☐	☐	☐	☐
Add company name	☐	☐	☐	☐
Add or remove rows as required	☐	☐	☐	☐

CADTH Reimbursement Review
Feedback on Draft Recommendation

Stakeholder information	
CADTH project number	Ebglyss
Brand name (generic)	lebrikizumab
Indication(s)	Atopic Dermatitis
Organization	The Lynde Institute for Dermatology & Lynderm Research Inc.
Contact information[a]	Name: Charles Lynde [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.

There is an unmet need for more treatment options for patients with moderate-to-severe atopic dermatitis. Dupilumab as a biologic IL-4/IL-13 inhibitor is not sufficient for the full heterogeneity in disease presentation and patient response.

Lebrikizumab binding only IL-13 can serve as a first line therapeutic, for example in patients who perhaps do not express other versions of atopic conditions or an alternative to those who are at higher risk for opportunistic infections such as conjunctivitis. Although it is suggested that lebrikizumab may increase short-term risk of conjunctivitis, dupilumab's safety profile has a higher risk of conjunctivitis when compared (note, indirect comparison) to lebrikizumab.

Lebrikizumab is also a q4w injection, when compared with dupilumab at q2w. This gives it a unique advantage over dupilumab. Over a year, q2w injections this leads to an additional 12 injections every year. Many patients for a variety of reasons do not self administer medication. Lebrikizumab may be a more suitable option for those with vasovagal responses to needles. The dosing schedule for lebrikizumab will reduce the congestion and spending on the overall healthcare system in dermatology with additional visits or home visits when comparing with dupilumab. A q4w dosing schedule may be more beneficial for those who need to travel for work, have busy schedules, ultimately reducing the burden of disease in this aspect.

JAK inhibitors such as abrocitinib and upadacitinib cannot be directly compared to an injectable biologic such as lebrikizumab or dupilumab as they have a different method of administration, they have a different safety profile, and have a different mechanism of action. All these factors need to be considered. The economic evidence portion of the Reimbursement Review references that JAK inhibitors in combination with TCS may result in a greater proportion of patients achieving EASI response when indirectly compared with lebrikizumab. However, a daily oral medication may not be the best choice for some patients considering a number of factors including lifestyle, contraindications, compliance amongst other things.

Overall, the reliance on one biologic available for public reimbursement is not sufficient, due to the heterogeneity of atopic dermatitis. Dupilumab is not suitable in for all moderate-to-severe patients. As a research center conducting many of the biologics, and JAK inhibitor trials for moderate-to-severe atopic dermatitis, we have seen first hand the need and place within the treatment landscape for lebrikizumab.

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	☒
N/A – We hold professional memberships to CDA / DAO however, were not individuals who directly consulted on the original draft recommendations.		
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.

Appendix 1. Conflict of Interest Declarations for Patient Groups

- To maintain the objectivity and credibility of the CADTH drug review programs, all participants in the drug review processes must disclose any real, potential, or perceived conflicts of interest.
- This conflict of interest declaration is required for participation. Declarations made do not negate or preclude the use of the feedback from patient groups and clinician groups.
- CADTH may contact your group with further questions, as needed.
- Please see the *Procedures for CADTH Drug Reimbursement Reviews* for further details.

A. Patient Group Information	
Name	Eczema Society of Canada
Position	Occasional Consultant (Charles Lynde only)
Date	25 Jul 2024
☒	I hereby certify that I have the authority to disclose all relevant information with respect to any matter involving this patient group with a company, organization, or entity that may place this patient group in a real, potential, or perceived conflict of interest situation.

B. Assistance with Providing Feedback		
1. Did you receive help from outside your patient group to complete your feedback?	No	☐
	Yes	☒
? Unsure how to answer question, feedback was related to professional knowledge outside of consultancy work with ESC.		
2. Did you receive help from outside your patient group to collect or analyze any information used in your feedback?	No	☒
	Yes	☐
If yes, please detail the help and who provided it.		

C. Previously Disclosed Conflict of Interest		
1. Were conflict of interest declarations provided in patient group input that was submitted at the outset of the CADTH review and have those declarations remained unchanged? If no, please complete section D below.	No	☒
	Yes	☐

D. New or Updated Conflict of Interest Declaration

3. List any companies or organizations that have provided your group with financial payment over the past two years AND who may have direct or indirect interest in the drug under review.

Company	**Check Appropriate Dollar Range**			
	$0 to 5,000	**$5,001 to 10,000**	**$10,001 to 50,000**	**In Excess of $50,000**
Eczema Society of Canada	☒	☐	☐	☐

Appendix 2. Conflict of Interest Declarations for Clinician Groups

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- This conflict of interest declaration is required for participation. Declarations made do not negate or preclude the use of the feedback from patient groups and clinician groups.
- CADTH may contact your group with further questions, as needed.
- Please see the *Procedures for CADTH Drug Reimbursement Reviews* for further details.
- For conflict of interest declarations:
  - Please list any companies or organizations that have provided your group with financial payment over the past two years AND who may have direct or indirect interest in the drug under review.
  - Please note that declarations are required for each clinician that contributed to the input.
  - If your clinician group provided input at the outset of the review, only conflict of interest declarations that are new or require updating need to be reported in this form. For all others, please list the clinicians who provided input are unchanged
  - Please add more tables as needed (copy and paste).
  - All new and updated declarations must be included in a single document.

A. Assistance with Providing the Feedback		
2. Did you receive help from outside your clinician group to complete this submission?	No	☒
	Yes	☐
If yes, please detail the help and who provided it.		
3. Did you receive help from outside your clinician group to collect or analyze any information used in this submission?	No	☒
	Yes	☐
If yes, please detail the help and who provided it.		
B. Previously Disclosed Conflict of Interest		
4. Were conflict of interest declarations provided in clinician group input that was submitted at the outset of the CADTH review and have those declarations remained unchanged? If no, please complete section C below.	No	☐
	Yes	☐
If yes, please list the clinicians who contributed input and whose declarations have not changed: • Clinician 1 • Clinician 2 • *Add additional (as required)*		

C. New or Updated Conflict of Interest Declarations

New or Updated Declaration for Clinician 1	
Name	*Charles W. Lynde on behalf of The Lynde Institute for Dermatology & Lynderm Research Inc.*
Position	*Medical Director, The Lynde Institute for Dermatology*
Date	*Please add the date form was completed 30-Jul-2024*
☒	**I hereby certify** that I have the authority to disclose all relevant information with respect to any matter involving this clinician or clinician group with a company, organization, or entity that may place this clinician or clinician group in a real, potential, or perceived conflict of interest situation.
Conflict of Interest Declaration	

List any companies or organizations that have provided your group with financial payment over the past two years AND who may have direct or indirect interest in the drug under review.				
Company	**Check Appropriate Dollar Range**			
	$0 to 5,000	**$5,001 to 10,000**	**$10,001 to 50,000**	**In Excess of $50,000**
AbbVie	☐	☐	☐	☒
Eli Lilly	☐	☐	☐	☒
LEO Pharma	☐	☐	☐	☒
Pfizer	☐	☐	☐	☒
Sanofi	☐	☐	☐	☒
Please note that we are a clinical research site, and amounts correlate with fees that the research facility receives to conduct trials.				

New or Updated Declaration for Clinician 2	
Name	*John N. Kraft*
Position	*Sub-Investigator & Dermatologist, The Lynde Institute for Dermatology & Lynderm Research Inc.*
Date	*Please add the date form was completed 30-Jul-2024*
☒	**I hereby certify** that I have the authority to disclose all relevant information with respect to any matter involving this clinician or clinician group with a company, organization, or entity that may place this clinician or clinician group in a real, potential, or perceived conflict of interest situation.

Conflict of Interest Declaration

List any companies or organizations that have provided your group with financial payment over the past two years AND who may have direct or indirect interest in the drug under review.				
Company	**Check Appropriate Dollar Range**			
	$0 to 5,000	**$5,001 to 10,000**	**$10,001 to 50,000**	**In Excess of $50,000**
AbbVie	☐	☐	☐	☒
Eli Lilly	☐	☐	☐	☒
LEO Pharma	☐	☐	☐	☒
Pfizer	☐	☐	☐	☒
Sanofi	☐	☐	☐	☒
Please note that we are a clinical research site, and amounts correlate with fees that the research facility receives to conduct trials.				

New or Updated Declaration for Clinician 3	
Name	*Carrie B. Lynde*
Position	*Sub-Investigator & Dermatologist, The Lynde Institute for Dermatology & Lynderm Research Inc.*
Date	*Please add the date form was completed 30-Jul-2024*
☒	**I hereby certify** that I have the authority to disclose all relevant information with respect to any matter involving this clinician or clinician group with a company, organization, or entity that may place this clinician or clinician group in a real, potential, or perceived conflict of interest situation.

Conflict of Interest Declaration				
List any companies or organizations that have provided your group with financial payment over the past two years AND who may have direct or indirect interest in the drug under review.				
Company	**Check Appropriate Dollar Range**			
	$0 to 5,000	**$5,001 to 10,000**	**$10,001 to 50,000**	**In Excess of $50,000**
AbbVie	☐	☐	☐	☒
Eli Lilly	☐	☐	☐	☒
LEO Pharma	☐	☐	☐	☒
Pfizer	☐	☐	☐	☒
Sanofi	☐	☐	☐	☒
Please note that we are a clinical research site, and amounts correlate with fees that the research facility receives to conduct trials.				

New or Updated Declaration for Clinician 4	
Name	*Francesca Cheung*
Position	*Sub-Investigator & General Practitioner with a Focused Practice in Disorders of the Skin, The Lynde Institute for Dermatology & Lynderm Research Inc.*
Date	*Please add the date form was completed 30-Jul-2024*
☒	**I hereby certify** that I have the authority to disclose all relevant information with respect to any matter involving this clinician or clinician group with a company, organization, or entity that may place this clinician or clinician group in a real, potential, or perceived conflict of interest situation.

Conflict of Interest Declaration				
List any companies or organizations that have provided your group with financial payment over the past two years AND who may have direct or indirect interest in the drug under review.				
Company	**Check Appropriate Dollar Range**			
	$0 to 5,000	**$5,001 to 10,000**	**$10,001 to 50,000**	**In Excess of $50,000**
AbbVie	☐	☐	☐	☒
Eli Lilly	☐	☐	☐	☒
LEO Pharma	☐	☐	☐	☒
Pfizer	☐	☐	☐	☒
Sanofi	☐	☐	☐	☒
Please note that we are a clinical research site, and amounts correlate with fees that the research facility receives to conduct trials.				

CADTH Reimbursement Review
Feedback on Draft Recommendation

Stakeholder information	
CADTH project number	SR0819-000 Stakeholder Feedback on Draft Recommendation
Brand name (generic)	Ebglyss
Indication(s)	Atopic Dermatitis
Organization	Pitanga Medical Group
Contact information[a]	Name: Hermenio Lima

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

We do not agree with the committee's recommendation for several reasons, which align with the specific unmet needs and unique strengths of Ebglyss (lebrikizumab) in the treatment of moderate-to-severe atopic dermatitis (AD):

1. **Unmet Need for More Treatment Options**: The recommendation acknowledges the need for additional treatment options but fails to address the documented limitations of existing therapies. The recommendation states: "CDEC acknowledged the need for additional treatment options that effectively reduce the severity and symptoms of AD; however, based on the submitted evidence, CDEC could not determine whether lebrikizumab would adequately meet this need due to the lack of comparative evidence as well as uncertainty about the place in therapy" (SR0819-000_DRAFT_REC).

However, this conclusion overlooks the well-documented need for more innovative biologics like Ebglyss due to the heterogeneity in disease presentation and patient response.

2. **Comparative Efficacy and Safety**: The committee's rationale hinges on the lack of direct comparative evidence to other biologics or JAK inhibitors and uncertainty in long-term safety data: "There was no direct evidence comparing lebrikizumab to other biologics or Janus kinase (JAK) inhibitors used to treat AD; however, one network meta-analysis (NMA) provided indirect evidence for the comparisons of interest" (SR0819-000_DRAFT_REC).

Ebglyss has unique strengths in its long-term efficacy and safety data, including up to 2 years of supporting data and Q4W dosing in the maintenance phase. This makes it a convenient and effective option for patients.

3. **Long-Term Efficacy and Safety Data**: The recommendation does not sufficiently acknowledge the strengths of Ebglyss' long-term data: "The longer-term safety and efficacy of lebrikizumab from the RCTs and extension study is uncertain due to limitations with the data which included an enriched population and carry-over effects for the 52-week data in the pivotal trials, and the lack of comparator group for the extension study" (SR0819-000_DRAFT_REC).

This fails to highlight Ebglyss' demonstrated higher skin efficacy compared to tralokinumab based on indirect comparisons and its unique mechanism of action with high binding affinity for IL-13 and slow disassociation rate.

4. **Patient and Clinician Needs**: The patient input section clearly identifies a significant need for new treatments that improve quality of life, sleep, and overall well-being, which Ebglyss can address: "Patient input received for this review identified a need for additional treatments for patients that can reduce severity and symptoms of AD, improve sleep quality and health-

related quality of life (HRQoL), have sustained benefits, and are safe" (SR0819-000_DRAFT_REC).

5. **Rationale for First-Line Therapy**: The place in therapy for Ebglyss as a first-line biologic needs to be clarified and highlighted. The committee's recommendation lacks this perspective: "The absence of comparative safety data as well as HRQoL outcomes preclude assessment of all factors necessary to balance all outcomes and unmet needs (including improved safety)" (SR0819-000_DRAFT_REC).

6. **Misunderstood Mechanism of Action**: The recommendation misinterprets the importance of the MOA of JAKs and their long-term inefficacy: "The MOA of JAKs determined their faster onset, which is apparent in short-term efficacy but are not sustained in the long-term to fulfill the need for moderate-to-severe AD management" (SR0819-000_DRAFT_REC).

Ebglyss' unique MOA and long-term efficacy up to 2 years make it a superior choice for sustained management of moderate-to-severe AD.

In conclusion, the stakeholder disagrees with the draft recommendation due to its failure to fully recognize the unmet need for more treatment options, the unique strengths of Ebglyss in long-term efficacy and safety, and the necessity of having alternative innovative biologics for the diverse patient population with moderate-to-severe AD.

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	☒

N/A

Clarity of the draft recommendation

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

The reasons for the recommendation are somewhat clear but require additional clarification. While the committee acknowledges the need for additional treatment options, their rationale focuses heavily on the lack of direct comparative evidence and uncertainties in long-term safety and efficacy. However, they do not adequately address the unique strengths and long-term benefits of Ebglyss, such as its specific efficacy in moderate-to-severe AD and its unique mechanism of action. The importance of providing alternative biologics due to the heterogeneous nature of AD and patient response variability is not sufficiently emphasized.

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

The implementation issues are mentioned but not comprehensively addressed. The recommendation notes the absence of comparative safety data and HRQoL outcomes, which preclude a full assessment of all outcomes and unmet needs. However, it does not provide clear guidance on how these gaps could be addressed in clinical practice or through further research. Additionally, the recommendation does not sufficiently discuss the potential impact of the lack of reimbursement on patients and healthcare providers, especially in terms of access to alternative treatment options and the practical aspects of incorporating Ebglyss into treatment protocols.

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

The reimbursement conditions and their rationale are not clearly stated in the recommendation. The committee recommends against reimbursement but does not offer detailed conditions under which reimbursement might be reconsidered. There is a lack of clarity on the specific criteria or additional evidence needed to support a positive reimbursement decision in the future. The recommendation could benefit from a more detailed explanation of what specific data or outcomes would address the committee's concerns and potentially change their stance on reimbursement.

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

Appendix 2. Conflict of Interest Declarations for Clinician Groups

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  - Please list any companies or organizations that have provided your group with financial payment over the past two years AND who may have direct or indirect interest in the drug under review.
  - Please note that declarations are required for each clinician that contributed to the input.
  - If your clinician group provided input at the outset of the review, only conflict of interest declarations that are new or require updating need to be reported in this form. For all others, please list the clinicians who provided input are unchanged
  - Please add more tables as needed (copy and paste).
  - All new and updated declarations must be included in a single document.

A. Assistance with Providing the Feedback		
2. Did you receive help from outside your clinician group to complete this submission?	No	☒
	Yes	☐
If yes, please detail the help and who provided it.		
3. Did you receive help from outside your clinician group to collect or analyze any information used in this submission?	No	☒
	Yes	☐
If yes, please detail the help and who provided it.		
B. Previously Disclosed Conflict of Interest		
4. Were conflict of interest declarations provided in clinician group input that was submitted at the outset of the CADTH review and have those declarations remained unchanged? If no, please complete section C below.	No	☒
	Yes	☐
If yes, please list the clinicians who contributed input and whose declarations have not changed: • Clinician 1 • Clinician 2 • *Add additional (as required)*		

C. New or Updated Conflict of Interest Declarations

New or Updated Declaration for Clinician 1	
Name	*CAVALCANTE LIMA FILHO, JOSE HERMENIO – CPSO# 92635*
Position	*Co-director Pitanga Medical Clinic – 928 Barton Street East, Hamilton ON L3L 8C8*
Date	*Please add the date form was completed (23-07-2024)*
☒	**I hereby certify** that I have the authority to disclose all relevant information with respect to any matter involving this clinician or clinician group with a company, organization, or entity that may place this clinician or clinician group in a real, potential, or perceived conflict of interest situation.
Conflict of Interest Declaration	

List any companies or organizations that have provided your group with financial payment over the past two years AND who may have direct or indirect interest in the drug under review.				
Company	**Check Appropriate Dollar Range**			
	$0 to 5,000	**$5,001 to 10,000**	**$10,001 to 50,000**	**In Excess of $50,000**
AbbVie	☐	☒	☐	☐
Sanofi	☐	☒	☐	☐
Leo Pharma	☒	☐	☐	☐
Eli-Lilly	☒	☐	☐	☐
Pfizer	☒	☐	☐	☐

New or Updated Declaration for Clinician 2	
Name	*LANZINI, ROSILENE CANZI ALMADA – CPSO# 99937*
Position	*Co-director Pitanga Medical Clinic – 928 Barton Street East, Hamilton ON L3L 8C8*
Date	*Please add the date form was completed (23-07-2024)*
☒	**I hereby certify** that I have the authority to disclose all relevant information with respect to any matter involving this clinician or clinician group with a company, organization, or entity that may place this clinician or clinician group in a real, potential, or perceived conflict of interest situation.

Conflict of Interest Declaration

List any companies or organizations that have provided your group with financial payment over the past two years AND who may have direct or indirect interest in the drug under review.				
Company	**Check Appropriate Dollar Range**			
	$0 to 5,000	**$5,001 to 10,000**	**$10,001 to 50,000**	**In Excess of $50,000**
Add company name	☐	☐	☐	☐
Add company name	☐	☐	☐	☐
Add or remove rows as required	☐	☐	☐	☐

New or Updated Declaration for Clinician 3	
Name	*Please state full name*
Position	*Please state currently held position*
Date	*Please add the date form was completed (DD-MM-YYYY)*
☒	**I hereby certify** that I have the authority to disclose all relevant information with respect to any matter involving this clinician or clinician group with a company, organization, or entity that may place this clinician or clinician group in a real, potential, or perceived conflict of interest situation.

Conflict of Interest Declaration

List any companies or organizations that have provided your group with financial payment over the past two years AND who may have direct or indirect interest in the drug under review.				
Company	**Check Appropriate Dollar Range**			
	$0 to 5,000	**$5,001 to 10,000**	**$10,001 to 50,000**	**In Excess of $50,000**
Add company name	☐	☐	☐	☐

CADTH

Feedback on Draft Recommendation

Stakeholder information	
CADTH project number	SR0819-000
Brand name (generic)	Lebrikizumab
Indication(s)	For the treatment of moderate-to-severe atopic dermatitis in adults and adolescents 12 years of age and older with a body weight of at least 40 kg, whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable.
Organization	Saskatchewan Dermatology Association
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.

Our clinician group disagrees with the draft recommendation of 'do not reimburse' for lebrikizumab.
The main reason stated for the draft recommendation is "CDEC could not determine whether lebrikizumab would adequately meet this need due to the lack of comparative evidence as well as uncertainty in the place of therapy." Considering to the robust amount of Canadian-specific feedback provided by multiple patient and clinician groups in the original submission, supported by peer-reviewed literature sources documenting high disease burdens and unmet needs for novel therapies provided to CADTH, the summary draft recommendation only superficially acknowledges the impact and unmet needs of AD in Canada as provided and voiced by patients and clinicians. More details from a clinician's standpoint can be found below.

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	☒

The 'do not reimburse' recommendation by CADTH has left clinician and patient groups advocating for AD disappointed. Echoing previous patient and clinician input, our clinician group supports public approval of lebrikizumab use as a first-line biologic in moderate to severe AD (msAD) due to clearly expressed unmet needs with regards to disease burdens, and lack of therapeutic options.

A more detailed analysis and response directly integrating patient and clinician input and unmet needs in the Canadian context should be issued for a 'do not reimburse' recommendation summary beyond clinical trial and NME comparative data analysis in order for transparency for our patient and clinician groups who have indicated exhaustion with burdens of disease, lack of therapies, and multiple real-life unmet needs.

CADTH had already issued a 'do not reimburse' recommendation for the only other IL13 inhibitor with less strong efficacy data (tralokinumab). This has impacted our practices in the sense that we have no other option for biologic therapy in Canada except for dupilumab for our patients. A 'do not reimburse' recommendation will continue to leave us with no other options for biologic therapy, including for those who have failed or have been intolerant.

Upon reviewing the CADTH report, and clinician and patient input, it appears clear from the Canadian patient and clinician experience, backed by peer reviewed literature, that despite some advancement in AD therapy,

there continues to be clear, significant unmet needs and gaps in Canada for msAD creating burdens on patients, treating healthcare practitioners, and the healthcare system.

Some major unmet needs include:

1. Both patient and clinician groups have clearly stated there is a strong need for more approved treatment options. Currently, we only have one FDA approved biologic therapy in msAD, which is dupilumab.
2. Clinician and patient group input also have clearly stated that there are a significant amount of patients that have failed or have had adverse events requiring discontinuation of biologic or JAK inhibitor therapy. Therefore, there are unmet needs for a new biologic therapy (see comments below on real-world experiences and review clinician input from original submission).
3. AD is a heterogenous disease, and there is no 'perfect' target found at this time. Some patients may respond to some medications and not to others. Therefore, relying on reimbursement of one biologic is not enough, especially given the points in #1 and #2.
4. No IL13 inhibitor has been approved by CADTH in the past, and none are publicly available. Tralokinumab received a final "do not reimburse' recommendation. IL13 is thought to play a primary role in AD skin, and brings in a novel mechanism compared to tralokinumab in the sense that lebrikizumab does not prevent binding to the IL13R2 decoy receptor, which promotes endogenous regulation, and has higher affinity and lasting effect which demonstrates high durability of response and recapture in trials. Furthermore, other distinguishing features of lebrikizumab include the possibility of less conjunctivitis, low rates of injection site reactions, and less concern for recalcitrant facial, head and neck atopic dermatitis which often requires discontinuation. Of importance, those on lebrikizumab demonstrate lower rates of skin infections, likely related to its mechanism (Bernado et al., 2023) which holds promise to the current crisis of infected AD seen in Canadian Indigenous communities (Asiniwasis et al., 2021).
5. Currently in practice, we have many patients who have failed or been intolerant to dupilumab and/or JAK1 inhibitors for such reasons (efficacy/safety failures) as well as traditional systemic immunosuppressants at this stage. A "do not reimburse" recommendations means we continue to lack other options to treat these patients, contributing to ongoing burdens of AD as described in previous clinician input.
6. If approved, lebrikizumab is the only biologic that would be used q4weeks in maintenance as demonstrated by clinical trial data with maintenance of response. This is a potential benefit with regards to time and cost savings.

Saskatchewan is one of many underserviced regions across Canada, and highly ruralized where burdens of AD are reflected in real life practice. JAK1s from a practical, real-life standpoint are hard to compare to biologic therapy. JAK1 inhibitors carry a different method of action, mode of administration, and safety profile that is not necessarily comparable to biologic therapy. In particular, JAK1 inhibitors carry a potentially more significant adverse safety monitoring profile, requiring recurrent labwork, have short half lives, and require ongoing safety monitoring. This is not always feasible whereas labs, imaging facilities and access to TB testing is not easily available in Saskatchewan, most magnified in rural and remote areas, including Indigenous communities, which presents a potential safety risk.

We also live in Saskatchewan, which has one of the highest per-capita rates of Indigenous peoples. Clinical experience and a building evidence base is demonstrating that atopic dermatitis is one of the most common conditions seen in Indigenous peoples across Canada, and is documented to be more severe in nature and secondarily infected (Asiniwasis, 2021; Asiniwasis 2022). Given that up to 60% of Canadian Indigenous peoples live rurally and remotely (OECD, 2021), and high rates of more severe AD and complications are faced, safer and easier options to implement and monitor are strongly needed. In particular, the safety profile of lebrikizumab and lack of bloodwork, imaging and TB test requirements ease burdens in remote and northern communities which relieves burdens off patients, practitioners and the healthcare system. Furthermore, we have many patients who have failed and/or tolerant to dupilumab or are not candidates for broader systemic immunosuppression. These rural and remote vulnerable populations require specific consideration in the

Canadian context. Approval of new medications also helps to establish cold chain practices in remote and northern areas.
It would be helpful to know if community dermatologists were consulted in CADTH's final recommendation. Most dermatologists in Canada are community based, face long waiting lists, and little subsidized healthcare system space for independent practice. Many underserviced areas face unique barriers and challenges to care and real-life challenges needing to be fully acknowledged in the CADTH final recommendation report, or if the uncertainty in the place in therapy came from a single clinician expert consultation. With regards to uncertainty in place of therapy, only one clinician(?) provided a statement that 'lebrikizumab would be considered a second line biologic after dupilumab'. In contrast, our clinician group believes that this would fit as a first-line biologic therapy for many of the reasons listed above.

In moderate to severe psoriasis, another chronic inflammatory disease with systemic associations, multiple biologic therapies have been approved, including multiple first-line options from each class of IL23, IL17, and TNFa inhibitors.

Dermatology likely is the specialty with the most off-label use of medications. Compared to other specialities, outside of psoriasis, we continue to often rely on outdated medications such as steroids (around since the 1950's) and broad systemic immunosuppression (around for several decades; carrying a multitude of potential systemic side effects as described in previous clinician input) for moderate to severe forms of inflammatory skin diseases. These older therapies, demonstrating high rates of failure and intolerance, place significant burdens on both the clinician, patient and system. There is a definite need for innovative alternatives carrying more favorable safety and efficacy profiles, and currently we only have one approved biologic at this time. We encourage CADTH to reassess their recommendation in hopes of access and coverage and removal of burdens off clinicians and patients considering the whole picture. Thank you!

References
-Bernardo, D., Bieber, T., & Torres, T. (2023). Lebrikizumab for the Treatment of Moderate-to-Severe Atopic Dermatitis. *American journal of clinical dermatology*, *24*(5), 753–764. https://doi.org/10.1007/s40257-023-00793-5
-Asiniwasis R, Chu D. Atopic Dermatitis and Canadian Indigenous Peoples: Burdens, Barriers, and Potential for Solutions. (2022). Canadian Dermatology Today.
https://canadianallergyandimmunologytoday.com/article/view/2-3-asiniwasis_et_al
-Asiniwasis, R. N., Heck, E., Amir Ali, A., Ogunyemi, B., & Hardin, J. (2021). Atopic dermatitis and skin infections are a poorly documented crisis in Canada's Indigenous pediatric population: It's time to start the conversation. *Pediatric Dermatology*, *38 Suppl 2*, 188–189. https://doi.org/10.1111/pde.14759

Clarity of the draft recommendation

3. Are the reasons for the recommendation clearly stated?	Yes	☐
	No	☒
See comments in #2		
4. Have the implementation issues been clearly articulated and adequately addressed in the recommendation?	Yes	☐
	No	☒
See comments in #2		
5. If applicable, are the reimbursement conditions clearly stated and the rationale for the conditions provided in the recommendation?	Yes	☐
	No	☒
See comments in #2		

Appendix 2. Conflict of Interest Declarations for Clinician Groups

- To maintain the objectivity and credibility of the CADTH drug review programs, all participants in the drug review processes must disclose any real, potential, or perceived conflicts of interest.
- This conflict of interest declaration is required for participation. Declarations made do not negate or preclude the use of the feedback from patient groups and clinician groups.
- CADTH may contact your group with further questions, as needed.
- Please see the *Procedures for CADTH Drug Reimbursement Reviews* for further details.
- For conflict of interest declarations:
  - Please list any companies or organizations that have provided your group with financial payment over the past two years AND who may have direct or indirect interest in the drug under review.
  - Please note that declarations are required for each clinician that contributed to the input.
  - If your clinician group provided input at the outset of the review, only conflict of interest declarations that are new or require updating need to be reported in this form. For all others, please list the clinicians who provided input are unchanged
  - Please add more tables as needed (copy and paste).
  - All new and updated declarations must be included in a single document.

A. Assistance with Providing the Feedback		
2. Did you receive help from outside your clinician group to complete this submission?	No	☒
	Yes	☐
If yes, please detail the help and who provided it.		
3. Did you receive help from outside your clinician group to collect or analyze any information used in this submission?	No	☒
	Yes	☐
If yes, please detail the help and who provided it.		

B. Previously Disclosed Conflict of Interest		
4. Were conflict of interest declarations provided in clinician group input that was submitted at the outset of the CADTH review and have those declarations remained unchanged? If no, please complete section C below.	No	☐
	Yes	☒
If yes, please list the clinicians who contributed input and whose declarations have not changed: • Rachel Asiniwasis MD		

C. New or Updated Conflict of Interest Declarations

New or Updated Declaration for Clinician 1	
Name	*Saskatchewan Dermatology Association*
Position	*Group Submission*
Date	*22-JUL-2024*
☒	**I hereby certify** that I have the authority to disclose all relevant information with respect to any matter involving this clinician or clinician group with a company, organization, or entity that may place this clinician or clinician group in a real, potential, or perceived conflict of interest situation.
Conflict of Interest Declaration	
List any companies or organizations that have provided your group with financial payment over the past two years AND who may have direct or indirect interest in the drug under review.	

Company	Check Appropriate Dollar Range			
	$0 to 5,000	$5,001 to 10,000	$10,001 to 50,000	In Excess of $50,000
Eli Lilly Canada	☒	☐	☐	☐
Add company name	☐	☐	☐	☐
Add or remove rows as required	☐	☐	☐	☐

New or Updated Declaration for Clinician 1	
Name	*Rachel Asiniwasis MD MSHS FRCPC FAAD*
Position	*Dermatologist See CDA Declaration from original submission*
Date	*22-JUL-2024*
☒	**I hereby certify** that I have the authority to disclose all relevant information with respect to any matter involving this clinician or clinician group with a company, organization, or entity that may place this clinician or clinician group in a real, potential, or perceived conflict of interest situation.

New or Updated Declaration for Clinician 1	
Name	*Kyle Cullingham MD*
Position	*Saskatchewan Dermatology Association*
Date	*22-JUL-2024*
☒	**I hereby certify** that I have the authority to disclose all relevant information with respect to any matter involving this clinician or clinician group with a company, organization, or entity that may place this clinician or clinician group in a real, potential, or perceived conflict of interest situation.

Conflict of Interest Declaration

List any companies or organizations that have provided your group with financial payment over the past two years AND who may have direct or indirect interest in the drug under review.

Company	Check Appropriate Dollar Range			
	$0 to 5,000	$5,001 to 10,000	$10,001 to 50,000	In Excess of $50,000
N/A	☐	☐	☐	☐
Add company name	☐	☐	☐	☐
Add or remove rows as required	☐	☐	☐	☐

New or Updated Declaration for Clinician 1	
Name	*Kirsten Walker MD*
Position	*Saskatchewan Dermatology Association*
Date	*22-JUL-2024*
☒	**I hereby certify** that I have the authority to disclose all relevant information with respect to any matter involving this clinician or clinician group with a company, organization, or entity that may place this clinician or clinician group in a real, potential, or perceived conflict of interest situation.

Conflict of Interest Declaration

List any companies or organizations that have provided your group with financial payment over the past two years AND who may have direct or indirect interest in the drug under review.

Company	Check Appropriate Dollar Range			
	$0 to 5,000	$5,001 to 10,000	$10,001 to 50,000	In Excess of $50,000
N/A	☐	☐	☐	☐
Add company name	☐	☐	☐	☐
Add or remove rows as required	☐	☐	☐	☐

New or Updated Declaration for Clinician 1	
Name	*Saskatchewan Dermatology Association*
Position	*Group Submission*
Date	*22-JUL-2024*
☒	**I hereby certify** that I have the authority to disclose all relevant information with respect to any matter involving this clinician or clinician group with a company, organization, or entity that may place this clinician or clinician group in a real, potential, or perceived conflict of interest situation.

Conflict of Interest Declaration

List any companies or organizations that have provided your group with financial payment over the past two years AND who may have direct or indirect interest in the drug under review.

Company	Check Appropriate Dollar Range			
	$0 to 5,000	$5,001 to 10,000	$10,001 to 50,000	In Excess of $50,000
Eli Lilly Canada	☒	☐	☐	☐
Add company name	☐	☐	☐	☐
Add or remove rows as required	☐	☐	☐	☐

CADTH Reimbursement Review

Feedback on Draft Recommendation

Stakeholder information	
CADTH project number	SR0819
Name of the drug and Indication(s)	Lebrikizumab (Ebglyss) for the treatment of moderate-to-severe atopic dermatitis in adults and adolescents 12 years of age and older with a body weight of at least 40 kg, whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable. Lebrikizumab can be used with or without topical corticosteroids.
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. Clarification is required to better explain the rationale for the negative recommendation given that: 1) statistically significant and clinically relevant benefits are documented for lebrikizumab vs. placebo; and 2) there appears to be no robust evidence to show the drug does not demonstrate comparable clinical benefit relative to one or more appropriate comparators.
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.

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.