CADTH

CADTH REIMBURSEMENT REVIEW

Stakeholder Feedback on Draft Recommendation

baricitinib (Olumiant)

(Eli Lilly Canada Inc.)

Indication: For the treatment of adult patients with severe alopecia areata.

August 29, 2024

CADTH Reimbursement Review
Feedback on Draft Recommendation

Stakeholder information	
CADTH project number	SR-0843-000
Brand name (generic)	Olumiant
Indication(s)	Severe Alopecia Areata
Organization	Canadian Alopecia Areata Foundation (CANAAF)
Contact information[a]	Name: Carolynne Harrison

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.

Table 1, reimbursement condition 1, 1.1 SALT score of 50% (also discussed in Table 2: consideration for initial of therapy, Q2):

- SALT score of 50% of SCALP hair loss – It is felt that **all** hair loss on the head including eyelashes, eyebrows and beard should be considered in the 50% scalp hair loss as a 50% "head" hair loss instead.
- Individuals with 40-45% scalp hair loss can present with complete or partial eyelash/eyebrow and beard hair loss. Current treatments may not be indicated in the treatment/targeting of this aspect of hair loss. More efficient for these patients to use a systemic drug to treat all scalp and facial hair loss than targeting only scalp hair loss and not other facial hair loss. Loss of eyelashes, eyebrows and beard hair also have a large impact (physiologic, financial and social). The Impact of eyebrow/eyelash/beard hair loss: protective from dust, pollen etc, anxiety, negative impact on self-image, harder to "hide", eyebrows are used as an important tool for communication and emotional expression.
- Expensive to cover up or "hide": microblading, eyebrow makeup (eyebrow loss), glue, eyeliner, false eyelashes (eyelash loss), keratin fibre powder (beard loss)
- Currently no standard treatment for eyelash and eyebrow loss and very limited off-label treatments (bimatoprost, tofacitinib)[1] whereas Baricitinib showed a meaningful increase in eyebrow and eyelash hair regrowth.
- Propose: Including Brigham Eyebrow Tool for Alopecia (BETA)[2] and Brigham Eyelash Tool for Alopecia (BELA)[3] score as a tool to measure "head" hair loss as well.

Table 1, Reimbursement condition 1, 1.2 duration of alopecia

- The time a patient has had alopecia before undergoing this treatment should be broader and up to the clinical judgment of the prescribing physician. Clinical trials are always very limiting but should not be considered ineffective for patients who have had alopecia for more than 8 years. Up until now, there have been no effective treatment options. Many patients have been hopefully waiting for many years for an answer.

1. Nguyen, B., Hu, J. K. & Tosti, A. Eyebrow and Eyelash Alopecia: A Clinical Review. *Am. J. Clin. Dermatol.* **24**, 55–67 (2023).

2. Tkachenko, E. *et al.* Brigham Eyebrow Tool for Alopecia: A Reliable Assessment of Eyebrow Alopecia Areata. *J. Investig. Dermatol. Symp. Proc.* **20**, S41–S44 (2020).

3. Manjaly, P. *et al.* Development and validation of the Brigham Eyelash Tool for Alopecia (BELA): A measure of eyelash alopecia areata. *J. Am. Acad. Dermatol.* **85**, 271–272 (2021).

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?		
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	*Carolynne Harrison*
Position	*President*
Date	*27-08-2024*
☒	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

CADTH Reimbursement Review
Feedback on Draft Recommendation

Stakeholder information	
CADTH project number	SR0843-000 Stakeholder Feedback on Draft Recommendation
Brand name (generic)	Olumiant (baricitinib)
Indication(s)	Alopecia areata
Organization	Atlantic Dermatology Expert group
Contact information[a]	Name: Irina Turchin

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

The Atlantic Dermatology Expert Group agrees and supports CDEC recommendations. Alopecia areata is an autoimmune form of hair loss and has severe impact on quality of life when moderate to severe. Based on available evidence from the ~~3~~2 clinical trials, BRAVE-AA1 and BRAVE-AA2 and lack of effective and safe alternative treatment options this expert group would recommend baricitinib as a first line systemic therapy for patients with severe alopecia areata. This is supported by the recent European expert consensus statement on the systemic treatment of alopecia areata.

This expert group supports reimbursement of baricitinib in adult patients with severe alopecia areata defined as SALT score of 50 or above. Clinical trial data supports reimbursement of baricitinib for patients with duration of the current episode of more than 6 months and less than 8 years.

The Atlantic Dermatology Expert group would also recommend to consider involvement of eyebrows and eyelashes as a special site due to the functional limitations (lack of eye protection from wind, dust) and severe impact on quality of life. In addition, there are no effective and safe treatment options to treat alopecia areata of the eyebrows and eyelashes. Baricitinib should be considered for patients with mild or moderate alopecia area (SALT up to 49) and noticeable involvement of eyebrows and eyelashes and DLQI of more than or equal to 10.

The Atlantic Dermatology Expert group supports review of initial treatment response at 36 weeks. SALT score of 20 or less at 36 weeks is defined as clinical response based on BRAVE-AA1 and BRAVE-AA2 data. However, based on the analyses from the BRAVE-AA1 and BRAVE-AA2, there is a subset of patients with severe disease who are gradual responders (28%) and late responders (8%) who may benefit from treatment for up to 52 weeks. This is also supported by the further increase in various endpoints from week 36 to week 52 seen in phase 3 clinical trials, including SALT 20 or less and eyebrow and eyelashes responses.

Therefore, this groups recommends to consider continuing treatment for patients with baseline severe disease for up to 52 weeks if SALT 20 or less was not achieved at week 36, with patient agreement and if there are no safety or tolerability concerns. In this scenario, the first clinical assessment would be done at 36 weeks and a follow up assessment should be done at week 52 to re-evaluate response to therapy.

The Atlantic Dermatology Expert Group supports the condition to re-evaluate the clinical response every 12 months.

Maintenance of SALT 20 response or less is appropriate clinical endpoint to maintain therapy. We agree that baricitinib should be prescribed by dermatologists with expertise in diagnosis and management of alopecia areata. It is not recommended to combine baricitinib with other systemic JAK inhibitors, biologic immunomodulators or systemic immunosuppressants.

The Atlantic Dermatology Expert group supports price review and reduction to allow for baricitinib reimbursement by the public and private payers.

References:

King B, Ohyama M, Kwon O, et al. Two Phase 3 Trials of Baricitinib for Alopecia Areata. N Engl J Med. 2022;386(18):1687-1699.

Rudnicka L, Arenbergerova M, Grimalt R, et al. European expert consensus statement on the systemic treatment of alopecia areata. J Eur Acad Dermatol Venereol. 2024;38:687-694.

King B, Shapiro J, Ohyama M, et al. When to expect scalp hair regrowth during treatment of severe alopecia areata with baricitinib: insights from trajectories analyses of patients enrolled in two phase III trials. *Br J Clin Dermatol*. 2023;189:666-673.

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

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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		
1. Did you receive help from outside your clinician group to complete this submission?	No	☒
	Yes	☐
2. Did you receive help from outside your clinician group to collect or analyze any information used in this submission?	No	☒
	Yes	☐
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	☐
• Not applicable		

C. New or Updated Conflict of Interest Declarations

New or Updated Declaration for Clinician 1	
Name	*Irina Turchin*
Position	*Dermatologist, Fredericton, NB*
Date	*28-08-2024*
☒	**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**

Abbvie	☐	☐	☐	☒
Eli Lilly	☐	☐	☒	☐
Pfizer	☒	☐	☐	☐

New or Updated Declaration for Clinician 2	
Name	*Kerri Purdy*
Position	*Dermatologist, Halifax, NS*
Date	*28-08-2024*
☒	**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**
Abbvie	☐	☒	☐	☐
Eli Lilly	☐	☐	☒	☐
Pfizer	☐	☒	☐	☐

New or Updated Declaration for Clinician 3	
Name	*Tracey Brown-Maher*
Position	*Dermatologist, St. Johns, NFLD*
Date	*28-08-2024*
☒	**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

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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	☐	☐	☒	☐
Pfizer	☐	☐	☒	☐
Eli Lilly	☐	☐	☒	☐

CADTH Reimbursement Review
Feedback on Draft Recommendation

Stakeholder information	
CADTH project number	SR0843-000
Brand name (generic)	Olumiant (Baricitinib)
Indication(s)	Alopecia Areata
Organization	Eastern Ontario Dermatology Group
Contact information[a]	Name: Cathryn Sibbald

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.

Alopecia Areata is an uncommon condition that is associated with significant psychosocial morbidity. Baricitinib has excellent quality evidence for efficacy in treating this condition and leading to regrowth in affected patients. There are no similarly effective medications at the moment that are reimbursed for patients.

We agree with the recommendation to reimburse, but strongly feel that the reimbursement criteria for initiation and renewal should be modified as follows:

We believe that the criteria for eligibility should not be restricted to a SALT score of 50% or greater, but rather a diagnosis of moderate to severe AA based on the AA scale (a newly developed clinician-reported measure designed for use in clinical practice, based on expert consensus from 22 clinicians). Criteria for upgrading of a moderate SALT (30-50%) to severe include rapid loss (a positive pull test), involvement of eyebrows or eyelashes, negative impact on psychosocial functioning, and inadequate response after 6 months of alternate treatments).
King BA, et al. J Am Acad Dermatol. 2022;86(2):359-364. Reprinted from J Am Acad Dermatol, 86/2, King BA, et al. Development of the alopecia areata scale for clinical use: results of an academic-industry collaborative effort, 359-364, Copyright 2022, with permission from Elsevier

Psychosocial functioning:
Having worked closely with patients for over 5 years (Dr Sibbald has a specialized AA clinic and has assessed and managed over 100 patients with AA), the impact on psychosocial functioning she has seen is devastating. Anxiety, depression and bullying are very prevalent in this population. Studies have confirmed almost a 6 fold increase in suicide attempts in affected patients. A significant proportion of patients have lost school and work productivity, and require mental health resources that they often cannot access. Effective treatment to regrow hair can have significant benefits for mental health and psychosocial functioning, which extends to family units and work communities.
Wang LH, Ma SH, Tai YH, Dai YX, Chang YT, Chen TJ, Chen MH. Increased Risk of Suicide Attempt in Patients with Alopecia Areata: A Nationwide Population-Based Cohort Study. Dermatology. 2023;239(5):712-719. doi: 10.1159/000530076. Epub 2023 Mar 15. PMID: 36921592.

Eyebrow and eyelash loss
In the clinical trials, baricitinib had clear efficacy in treating eyebrow and eyelash loss. Despite the committee's evaluation of low certainty of the strength of this evidence, there was a clear statistically significant increase in hair growth for both eyelashes and eyebrows with the use of baricitinib. There

are no other medications approved for eyebrow and eyelash loss in alopecia areata, and these are areas that are exceptionally difficult for patients to camouflage, as tattoos and prosthetics are often unnatural and fiscally prohibitive.		
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? **Not applicable as we did not provide input in the initial submission.**		
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 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	*Cathryn Sibbald*
Position	*Dermatologist*
Date	*23-AUG-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**
Pfizer	☐	☒	☐	☐
Sanofi	☒	☐	☐	☐
Incyte	☐	☒	☐	☐

New or Updated Declaration for Clinician 2	
Name	*Yuka Asai*
Position	*Dermatologist*
Date	*2024 Aug 29*
☒	**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**
Pfizer	☒	☐	☐	☐
Lilly	☒	☐	☐	☐
Sanofi	☒	☐	☐	☐
Abbvie	☒			
Incyte	☒			
Amgen	☒			
Janssen	☒			

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

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

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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

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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	SR0843
Brand name (generic)	Olumiant (Baricitinib)
Indication(s)	Treatment of Adult Patients with Severe Alopecia Areata
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 agrees with the committee's recommendation.
In clinical practice, it is well known among physicians that patients with severe forms of alopecia areata (AA) are often of the most psychosocially impacted, and are the among the most proactively treatment seeking and compliant with treatment plans. This information globally indicates, as also supported by literature, that the disease is incredibly impactful, off-label therapies have not traditionally worked, and need for novel and efficacious treatment is meaningful for them. Patients often struggle with stigmatization, abnormal appearance from the disease. The disease itself is can be physically symptomatic; patients will represent with inflammation and symptoms such as chronic pruritus when the disease is active.

Further considerations include there are no first-line systemic treatment for severe AA which indicates an unmet need. There are no approved options. High rates of failure and frustration are seen with severe AA in clinical practice, with topicals proving almost useless, and intralesional steroid injections are greatly limited by effectiveness, the need for often monthly standing injection appointments with dermatology, and the fact that severe forms cannot be fully treated with intralesional steroids due to the wide surface area of involvement. Additionally, treatment of eyebrows and eyelashes are challenging and often fail topical therapies.

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	☐

Although SDA did not submit stakeholder input on the original CADTH submission, it is good to see that patient needs were directly acknowledged and integrated in the summary of recommendations.

Clarity of the draft recommendation

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

Yes. Conditions laid out for baricitinib include adults with severe AA who meet criteria including SALT score of 50 or above, duration of the current AA episode of more than 6 months and less than 8 years. The recommendation report also comments on statistically significant and clinically meaningful scalp, eyebrow and eyelash hair regrowth compared to placebo at 36 weeks in patients with a minimum of 50% scalp involvement (eg. severe disease) as demonstrated by the BRAVE-AA1 and -AA2 trials. Patient unmet needs were also considered and explained directly in the rationale for recommendation. Reimbursement conditions include

providing beneficial proof of clinical effect as defined as a SALT score of 20 or less at ~~37~~ 36 weeks and every 12 months with maintenance required which we believe is appropriate. Some clinical considerations are elaborated on below.

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

Yes. Conditions laid out for baricitinib include adults with severe AA who meet criteria including SALT score of 50 or above, duration of the current AA episode of more than 6 months and less than 8 years, with response to treatment reassessed at 36 weeks as demonstrated in the pivotal trials. Although some patients may require longer to respond given the nature and course of the disease (eg. hair growth response may take longer), 36 weeks is a reasonable first reassessment time. For those who take longer to respond and have a partial but clinically meaningful response at a later date (eg. 52 weeks), we would recommend to allow for longer time beyond 36 weeks for reassessment and reimbursement.
Although those greater than 60-70 years were not well represented, from a clinician's standpoint it is reasonable to determine eligibility based on clinical judgement.

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

Something CADTH to consider is to expand criteria to 'real life' situations – there are patients that have had this for longer than 8 years and are likely the most psychosocially impacted. Although 8 years may have been specified in the trials, consider expanding this to a duration that long term and impactful on the patient. This can be determined through a clinical exam and global assessment. With regards to safety and benefit, from our understanding several years of safety data is present for baricitinib across other disease states, including atopic dermatitis and rheumatoid arthritis.

Thank you for considering our clinician input! We believe that this targeted and studied medication for severe AA will allow for new hope for our patients suffering from this condition.

Saskatchewan Dermatology Association

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- 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		
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	☐
•		

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	*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*
Position	*Dermatologist*
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	☐	☒ Advisory boards – Alopecia areata	☐	☐
Add company name	☐	☐	☐	☐
Add or remove rows as required	☐	☐	☐	☐

New or Updated Declaration for Clinician 1	
Name	*Kyle Cullingham MD*
Position	*Dermatologist*
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	*Brittany Waller MD*
Position	*Dermatologist*
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	
Position	
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	SR0843
Name of the drug and Indication(s)	baricitinib (Olumiant) For the treatment of adult patients with severe alopecia areata
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. Editorial reframe of language to focus on reimbursement criteria instead of clinical use recommendations
b) Reimbursement conditions and related reasons
Please provide details regarding the information that requires clarification.
c) Implementation guidance

CADTH

CADTH Reimbursement Review
Feedback on Draft Recommendation

Stakeholder information	
CADTH project number	SR0843-000
Brand name (generic)	OLUMIANT® (baricitinib)
Indication(s)	For the treatment of adult patients with severe alopecia areata.
Organization	Eli Lilly Canada Inc.
Contact information[a]	[redacted]

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

Lilly is overall aligned with the draft recommendation and agrees that baricitinib should be a first-line systemic treatment option for severe alopecia areata given its demonstrated efficacy and safety endpoints in clinical trials and aligned with clinical practice.

Lilly agrees that treatment with baricitinib should generally be for patients with SALT scores of 50 or above, given that the BRAVE-AA1 and BRAVE-AA2 trials studied patients who met this criterion. However, there are underappreciated efficacy of Olumiant specific to eyelash (EL) or eyebrow (EB) hair loss. As the Product Monograph's Recommended Dose and Dosage Adjustment section states: *"For patients with nearly complete or complete scalp hair loss, **and/or** substantial eyelash or eyebrow hair loss, consider starting with 4 mg once daily."* This highlights the importance of EB / EL involvement to the presentation of severe AA[1], and that there are patients who may meet the eyelash (EL) or eyebrow (EB) hair loss criterion (with or without scalp hair loss) that would benefit from treatment with baricitinib[2]. EL or EB hair is critical for patients as its presence or absence impacts visual identification, as well as patients' quality of life and mental health[1]. It should be noted that baricitinib treatment should be considered in patients with EL or EB hair loss *without* SALT scores of 50 or above as well those who meet the SALT score requirement, given baricitinib's demonstrated efficacy in improving EL or EB hair growth in clinical trials.

Also Lilly maintains its position related to two points on CDA reanalysis of pharmacoeconomic analysis:

1. *"adopting SALT30 as the primary response outcome" -page 27*
   Response: There are 3 levels of response thresholds: $SALT_{30}$, $SALT_{50}$ and $SALT_{75}$. These relative improvements from baseline SALT score were used as the definition of response in the CEM rather than the absolute SALT score such as SALT≤20 for several reasons. Firstly, the use of an improvement from baseline response measure is aligned with modelling precedents in other dermatology indications, including atopic dermatitis. In addition, the $SALT_{75}$ response is used in the model when $SALT_{50}$ (the base case analysis) is selected in order to obtain a more granular calculation of the total QALYs. The $SALT_{75}$ response is relatively aligned with the SALT≤20 endpoint from the BRAVE-AA trials. This is demonstrated in Table 5 below, which shows the greatest absolute SALT score (i.e., the poorest hair regrowth) that would be achieved after a $SALT_{50}$ and $SALT_{75}$ response (improvement in SALT

score of 50% and 75%, respectively), based on the mean baseline SALT scores from the BRAVE-AA1 and BRAVE-AA2 trials.
It would therefore be expected that the use of SALT≤20 in the CEM would be relatively aligned with the scenario analyses, where $SALT_{75}$ is used as the definition of response in the model. It would further be expected that the use of SALT≤20 in the model would be associated with similar challenges to the $SALT_{75}$ response, which Lilly considered to result in this definition of response being overly restrictive and failing to adequately capture sufficient clinical benefit to justify continuing treatment after the trial induction period than using $SALT_{50}$. $SALT_{30}$ on the other end would deviate much further from the clinical trial population and the primary endpoint, without basis for continued treatment for an extended period of time for non-responder patients. Hence, the use of $SALT_{50}$ is considered the most appropriate definition of response outcome.

2. *"assuming equal costs associated with drug acquisition, drug monitoring, and disease management for the 'BSC' health state regardless of initial treatment (baricitinib or no active treatment)" -page 27*
Response: Lilly maintains its position that patients who have lost response after treatment with baricitinib, would be less likely to engage with BSC compared with those receiving 'no active treatment'. Thus, there should not be equal costs associated with drug acquisition, drug monitoring, and disease management for the 'BSC' health state regardless of initial treatment (baricitinib or no active treatment) as in the CDA reanalysis.
A patient who received 'no active treatment' would be more willing to experiment with off-label treatments after failing to respond compared to someone who received baricitinib (a licensed treatment with proven efficacy and a tolerable safety profile). Patients who received 'no active treatment' are more likely to remain hopeful about an off-label, low efficacy treatment if their prior options were similar or less effective.
Using the same rationale, patients who received baricitinib would likely be less hopeful for success with BSC, given that the most effective and tolerable option had already failed. Prescribing dermatologists would similarly become less willing and/or confident in prescribing these poorly tolerated and low efficacy treatments if the best available option (baricitinib) had failed. This concept is captured in the analysis by assuming that the introduction of baricitinib would reduce BSC use compared to current treatment practices (as modelled in the comparator arm) if a patient were to fail to respond to baricitinib.

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?		

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.

Reference:

1. Starace M, Cedirian S, Alessandrini AM, et al. Impact and Management of Loss of Eyebrows and Eyelashes. Dermatol Ther (Heidelb). 2023;13(6):1243-1253.
2. King BA, Mesinkovska NA, Craiglow B, et al. Development of the alopecia areata scale for clinical use: Results of an academic-industry collaborative effort. J Am Acad Dermatol. 2022;86(2):359-364.