CADTH

CADTH REIMBURSEMENT REVIEW

Stakeholder Feedback on Draft Recommendation

Bimekizumab (Bimzelx)

(UBC Canada Inc.)

Indication: Psoriasis, moderate to severe plaque

March 17, 2022

CADTH

CADTH Reimbursement Review

Feedback on Draft Recommendation

Stakeholder information	
CADTH project number	SR0698
Name of the drug and Indication(s)	Bimzelx (bimekizumab) for the treatment of moderate to severe plaque psoriasis in adult patients who are candidates for systemic therapy or phototherapy
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	☐
	No requested revisions	X

2. Change in recommendation category or conditions Complete this section if major or minor revisions are requested
Please identify the specific text from the recommendation and provide a rationale for requesting a change in recommendation.

3. Clarity of the recommendation Complete this section if editorial revisions are requested for the following elements
a) Recommendation rationale
Please provide details regarding the information that requires clarification.
b) Reimbursement conditions and related reasons
Please provide details regarding the information that requires clarification.
c) Implementation guidance
Please provide high-level details regarding the information that requires clarification. You can provide specific comments in the draft recommendation found in the next section. Additional implementation questions can be raised here.

Outstanding Implementation Issues

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

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

CADTH Reimbursement Review
Feedback on Draft Recommendation

Stakeholder information	
CADTH project number	SR0698-000
Brand name (generic)	Bimekizumab
Indication(s)	Psoriasis, moderate to severe plaque
Organization	Canadian Psoriasis Network (CPN) and Canadian Association of Psoriasis Patients (CAPP)
Contact information[a]	Name: Antonella Scali and Rachael Manion

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.

We agree with the recommendation that bimekizumab be reimbursed for the treatment of moderate to severe plaque psoriasis in adult patients who are candidates for systemic therapy or phototherapy. Our priority is for safe, efficacious treatments to be available to all psoriasis patients in Canada. This new treatment option is an important addition to the psoriasis treatment toolkit as it is expected that plaque psoriasis treatments will stop working for a given patient over time as their immune system adapts to the treatment.

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?

While the summary of the patient input is informative, it is short, demonstrating the challenge of distilling responses from 95 individuals into an 11-page patient input submission, into a summary for CDEC, and then into a final recommendation. Neither CPN nor CAPP received an opportunity to review or comment on the summary of the organizations' feedback through this HTA process as was expected. For this reason, we were not able to raise these concerns earlier in the process.

Though the broad strokes of experiences appear to be captured, important nuances were not, including patients' needs to change medications several times over the course of their condition; the pain and distress experienced by some respondents; and the feelings expressed when one finds a treatment that works after a long period of time struggling with the impacts of psoriatic disease. While there are many different treatments available to patients in Canada, it is essential that committee members understand that the existing treatment options do not work for all patients and that there remain unmet needs in this community. For these reasons we suggest that CADTH adapt its process to accept submissions from individual patients so that there is less of a filtering of information to the final 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. The implementation issues and responses are the same as other interleukin inhibitors and other biologics. The implementation issues do not reflect the considerations for initiating therapies as a result of differing biosimilar policies across Canada. These policies – in particular, tiering of biologics / biosimilars in place in Alberta and Manitoba – can impact initiation of this new therapy to the detriment of patients in these jurisdictions.		
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	*Antonella Scali (CPN) and Rachael Manion (CAPP)*
Position	*Executive Director*
Date	*16-03-2022*
☒	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	SR0698-000
Brand name (generic)	Bimzelx (bimekizumab)
Indication(s)	For the treatment of moderate to severe plaque psoriasis (PsO) in adult patients who are candidates for systemic therapy or phototherapy
Organization	UCB Canada Inc.
Contact information[a]	[redacted]

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

UCB Canada Inc. (UCB) agrees with the committee's draft recommendation of BIMZELX (bimekizumab) for the treatment of moderate to severe plaque psoriasis in adult patients who are candidates for systemic therapy or phototherapy.

Clinical Feedback

UCB agrees with the clinical expert consulted for the review that "there remains an unmet need for highly effective and safe treatments that are accessible and easy to use" (*Stakeholder Perspectives*, page 7). UCB further agrees with the clinical expert's feedback that "clinicians expect that patients will achieve a higher threshold of improvement [than PASI 75] with newer biologics" (*Stakeholder Perspectives*, page 7).

UCB agrees with CDEC's conclusion that "bimekizumab addresses some of the priority needs identified by patients, in particular providing clearance of plaques" (*Rationale for the Recommendation*, page 3). As a highly effective treatment that provides superior efficacy vs. other biologics in achieving higher thresholds of improvement (PASI 90 and PASI 100), bimekizumab addresses the unmet need identified by the clinical expert and patient organizations that contributed to the review. In Phase 3 clinical trials, bimekizumab demonstrated superiority in achieving PASI 90 and PASI 100 vs. secukinumab[1], another IL-17, in addition to ustekinumab[2], adalimumab[3], and placebo[4] at week 16. Bimekizumab also demonstrated superior long-term efficacy over secukinumab based on the PASI 100 response rate at week 48 of randomized treatment.[1] The indirect treatment comparison (ITC) submitted to CADTH also suggested that bimekizumab had the highest probability of achieving PASI 90 and PASI 100 response in the initial treatment period vs. available biologics/biosimilars, recognizing that ITCs are associated with uncertainty, as CDEC noted in the recommendation (*Rationale for the Recommendation*, page 3). Moreover, bimekizumab was well-tolerated and had a good long-term safety profile with no new safety signals identified over two years of treatment.[1–5]

Economic Feedback

UCB wishes to clarify that the assumption in the economic and budget impact analyses that 8.5% of patients would receive bimekizumab every 4 weeks instead of every 8 weeks in the maintenance phase is likely an overestimate (*Discussion Points,* page 6). The assumption of 8.5% was based on the proportion of patients in the clinicals trials of bimekizumab that weighed over 120 kg, regardless of whether they achieved complete skin clearance. The dosing in the product monograph approved by Health Canada stipulates that maintenance dosing every 4 weeks may be considered for patients with a body weight ≥ 120 kg and who did not achieve a complete skin response. Therefore, in clinical practice, a smaller proportion than 8.5% of patients would be expected to weigh over 120 kg and fail to achieve complete skin clearance at week 16.

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	☐

UCB agrees with the rationale for the recommendation: that treatment with bimekizumab was associated with statistically significant and clinically meaningful improvements in skin clearance vs. placebo, ustekinumab, adalimumab, and secukinumab, and in doing so addresses the unmet need identified by patients and the clinical expert for complete skin clearance (*Rationale for the Recommendation*, page 3).

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

UCB acknowledges the implementation consideration identified by CADTH in Table 2 of the recommendation relating to more frequent maintenance dosing required in some patients (*Table 2. Implementation Guidance from CDEC,* page 5). Per the final product monograph approved by Health Canada, maintenance dosing every 4 weeks may be considered for patients with a body weight ≥ 120 kg and who did not achieve a complete skin response.[6] While the cost of treatment during the maintenance period would increase for these patients, it is not expected that a significant proportion of patients (i.e., < 8.5%) would require more frequent dosing.

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 reasons provided in Table 1 are clearly stated.

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

References

1. Reich K, Warren RB, Lebwohl M, et al. Bimekizumab versus Secukinumab in Plaque Psoriasis. *N Engl J Med*. Published online April 23, 2021:Epub ahead of print. doi:10.1056/NEJMoa2102383

2. Reich K, Papp KA, Blauvelt A, et al. Bimekizumab versus ustekinumab for the treatment of moderate to severe plaque psoriasis (BE VIVID): efficacy and safety from a 52-week, multicentre, double-blind, active comparator and placebo controlled phase 3 trial. *Lancet*. 2021;397(10273):487-498. doi:10.1016/S0140-6736(21)00125-2

3. Warren RB, Blauvelt A, Bagel J, et al. Bimekizumab versus Adalimumab in Plaque Psoriasis. *N Engl J Med*. Published online April 23, 2021:Epub ahead of print. doi:10.1056/NEJMoa2102388

4. Gordon KB, Foley P, Krueger JG, et al. Bimekizumab efficacy and safety in moderate to severe plaque psoriasis (BE READY): a multicentre, double-blind, placebo-controlled, randomised withdrawal phase 3 trial. *Lancet*. 2021;397(10273):475-486. doi:10.1016/S0140-6736(21)00126-4

5. Strober B, Asahina A, Mrowietz U, et al. Bimekizumab response maintenance through two years of treatment in patients with moderate to severe plaque psoriasis who responded after 16 weeks: Interim results from the BE BRIGHT open-label extension trial. In: *American Academy of Dermatology Frontiers in Research, Science, and Technology (FiRST)*. ; 2021.

6. Health Canada. Bimzelx (bimekizumab) Product Monograph. Published online February 14, 2022. Accessed February 17, 2022. https://pdf.hres.ca/dpd_pm/00064702.PDF