CADTH

CADTH REIMBURSEMENT REVIEW

Stakeholder Feedback on Draft Recommendation

BELIMUMAB (BENLYSTA)

(GlaxoSmithKline Inc.)

Indication: In addition to standard therapy for treatment of active lupus nephritis in adult patients.

January 06, 2023

CADTH

CADTH Reimbursement Review

Feedback on Draft Recommendation

Stakeholder information	
CADTH project number	SR0746-000
Brand name (generic)	Benlysta (Belimumab)
Indication(s)	Lupus nephritis
Organization	Canadian Network for Improved Outcomes in SLE
Contact information[a]	Name: Dr. Konstantinos Tselios

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.		

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	☒

1. In Paragraph 3 of the Initiation, it is recommended that patients who previously failed both cyclophosphamide and mycophenolate mofetil should not be reimbursed for belimumab. Although such patients were excluded from the BLISS-LN trial, it is exactly these patients that have very limited therapeutic options and will likely develop end-stage kidney disease. Belimumab in combination with cyclophosphamide or mycophenolate mofetil may provide benefit. We request that this paragraph will be reconsidered and mention (exclude) only patients with advanced chronic kidney disease (eGFR < 30 mL/min/1.73m^2).
2. In Paragraph 5.1 of the Renewal, it is recommended that reimbursement will only continue if the patients achieve a reduction of the daily dose of oral glucocorticoids to ≤7.5mg of prednisone or equivalent. Given that the patients with lupus nephritis usually start with high doses of glucocorticoids (50-60mg/day of prednisone) and the rate of tapering varies depending on the response, we request that this target should be required for reimbursement at the timepoint of 18 months.

[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		
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:

1. **Dr. Konstantinos Tselios**
2. **Dr. Robert Ting**
3. **Dr. Janet Pope**
4. **Dr. Alexandra Legge**
5. **Dr. William Fung**
6. **Dr. Andrew House**
7. **Dr. Dafna D. Gladman**
8. **Dr. Navdeep Tangri**
9. **Dr. Justin Shamis**
10. **Dr. Murray B. Urowitz**
11. **Dr. Sahil Koppikar**
12. **Dr. Amanda Steiman**
13. **Dr. Thomas Appleton**
14. **Dr. Sylvie Ouellette**
15. **Dre Josiane Bourré-Tessier**
16. **Dr. Catherine Ivory**
17. **Dr. Maqbool Sheriff**
18. **Dr. Christine Peschken**
19. **Dr. Sean Barbour**

20. **Dr. Stephanie Keeling**
21. **Dr. Hugues Allard-Chamard**
22. **Dr. Michele Tupchong**
23. **Dr. Shelly Dunne**
24. **Dr. Ceri Anne Richards**
25. **Dr. Juris Lazovskis**
26. **Dr. Megan R.W. Barber**
27. **Dr. Laura Ellen Berall**
28. **Dr. Derek Haaland**
29. **Dr. Louise Moist**
30. **Dr. Hector Arbillaga**
31. **Nathalie Rozebojm, RN**

CADTH Reimbursement Review
Feedback on Draft Recommendation

Stakeholder information	
CADTH project number	
Brand name (generic)	Belimumab
Indication(s)	For the treatment of adult patients with active, autoantibody-positive, systemic lupus erythematosus (SLE) who are receiving standard therapy
Organization	The Toronto Lupus Program, The University of Toronto
Contact information[a]	Dr. Zahi Touma

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 stakeholders recommendation and offer further explanation of our recommendations in the attached letter.		
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. We have made some further clarifications		
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. Yes, they have been clearly articulated but we have suggested some further editing to make it straight forward.		
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

- 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: • Dr. Zahi Touma – see below • Dr. Dafna Gladman – see below • Dr. Joan Wither – see below • Dr. Jorge Sanchez-Guerrero – nothing to disclose		

C. New or Updated Conflict of Interest Declarations

New or Updated Declaration for Clinician 1	
Name	*Dr. Zahi Touma*
Position	*Director, Toronto Lupus Program at UHN* *Associate Professor of Medicine, University of Toronto Institute of Health Policy, Management and Evaluation Institute of Medical Sciences,* *Adjunct Scientist, Institute for Work and Health* *Clinician-Scientist, Rheumatology, University Health Network* *Scientist, Schroeder Arthritis Institute, Krembil Research Institute*

Date	*05-01-2023*
☒	**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	☐	☒	☐	☐
AstraZeneca	☐	☒	☐	☐
UCB	☐	☒	☐	☐
BioPharma	☐	☒	☐	☐
GlaxoSmithKline	☐	☒	☐	☐
Merck	☐	☒	☐	☐
KgaA	☐	☒	☐	☐
AMPEL BioSolutions	☐	☒	☐	☐
Sarkana Pharma	☐	☒	☐	☐

New or Updated Declaration for Clinician 2

Name	*Dafna D. Gladman*
Position	*Professor of Medicine, University of Toronto Senior Scientist, Schroeder Arthritis Institute, Krembil Research Institute Deputy Director, Centre for Prognosis Studies in The Rheumatic Diseases Toronto Western Hospital*
Date	*01-05-2023*
☒	**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	☐	☒	☐	☐
Janssen	☐	☒	☐	☐
Gilead	☐	☒	☐	☐
Novartis	☐	☒	☐	☐
Pfizer	☐	☒	☐	☐

Bristol-Myers Squibb	☐	☒	☐	☐
Galapagos	☐	☒	☐	☐
UCB Pharma	☐	☒	☐	☐
Celgene	☐	☒	☐	☐

New or Updated Declaration for Clinician 3	
Name	*Joan Elizabeth Wither*
Position	*Professor Medicine and Immunology U of T, Staff Physician, University Health Network*
Date	*05-01-2023*
☒	**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**
Astra Zeneca	☒	☐	☐	☐
Pfizer	☐	☐	☐	☒

New or Updated Declaration for Clinician 4	
Name	*Dr. Jorge Sanchez-Guerrero*
Position	*Professor of Medicine, University of Toronto* *Clinician Investigator, Krembil Research Institute*
Date	*2023-01-06*
☒	**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 5

CADTH Reimbursement Review

Feedback on Draft Recommendation

Stakeholder information	
CADTH project number	SR0746
Name of the drug and Indication(s)	Belimumab (Benlysta) for of active lupus nephritis
Organization Providing Feedback	FWG

1. Recommendation revisions Please indicate if the stakeholder requires the expert review committee to reconsider or clarify its recommendation.		
Request for Reconsideration	**Major revisions:** A change in recommendation **category** or patient **population** is requested	☐
	Minor revisions: A change in reimbursement **conditions** is requested	☐
No Request for Reconsideration	**Editorial revisions:** Clarifications in recommendation **text** are requested	X
	No requested revisions	☐

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

3. Clarity of the recommendation Complete this section if editorial revisions are requested for the following elements
a) Recommendation rationale
Please provide details regarding the information that requires clarification.
b) Reimbursement conditions and related reasons

Please provide details regarding the information that requires clarification.
• Regarding initiation criteria #1, sub-bullets of the description of the classes of lupus nephritis (LN) may improve clarity. For instance:
  ○ Class III with or without class V
  ○ Class IV with or without class V
  ○ Class V (i.e., pure class V)

c) Implementation guidance

CADTH Reimbursement Review
Feedback on Draft Recommendation

Stakeholder information	
CADTH project number	SR0746-000
Brand name (generic)	belimumab (Benlysta)
Indication(s)	Lupus nephritis
Organization	Canadian Arthritis Patient Alliance, Canadian Skin Patient Alliance, Arthritis Society Canada, CreakyJoints Canada
Contact information[a]	Name: Laurie Proulx

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 are pleased with the recommendation to reimburse belimumab (Benlysta) for people with lupus nephritis. People with systemic lupus erythematosus (SLE) and lupus nephritis have not benefited from significant changes in treatments for over thirty years. They have limited treatment options, and some will benefit tremendously from the committee's recommendation.

We ask that CADTH re-consider its recommendation for belimumab (Benlysta) for people with SLE. There remains a number of unmet patient needs as described in this video by Nadine Lalonde, as she has lived with SLE for over ten years. There is the benefit of having over ten years of clinical experience with belimumab (Benlysta) that has demonstrated the value of the medication in addressing patient-important outcomes like fatigue, musculoskeletal pain, skin manifestations, and the use of prednisone consistent with the 2019 update of the EULAR recommendations for the management of systemic lupus erythematosus. You may also wish to consider the review "10 Years of belimumab experience: What have we learnt?" even if the authors are affiliated with GlaxoSmithKline which could be viewed as a conflict of interest. The article provides useful context and clinical data and cites many prominent academic publications about belimumab (Benlysta).

It would be extremely valuable to our community if CADTH used belimumab (Benlysta) as a learning opportunity in its efforts to transition to using real-world evidence for decision-making. It is critical that patient organizations and patients with lived experience of SLE be meaningfully engaged in developing and implementing real-world evidence in support of ongoing reviews of belimumab (Benlysta) and other SLE medications and treatments.

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. Upon examination of the reimbursement conditions, we ask that clinical judgement be noted as a consideration when interpreting the cut offs for proteinuria levels and eGFR. We are concerned with the criteria for renewal that requires specific proteinuria levels, eGFR, and reductions in oral corticosteroids. These criteria should provide some flexibility in application for people with SLE and clinicians who may see improvement in their health status. Shared decision-making is important which should consider personalized patient values, risks, and benefits.		

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

CADTH

CADTH Reimbursement Review
Feedback on Draft Recommendation

Stakeholder information	
CADTH project number	SR0746-000
Brand name (generic)	Belimumab (Benlysta)
Indication(s)	In addition to standard therapy for treatment of active lupus nephritis in adult patients.
Organization	Lupus Canada
Contact information[a]	Name: Leanne Mielczarek

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. The lupus community is hoping that there is an opportunity to appeal to CADTH to also consider recommending Belimumab for public funding to include ALL patients with lupus deemed as candidates by their rheumatologists to experience the immense benefit of this drug therapy.		

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	*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 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. Someone from GlaxoSmithKline provided a few academic publications about belimumab (Benlysta) based on our interest in receiving this information. We do not have access to academic libraries and this was helpful in completing this response.		
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	☐	☐	☐	☐

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	Leanne Mielczarek
Position	Executive Director
Date	06-01-2023
☒	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.

Lupus Canada spoke with several non-renal lupus patients regarding the need for a positive recommendation for reimbursement for ALL patients living with lupus.

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.

We applaud CADTH for the recent positive recommendation of Belimumab for lupus nephritis for public reimbursement. However, the impact of this drug therapy has been immense and limiting to a wide group of lupus patients as it is very costly. We appeal to CADTH to also consider a positive recommendation for non-renal patients as there are limited number of treatment options and the lack of treatment advances especially in contrast to other rheumatic diseases. There are substantial unmet needs of those living with lupus.

We received input from three (3) non-renal lupus patients, Judy, Paula and Kristina.

"*Without the Belimumab injection my fingers would not allow me to even type, the stress I had was affecting my whole family not just me, the patient. The medication has helped control the ongoing inflammation of my bones/joints. And with now much discomfort nor felt side effect so far. Before taking Benlysta, the bones in my hand, fingers, knee, and hip were all swollen and stiff which made it not possible for me to bent them to perform my daily life routine. Life was miserable and not worth living with the pain. The self auto injection has also made it very easy to administer that I am not scared of doing it at home myself. I am very thankful to be one of the lucky patients being able to get assistance with the high-cost medication which will not otherwise be possible for me to have. DEFINITELY WOULD PLEAD for the possibility of having the medication be dollar assisted to help any SLE patient like myself as lupus can affect any part of our body and not just renal or heart or……"* Judy, a non-renal lupus patient.

"I am a 55 year old female who has lupus. I have had a diagnosis of lupus since 2008 and symptoms for many years prior to this. I am an RN currently working in an out-patient cardiology/heart failure program. Previous to this position I worked in the Emergency Room and the Intensive Care Unit but unfortunately was not able to handle the long hours and night shifts due to worsening lupus symptoms.

In 2013 I developed lupus pericarditis. This was treated with a long course of prednisone, and I was unable to work due to the many debilitating side effects of associated with this drug. I was on sick leave from work for 6 months. I have continued to experience exacerbations of mild to moderate pericarditis requiring further rounds of steroids and other immunosuppressive agents.

My rheumatologist prescribed a monthly infusion of belimumab (Benlysta) in 2018. I was able to switch to the weekly subcutaneous injections when they became available a couple of years later as IV access was challenging.

Starting on this medication was a game changer for me. Most notable was the improvement in my energy levels. I was more productive both at work with less sick time and in my home life. I had less joint pain, less mouth sores, less fatigue, less skin rashes and overall, less of all of my symptoms. But most importantly, less chest discomfort from the pericarditis.

As a cardiac nurse, I am very well aware of the implications of chronic pericarditis. Complications I could be facing in the future include the potential debilitating effects from restrictive cardiomyopathy in which the heart cannot stretch and expand due to scar tissue built up as a result of chronic inflammation. This may result in a pericardiectomy in which the scarred and thickened lining of the heart (pericardium) would need to be surgically removed (through an open sternum) in order to allow the heart to beat without being restricted or squeezed.

I have recently reduced my regular hours at work changing to a 'relief/casual' position in order to spend time with my new grandsons and to focus on my health. I no longer have the group drug plan (coverage) I had as a regular employee and am struggling to figure how I can afford to stay on belimumab as many drug plans have drug limits or will not coverage this drug at all.

While I applaud the CADTH's recent decision to cover the costs of this medication for patients with renal involvement as a complication of their lupus, I APPEAL to you with all my heart to please include all patients with lupus deemed candidates by their rheumatologist to experience the immense benefit of this drug therapy." Paula, a non-renal lupus patient

"*Benlysta has been great for clearing up my lupus skin issues. In 2016 I started developing ulcers in my mouth and on my lips and genital region as well as arthritis in my elbows, hands, and knees. I also started losing my hair and developed rashes on my face. I was able to get some temporary relief from the ulcers with steroid creams, but the ulcers would soon return. Due to the sensitive nature of the area affected steroid use was not advised long term and there were no other options as I was already on several immunosuppressants. Similarly, I had been using steroid creams on my face for over a decade and the dermatologists were concerned about the long-term impacts of thinning skin and dependency so they said I could not use them any longer. This meant I didn't have any treatment options that were effective and had to just live with the large itchy red patches covering my face.*

I started Benlysta at the end of 2016/early 2017 and began to notice my hair had stopped falling out after a few months and was actually starting to grow back. My ulcers also began to slowly heal and become less painful and eventually didn't return. My face also began to clear up and the redness disappeared. Over the following several years I did not have any recurrence of the ulcers, joint pain, or hair loss while on the Benlysta and I didn't need to use any of the steroid creams. This was a major improvement to my daily life as I was struggling to eat or even drink water with the mouth ulcers. Benlysta has been a real game changer for me with amazing results and no side effects. I cannot recommend it enough for others as historically treatment options have been limited for lupus and often come with terrible side effects. If this drug was

widely available, I think it would change so many peoples lives for the better." Kristina, a non-renal lupus patient

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**
AstraZeneca Canada	☐	☐	☐	☐
GSK Pharmaceuticals	☐	☐	☐	☐
Add or remove rows as required	☐	☐	☐	☐