CADTH

CADTH REIMBURSEMENT REVIEW

Stakeholder Feedback on Draft Recommendation

deucravacitinib (Sotyktu)

(Bristol Myers Squibb)

Indication: For the treatment of adult patients with moderate to severe plaque psoriasis who are candidates for systemic therapy or phototherapy.

March 31, 2023

CADTH

CADTH Reimbursement Review
Feedback on Draft Recommendation

Stakeholder information	
CADTH project number	SR0756-000-000 Stakeholder Feedback on Draft Recommendation
Brand name (generic)	Sotyktu (deucravacitinib)
Indication(s)	Psoriasis, moderate to severe plaque
Organization	The Atlantic Provinces 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	☒

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 Atlantic Provinces Dermatology Expert group disappointed to learn that the CADTH Drug Expert Committee (CDEC) proceeded with a recommendation not to reimburse deucravacitinib for the treatment of moderate-to-severe psoriasis in adult patients who are candidates for systemic therapy or phototherapy and disagrees with this decision.

This group disagrees with the decision to compare deucravacitinib therapeutic benefit to biologic therapies. Deucravacitinib is an oral small molecule that should be compared to other oral systemic therapies, such as methotrexate, acitretin, cyclosporin and apremilast. While performing comparisons, this group encourages review of safety, tolerability and efficacy of each agent in comparison (indirect for traditional systemic therapies and direct for apremilast) to deucravacitinib. Upon review of POETYK PSO-1 and PSO-2 trial data this groupd believes that deucravacitinib has favourable safety and tolerability profile when compared to all available oral therapies and superior efficacy to most of these treatments. In this instance, this group disagrees with the clinical expert that deucravacitinib should be reserved for patients who failed first line traditional systemics. Decravacitinb represents a major improvement in oral systemic psoriasis management in regards to efficacy, safety and tolerability.

This group disagrees with the clinical expert that needle-averse patients would prefer an infrequent subcutaneous injection of a more efficacious biologic over once daily oral medication. The clinicians in this group found that many patients prefer ease and convenience of oral medication over injectables. This has been supported by the UPLIFT survey that reported that 84% of patients reported that injectable treatments are burdensome. Twenty four percent of patients in this cohort identified mental anxiety about peparing for self-injection the most common reason for the perceived burden. Needle fatique was identified as one of the reasons for injectable treatment discontinuation in UPLIFT survey. Furthermore, in clinical practice, clinicians encounter patients with disabilities (autism, trisomy 21, loss of limb) where injectable treatments add to the overall care burden and oral treatment with no laboratory monitoring would be life changing for these patients.

This group disagrees with the clinical expert that deucravacitinib does not address any of the unmet needs in plaque psoriasis and the expert did not anticipate that it would cause a shift in the current treatment paradigm. UPLIFT survey, a multinational survey of 3806 patients (403 Canadian patients)

with psoriasis and/or psoriatic arthritis, reporting 66% of patient found oral therapies burdensome. Top reasons why patients considered oral treatments to be burdensome included side effects (33%), frequency of dosing (32%), and required blood work monitoring (29%). In this survey, more than half (57%) of patients discontinued oral treatments due to lack of effectiveness (28%), loss of treatment effectiveness over time (22%), adverse events on organs (19%), and lack of tolerability (18%). This survey really highlighted an unmet need to have more effective and safe oral treatment options to manage moderate-to-severe psoriasis. There are currently no approved oral systemic therapies for the treatment of moderate-to-severe psoriasis that balance great efficacy and a favourable safety profile. Currently available systemic treatment options have significant shortcomings when it comes to safety. Methotrexate use can be associated with poor tolerability (fatigue, nausea), liver toxicity, bone marrow suppression, and pulmonary inflammation. Its use is particularly challenging in the elderly population due to its narrow therapeutic window and not uncommon errors in its administration (daily instead of weekly). Acitretin is contraindicated in women of childbearing potential and can be associated with liver toxicity, elevation of lipids, and hairloss in older women. Cyclosporine is used as an anti-rejection treatment in transplant medicine and is associated with numerous side effects. Hypertension and renal toxicity are dose-dependent and are seen in majority of patients treated with cyclosporine, and as such it is not recommended for long-term use to treat psoriasis. There is also increased risk of malignancy. In addition, it is expensive with additional costs of intensive blood work monitoring. Deucravacitinib represents new oral treatment for moderate-to-severe psoriasis with excellent efficacy, favourable safety profile and added convenience of once daily dosing. In Poetyk PSO1 and PSO2 trials 53-58.4% of patients had achieved PASI 75 at week 16, and 53-65% of patients had PASI 75 at week 52. Both trials demonstrated meaningful and significant improvements in DLQI and a very favourable safety profile, similar to placebo at weeks 16 and 52.

The statement that apremilast is infrequently prescribed in Canada is unfounded. It is experience of this group that apremilast is the treatment that is preferred by some patients over biologic therapy due to its safety and tolerability. No requirement for laboratory monitoring presented a major breakthrough in oral systemic psoriasis management, and was welcome by many psoriasis patients and their treating physicians. Unfortunately, due to negative CADTH recommendation on reimbursement apremilast use was restricted to the moderate-to-severe patient population with private insurance. This group believes that apremilast is a relevant comparator when it comes to safety and efficacy of deucravacitinib.

It is experience of this group that efficacy, favourable safety profile and tolerability, and convenience translate to patient treatment satisfaction and drug survival in clinical practice as such this group believes that treatment with deucravacitinib should translate to HRQoL improvements in moderate-to-severe treatment population.

References:

1. Lebwohl M, Langley RG, Paul C, Puíg L, Reich K, van de Kerkhof P, Wu HL, Richter S, Jardon S, Gisondi P. Evolution of Patient Perceptions of Psoriatic Disease: Results from the Understanding Psoriatic Disease Leveraging Insights for Treatment (UPLIFT) Survey. Dermatol Ther (Heidelb). 2022 Jan;12(1):61-78. doi: 10.1007/s13555-021-00635-4. Epub 2021 Oct 25. Erratum in: Dermatol Ther (Heidelb). 2022 Jan 6;: PMID: 34704231; PMCID: PMC8547901.

2. Piaserico S, Conti A, Lo Console F, De Simone C, Presti- nari F, Mazzotta A, et al. Efficacy and safety of systemic treatments for psoriasis in elderly patients. Acta Derm Venereol 2014; 94: 293–297.
3. Inzinger M, Weger W, Heschl B, Salmhofer W, Quehen- berger F, Wolf P. Methotrexate vs. umaric acid esters in moderate-to-severe chronic plaque psoriasis: data registry report on the efficacy under daily life conditions. J Eur Acad Dermatol Venereol 2013; 27: 861–866.
4. Lucka, T.C., Pathirana, D., Sammain, A., Bachmann, F., Rosumeck, S., Erdmann, R., Schmitt, J., Orawa, H., Rzany, B. and Nast, A. (2012), Efficacy of systemic therapies for moderate-to-severe psoriasis: a systematic review and meta-analysis of long-term treatment. Journal of the European Academy of Dermatology and Venereology, 26: 1331-1344. https://doi.org/10.1111/j.1468-3083.2012.04492.x
5. Warren, Richard B., and Christopher EM Griffiths. "Systemic therapies for psoriasis: methotrexate, retinoids, and cyclosporine." *Clinics in dermatology* 26.5 (2008): 438-447.
6. Paul, Carle F., et al. "Risk of malignancies in psoriasis patients treated with cyclosporine: a 5 y cohort study." *Journal of investigative dermatology* 120.2 (2003): 211-216.
7. Papp, Kim, et al. "Efficacy of apremilast in the treatment of moderate to severe psoriasis: a randomised controlled trial." *The Lancet* 380.9843 (2012): 738-746.
8. Papp, Kim, et al. "Apremilast, an oral phosphodiesterase 4 (PDE4) inhibitor, in patients with moderate to severe plaque psoriasis: results of a phase III, randomized, controlled trial (Efficacy and Safety Trial Evaluating the Effects of Apremilast in Psoriasis [ESTEEM] 1)." *Journal of the American Academy of Dermatology* 73.1 (2015): 37-49.
9. Paul, C., et al. "Efficacy and safety of apremilast, an oral phosphodiesterase 4 inhibitor, in patients with moderate-to-severe plaque psoriasis over 52 weeks: a phase III, randomized controlled trial (ESTEEM 2)." *British Journal of Dermatology* 173.6 (2015): 1387-1399.
10. Crowley, Jeffrey, et al. "Long-term safety and tolerability of apremilast in patients with psoriasis: Pooled safety analysis for≥ 156 weeks from 2 phase 3, randomized, controlled trials (ESTEEM 1 and 2)." *Journal of the american academy of dermatology* 77.2 (2017): 310-317.
11. Armstrong, April W., et al. "Deucravacitinib versus placebo and apremilast in moderate to severe plaque psoriasis: efficacy and safety results from the 52-week, randomized, double-blinded, placebo-controlled phase 3 POETYK PSO-1 trial." *Journal of the American Academy of Dermatology* 88.1 (2023): 29-39.
12. Strober B, Thaçi D, Sofen H, Kircik L, Gordon KB, Foley P, Rich P, Paul C, Bagel J, Colston E, Throup J, Kundu S, Sekaran C, Linaberry M, Banerjee S, Papp KA. Deucravacitinib versus placebo and apremilast in moderate to severe plaque psoriasis: Efficacy and safety results from the 52-week, randomized, double-blinded, phase 3 Program fOr Evaluation of TYK2 inhibitor psoriasis second trial. J Am Acad Dermatol. 2023 Jan;88(1):40-51. doi: 10.1016/j.jaad.2022.08.061. Epub 2022 Sep 14. PMID: 36115523.

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	☒
Not applicable. This group did not provide initial input.		
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.		
	Yes	☒

4. Have the implementation issues been clearly articulated and adequately addressed in the recommendation?	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.		
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 2. Conflict of Interest Declarations for Clinician Groups

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

A. Assistance with Providing the Feedback		
2. Did you receive help from outside your clinician group to complete this submission?	No	☒
	Yes	☐
If yes, please detail the help and who provided it.		
3. Did you receive help from outside your clinician group to collect or analyze any information used in this submission?	No	☒
	Yes	☐
If yes, please detail the help and who provided it.		
B. Previously Disclosed Conflict of Interest		
4. Were conflict of interest declarations provided in clinician group input that was submitted at the outset of the CADTH review and have those declarations remained unchanged? If no, please complete section C below.	No	☐
	Yes	☒
If yes, please list the clinicians who contributed input and whose declarations have not changed: • Clinician 1 – Irina Turchin • Clinician 2 – Tracey Brown-Maher • Clinician 3 – Anne-Marie Hunt • Clinician 4 – Catherine Rodriguez • Clinician 5 – Nicole Maillet-Lebel • Clinician 6 – Ian Landells • Clinician 7 – Wayne Gulliver • Clinician 8 – Kamal Ohson • Clinician 9 – Marc Bourcier		

C. New or Updated Conflict of Interest Declarations

Name: Irina Turchin

Position: Dermatologist, Fredericton, NB

Date: 27-March-2023

X **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.

Table 1: Conflict of Interest Declaration for Clinician 1

	Check appropriate dollar range*			
Company	**$0 to $5,000**	**$5,001 to $10,000**	**$10,001 to $50,000**	**In excess of $50,000**
Abbvie				x
Amgen	x			
Bausch Health		x		
BMS		x		
Eli Lilly		x		
Janssen			x	
Novartis		x		
Sun Pharma	x			
UCB		x		

* Place an X in the appropriate dollar range cells for each company.

Name: Dr. Tracey Brown-Maher

Position: Dermatologist / Principal Investigator, St. Johns, NL

Date: 27-March-2023

X **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.

Table 1: Conflict of Interest Declaration for Clinician 2

	Check appropriate dollar range*			
Company	**$0 to $5,000**	**$5,001 to $10,000**	**$10,001 to $50,000**	**In excess of $50,000**
Abbvie				X

Amgen		X		
Bausch Health			X	
BMS		X		
Eli Lilly			X	
Janssen			X	
Novartis			X	
SunPharma		X		
UCB			X	
LeoPharma			X	
Sanofi		X		
JAMP	X			
Boehringer Ingelheim	X			
Pfizer		X		
Galderma		X		

* Place an X in the appropriate dollar range cells for each company.

Name: Anne-Marie Hunt

Position: Dermatologist, Saint John, NB

Date: March 27th 2023

X **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.

Table 1: Conflict of Interest Declaration for Clinician 3

	Check appropriate dollar range*			
Company	**$0 to $5,000**	**$5,001 to $10,000**	**$10,001 to $50,000**	**In excess of $50,000**
Abbvie	x			
Amgen	x			
Bausch Health	x			

BMS	x			
Eli Lilly	x			
Janssen	x			
Novartis	x			
SunPharma	x			
UCB	x			

* Place an X in the appropriate dollar range cells for each company.

Name: Catherine Rodriguez

Position: Dermatologist, Charlottetown, PE

Date: March 27th 2023

X **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.

Table 1: Conflict of Interest Declaration for Clinician 4

	Check appropriate dollar range*			
Company	**$0 to $5,000**	**$5,001 to $10,000**	**$10,001 to $50,000**	**In excess of $50,000**
Abbvie	x			
Amgen	x			
Bausch Health	x			
BMS	x			
Eli Lilly	x			
Janssen	x			
Novartis	x			
SunPharma	x			
UCB	x			

* Place an X in the appropriate dollar range cells for each company.

Name: Nicole Maillet-Lebel

Position: Dermatologist in Moncton, New-Brunswick

Date: 26-03-2023

X **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.

Table 1: Conflict of Interest Declaration for Clinician 5

	Check appropriate dollar range*			
Company	**$0 to $5,000**	**$5,001 to $10,000**	**$10,001 to $50,000**	**In excess of $50,000**
Abbvie		X		
Amgen	X			
Bausch Health	X			
BMS	X			
Eli Lilly	X			
Janssen		X		
Novartis	X			
SunPharma	X			
UCB	X			
Bioscript	X			

* Place an X in the appropriate dollar range cells for each company.

Name: Ian Landells

Position: Dermatologist, St. Johs, NL

Date: 28-Mar-2023

X **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.

Table 1: Conflict of Interest Declaration for Clinician 6

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			X	
Bausch Health			X	
BMS			X	
Eli Lilly		X		
Janssen			X	
Novartis		X		
SunPharma		X		
UCB		X		

Name: Dr. Wayne Gulliver

Position: Professor of Medicine and Dermatology, St. John's, NL

Date: 29 March 2023

X **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.

Table 1: Conflict of Interest Declaration for Clinician 7

	Check appropriate dollar range*			
Company	$0 to $5,000	$5,001 to $10,000	$10,001 to $50,000	In excess of $50,000
Abbvie				X
Amgen			X	
Bausch Health			X	
BMS			X	
Eli Lilly			X	
Janssen			X	
Novartis				X
SunPharma			X	
UCB			X	

* Place an X in the appropriate dollar range cells for each company.

Name: Dr Kamal Ohson

Position: Dermatologist, St. John's, NL

Date: March 28, 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.

Table 1: Conflict of Interest Declaration for Clinician 8

	Check appropriate dollar range*			
Company	**$0 to $5,000**	**$5,001 to $10,000**	**$10,001 to $50,000**	**In excess of $50,000**
Abbvie			x	
Amgen	x			
Bausch Health	x			
Eli Lilly	x			
Janssen			x	
Novartis	x			
SunPharma	x			
UCB	x			

* Place an X in the appropriate dollar range cells for each company.

Name: Marc Bourcier

Position: Dermatologist, Moncton, NB

Date: 28-03-2023

X **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.

Table 1: Conflict of Interest Declaration for Clinician 9

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			X	
Amgen		X		
Bausch Health		X		
BMS		X		
Eli Lilly		X		
Janssen	X			
Novartis	X			
SunPharma	X			
UCB	X			

* Place an X in the appropriate dollar range cells for each company.

CADTH

CADTH Reimbursement Review
Feedback on Draft Recommendation

Stakeholder information	
CADTH project number	SR0756-000
Brand name (generic)	Deucravacitinib
Indication(s)	Psoriasis, moderate to severe plaque
Organization	Canadian Dermatology Association (CDA)
Contact information[a]	Caroline Herzberg [redacted]

Stakeholder agreement with the draft recommendation

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

The CDA does not agree with the "Do Not Reimburse" recommendation. We are of the opinion that patient preference and compliance, which are intrinsically intertwined, were not fully considered. More specifically,

- The clinical expert consulted did not mention that for the ~53-58% of patients who reached PASI 75 and are happy, and likely most of the 27-35% of those who reached PASI 90 (POETYK 1 and 2 data), these patients will likely stay on this drug.
- Patient group inputs identified that there was a demand for "easier to take, e.g., dosing schedule, route of administration" medication options and that they wanted new treatment options to have "reduced side effects". Deucravacitinib satisfies both of these asks as it is a once-a-day pill and has less side effects compared to injectable biologic and biosimilar options currently available.

The CDA also does not conclude that this drug would result in larger costs overall if patients later switch to a biologic or biosimilar. If deucravacitinib is able to meet patients needs and preferences, and there is comparable public coverage and criteria with biologics/biosimilars, dermatologists and patients would only consider a treatment plan change when a new and more efficacious oral therapy option became available.

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	☐

Not applicable. Clinician input was not provided earlier by the CDA.

Clarity of the draft recommendation

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

It is unclear how reimbursement of deucravacitinib would be more costly due to efficacy if prescribed prior to a biologic or biosimilar being prescribed. Comments in the draft recommendation appears not to have taken into consideration the treatment planning discussion a dermatologist would have had with his or her patient about the difference in costs and expected treatment outcomes between deucravacitinib (an oral therapy option) and a biologic/biosimilar (an injectable therapy option).

Excerpt from page 11 with comment in question highlighted:

> CADTH was unable to fully mitigate conceptual limitations associated with the model due to structural inflexibility and non-intuitive programming. As deucravacitinib is less expensive per treatment year than most biologic therapies currently being reimbursed, its use is likely to result in cost-savings to jurisdictional drug plans over the short term (i.e., within a 3-year time horizon) as more expensive therapies would be displaced. However, due to its lower efficacy (as suggested in the sponsor's NMA), it is likely that the use of deucravacitinib will delay rather than prevent the use of more expensive and more effective therapies, and thus reimbursement may result in an overall increase in costs over the course of each patients' life.

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	☒

The CDA does not agree with the "Do Not Reimburse" recommendation for the reasons mentioned above. Simply put, it creates a disadvantage for those patients who prefer a pill option and are one of the 53-58% of patients who reached PASI 75 or of the 27-35% who reached PASI 90 and are content with the results achieved.

The CDA agrees with the clinical expert's opinion that (1) deucravacitinib can have a defined role as an oral alternative for patients who prefer an oral treatment, (2) deucravacitinib should be reserved for patients who have failed first line traditional systemics (methotrexate, acitretin, cyclosporine), (3) therapy treatment response should be assessed after 12 to 16 weeks, and then at 1 year, (4) deucravacitinib should be discontinued if patients experience a significant adverse effect (e.g., hypersensitivity, serious infection), and (5) deucravacitinib should be prescribed by dermatologists.

[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	☐
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	☐
Clinician input was not provided earlier by the CDA.		

C. New or Updated Conflict of Interest Declarations

New or Updated Declaration for Clinician 1	
Name	**Susan Poelman, MD, FRCPC**
Position	**Chair, CDA Pharmacy and Therapeutics Advisory Board**
Date	**29-03-2023**
☒	**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**
Celgene	☒	☐	☐	☐

Eli Lilly	☒	☐	☐	☐
Novartis	☐	☒	☐	☐
AbbVie	☐	☒	☐	☐
Bausch Health	☒	☐	☐	☐
UCB	☒	☐	☐	☐
Janssen	☒	☐	☐	☐
Sun Pharma	☒	☐	☐	☐

New or Updated Declaration for Clinician 2	
Name	**Alexandra Kuritzky, MD, FRCPC**
Position	**Member, CDA Pharmacy and Therapeutics Advisory Board**
Date	**31-03-2023**
☒	**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**
Sanofi	☒	☐	☐	☐
Eli Lilly	☒	☐	☐	☐
AbbVie	☒	☐	☐	☐
Pfizer	☒	☐	☐	☐
Bausch Health	☒	☐	☐	☐
UCB	☒	☐	☐	☐
Janssen	☒	☐	☐	☐
Sun Pharma	☒	☐	☐	☐

CADTH

CADTH Provisional Funding Algorithm Feedback on Draft Report

Stakeholder information	
CADTH project number	SR0756-000
Condition under review	Psoriasis
Organization	Fraser Health Dermatology Group
Contact information[a]	Name: Gurbir Dhadwal Title: Dermatologist Email: [redacted] Phone: [redacted]

[a] CADTH may contact this person if comments require clarification. Contact information will not be included in any public posting of this document by CADTH.

SECTION 1: IMPLEMENTATION ADVICE
For reports without implementation advice, skip to Section 2

Stakeholder agreement with the draft provisional funding algorithm

1. Please indicate if the stakeholder agrees with the implementation advice.	Yes	☐
	No	☒

We do not agree with the draft recommendation that deucravacitinib not be reimbursed for the treatment of adult patients with moderate to severe plaque psoriasis who are candidates for systemic therapy or phototherapy. The recommendation sites "The evidence considered by CDEC did not sufficiently demonstrate a therapeutic benefit of deucravacitinib relative to biologics that are available in Canada."

We disagree as we do feel this medication should be available to patients in Canada. Regarding not showing a benefit over biologics, this medication is not a biologic medication, and we would see it being used as an alternative oral systemic medication rather than compared to biologics. Where this medication does show benefit in its phase three trials over apremilast, which is an oral systemic medication used in Canada.

Implementation advice panel consideration of the stakeholder input

2. Does the draft advice demonstrate that the panel has considered the stakeholder input that your organization provided to CADTH?	Yes	☐
	No	☐

Not applicable – we did not provide input during the initial stakeholder input.

However we would note that the clinician expert consulted by CADTH stated that deucravacitinib does not address any of the unmet needs in plaque psoriasis. But they did note that it was "difficult to define a role for deucravacitinib **except** as an oral alternative to the biologics for patients who prefer oral treatment."

We do see a group of patients that are needle phobic and never move on to biologic therapy for the reason of wanting to avoid injections alone, and they are left untreated/partially treated with current systemic therapies. It would be useful to have another oral alternative for those patients.

Clarity of the draft implementation advice

3. Are the reasons for the panel's advice clearly stated in the draft report?	Yes	☐
	No	☒

We found the following statement regarding budget impact difficult to interpret:
"However, due to its lower efficacy (as suggested in the sponsor's NMA), it is likely that the use of deucravacitinib will delay rather than prevent the use of more expensive and more effective therapies, and thus reimbursement may result in an overall increase in costs over the course of each patients' life."

None of the medications used for psoriasis are curative, so the more time that one spends on a less expensive medication, the less the total overall cost should be. The entire step wise criteria for psoriasis seems to be built on this premise. The first line therapy is methotrexate. It is one of the least effective systemic medicines we have for psoriasis. But given the low cost, even if only a minority of patients stay on long term, we would think this leads to cost savings. Even more confusing is that cyclosporin is included in the algorithm for psoriasis biologics and it has a maximum use limit for 2 years and then patients inevitably end up on a biologic.

The rational does not explain why this medication couldn't be used before biologics for patients that want to avoid injections, and this could also lead to cost savings as this medication appears from the CADTH report to be less expensive than biologics.

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

If not, please provide details regarding the information that requires clarification.

SECTION 2: PROVISIONAL FUNDING ALGORITHM

Stakeholder agreement with the draft provisional funding algorithm

5. Please indicate if the stakeholder agrees with the draft provisional funding algorithm.	Yes	☐
	No	☒

There is a recommendation to not fund the medication. The CADTH clinical expert recommended "Advanced therapy, such as deucravacitinib, should be reserved for patients who have failed first line traditional systemics (methotrexate, acitretin, cyclosporine)". We would actually recommend funding more in line with the above where deucravacitinib is funded after failure of one tradition systemic medication. The clinician input notes that apremilast is not used in Canada, but we would argue that we do tend to use apremilast in the situation where someone has failed one traditional systemic, and is needle phobic. Deucravacitnib should be used in a similar method, and has been shown to be more effective than apremilast.

Clarity of the draft provisional funding algorithm

6. Is the proposed provisional algorithm clearly represented and described in the draft report?	Yes	☒
	No	☐

If not, please provide details regarding the information that requires 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.
- 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 algorithm process 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	*Dr. Aaron Wong*
Position	*Dermatologist, NW Dermatology Inc.*
Date	*29-03-2023*
☒	**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**
Novartis	☒	☐	☐	☐
Abbvie	☒	☐	☐	☐
J&J	☒	☐	☐	☐
Janssen	☒	☐	☐	☐
Amgen	☒	☐	☐	☐
Sun Pharma	☒	☐	☐	☐
UCB	☒	☐	☐	☐
Eli Lilly	☒	☐	☐	☐
Cerave / L'Oreal	☒	☐	☐	☐
Sanofi	☒	☐	☐	☐
Galderma	☒	☐	☐	☐
Bausch Health	☒	☐	☐	☐

New or Updated Declaration for Clinician 2	
Name	Gordon Jung
Position	Clinical Instructor, Department of Dermatology & Skin Science, University of British Columbia
Date	30MAR2023
☒	**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**
Sun Pharma	☒	☐	☐	☐
UCB	☒	☐	☐	☐
Eli Lilly	☒	☐	☐	☐

Clinician 3

Name: Se Mang Wong

Position: Dermatologist

Date: 30-03-2023

☒ **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.

Table 1: Conflict of Interest Declaration for Clinician 1

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	x			
Amgen	x			
Bausch		x		
Boehringer Ingelheim	x			
Bristol Meyers Squibb	x			
Eli-Lilly	x			
Galderma	x			
Janssen	x			
Johnson & Johnson	x			
Leo Pharma	x			
Novartis		x		
Pfizer	x			
Sun Pharma	x			
UCB Pharma	x			

* Place an X in the appropriate dollar range cells for each company

New or Updated Declaration for Clinician 1	
Name	*Dr. Gurbir Dhadwal*
Position	*Dermatologist,*
Date	*29-03-2023*
☒	**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
Novartis	☒	☐	☐	☐
Abbvie	☐	☐	☒	☐
BMS	☒	☐	☐	☐
Janssen	☒	☐	☐	☐
Amgen	☒	☐	☐	☐
Sun Pharma	☐	☒	☐	☐
UCB	☐	☒	☐	☐
Eli Lilly	☒	☐	☐	☐
Bausch Health	☒	☐	☐	☐

CADTH

CADTH Reimbursement Review

Feedback on Draft Recommendation

Stakeholder information	
CADTH project number	SR0756
Name of the drug and Indication(s)	Deucravacitinib (Sotyktu) for plaque psoriasis
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.

Version: 1.0
Publication Date: TBC
Report Length: 2 Pages

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

CADTH Reimbursement Review
Feedback on Draft Recommendation

Stakeholder information	
CADTH project number	SR0756-000-000 Stakeholder Feedback on Draft Recommendation
Brand name (generic)	Deucravacitinib
Indication(s)	Psoriasis, moderate to severe plaque
Organization	Canadian Psoriasis Network, Canadian Association of Psoriasis Patients, Canadian Skin Patient Alliance
Contact information[a]	Name: Antonella Scali, [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.

We are writing on behalf of the Canadian Psoriasis Network (CPN), the Canadian Association of Psoriasis Patients (CAPP), and the Canadian Skin Patient Alliance (CSPA) to provide feedback on CADTH's draft reimbursement recommendation for deucravacitinib (Sotyktu) for plaque psoriasis. CPN and CAPP made a joint submission to CADTH's review process for this treatment and CPN, CAPP, and CSPA appreciate the opportunity to provide feedback highlighting our key concerns with the draft recommendation based on the findings of the patient input submission survey and interviews. Based on these findings, we encourage CADTH to reconsider its draft recommendation.

As described in CPN and CAPP's joint submission, plaque psoriasis is a chronic and potentially debilitating disease that can pose many challenges, including high prevalence, chronicity, disfiguration, sleep deprivation, disability, and associated comorbidities. Psoriasis is linked to anxiety, depression, and social isolation, and can interfere with relationships, productivity, family life, and work life. Additionally, experiences of stigma are common among people with psoriasis. The physical, psychological, social, and economic impact of psoriasis can significantly burden people and their families. Access to effective care and appropriate treatment is needed but management of psoriasis can be complex partly due to varied patient response to treatments, differences in social determinants of health, lifestyle considerations, and other factors that affect one's condition. Moreover, due to the chronicity of this disease, patients are concerned about recurrence and resistance to earlier therapies.

Specifically, we support a reconsideration of the draft recommendation given that 1) there is no single treatment that works for all patients with plaque psoriasis; 2) plaque psoriasis is a chronic disease and treatment needs often change over time; 3) lack of treatment administration options may impact a person's ability to access or adhere to treatment.

n.b., COI information remains unchanged for CPN and CAPP from the patient input submission. COI information for CSPA has been added below.

Expert committee consideration of the stakeholder input		
2. Does the recommendation demonstrate that the committee has considered the stakeholder input that your organization provided to CADTH?	Yes	☐
	No	☒

If not, what aspects are missing from the draft recommendation?

In review of the rationale and discussion points outlined in the draft recommendation, we submit that the following concerns presented in CPN and CAPP's patient input submission are not adequately addressed or accounted for:

Key concern – the need for treatment options

Treating plaque psoriasis can be an onerous process and for many, it involves failing on several different medications before finding one that is effective for the individual. Given the chronicity of the disease, treatment needs may also change over time. Many factors may contribute to this, including the individual's unique response to treatments, as well as the nature of psoriasis and the tendency for people to build a tolerance to treatments over time. People with plaque psoriasis are fortunate in that there are several treatment options that have market authorization from Health Canada. However, there are still unmet needs with the available treatments, and not all of these treatments are available to all patients in Canada.

Though many people can manage symptoms with conventional treatments–including topicals, phototherapy, and first-line oral systemic drugs like methotrexate–people with moderate to severe symptoms and/or with psoriasis on certain areas of the body (e.g., hands, feet, genitals, face) may require more targeted systemic drugs or biologics. It is common for patients to experience a time-limited usefulness of an advanced therapy before their immune system essentially begins to "outsmart" the drug. As a result, people with psoriasis need access to multiple treatment options. Many people worry that options may run out, only to have their moderate to severe plaque psoriasis return, and with it the itchiness, pain, fatigue, stress, stigma, and discrimination that they have experienced in the past. Some patients have been unable to work without an effective treatment; some have been unable to get out of bed.

There are also unique treatment considerations for different sub-populations. For example, sex and gender play a role in terms of management of plaque psoriasis. Women who may be planning to get pregnant–or who are pregnant–have important questions about which treatments are safe to use when conceiving, during pregnancy, when delivering, and when breastfeeding. Moreover, certain treatments should be avoided in patients who have, or are at higher risk of developing, particular comorbidities. In addition, patients may require a different treatment for a short period of time, such as to address a flare. For this reason, psoriasis patients continue to need new treatment options.

The heterogenous nature of the disease is evidenced by the input from patients that informed CPN and CAPP's joint patient input submission. Of the two survey participants who indicated that they have had experience with deucravacitinib with successful results, the following numbers also report having tried other treatments: topical corticosteroids (100%, n=2), topical vitamin D derivatives (50%, n=1), topical combination treatments (100%, n=2), methotrexate (50%, n=1), and phototherapy (50%, n=1). All these treatments were rated from "ineffective" to "very ineffective" by the survey participants and caused them to develop skin thinning (50%, n=1), skin itching (50%, n=1), and to develop a new rash/acne (50%, n=1).

For these reasons, **it is essential to the management of plaque psoriasis that treatment options be available to patients throughout their lives**–this is not a disease that can be cured nor managed long-term by a single treatment option.

Key concern – mode of administration matters

Moreover, the modality of treatment delivery matters. Though injectable treatment administration is suitable for many people with moderate-to-severe plaque psoriasis, 10% of CPN's 2022 community survey participants who have psoriasis (n=502) have concerns about self-injections, regardless of their past treatment experience.

The deucravacitinib clinical trial patient who we interviewed for CPN and CAPP's joint patient input submission stated that if the clinical trial was for an injectable medication, "I wouldn't be able to take an injection." He emphasized that he "hates needles" and that he wouldn't be on this medication if it was an injection.

He also shared, "Having this is painful, itchy, it bleeds, but once you get passed all that, if you get a dermatologist and he gives you what you need, and if this drug hits the market, it's going to be fantastic for people. I'm glad I got to participate in being a lab rat. This drug is a miracle drug – for something that they said there's no cure for this is as close as it gets". He says he would "recommend this drug to everyone". Three years later, he reports that the treatment is still very effective – "it's been a godsend for me".

This person had significant disruptions to his life because of plaque psoriasis. Before he found an effective treatment, he had to wear long sleeved shirts all the time, which was problematic for the type of work he does. This caused distress and disruption to his work life. He also shared that psoriasis put a "big damper" on his relationship with his wife because of "the way it was and the way it looked". He reports that things were rocky for them even after over 40 years of marriage. He says that successful treatment has helped these areas of his life tremendously.

Though this is one person's story, it reflects the range of needs, considerations, and concerns that many people in our community have about taking treatments to manage their disease over the course of their lives, including deliberating foregoing treatment all together because of how it is administered. **Having more than one option for advanced oral therapy gives people greater opportunity for finding a treatment that is safe, effective, and appropriate for them.**

This is one example of why **people with severe forms of psoriatic disease that cause significant disruptions to their health, lives, and well-being benefit greatly from options for treatments and treatment delivery modalities that are feasible and accessible to them.**

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. See discussion points above.		
5. If applicable, are the reimbursement conditions clearly stated and the rationale for the conditions provided in the recommendation?	Yes	☐
	No	☐
If not, please provide details regarding the information that requires clarification. N/A		

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

Appendix 1. Conflict of Interest Declarations for Patient Groups

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

A. Patient Group Information	
Name	*Canadian Skin Patient Alliance (Rachael Manion)*
Position	*Executive Director*
Date	*April 4 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.		
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**
Bristol-Myers Squibb	☐	☐	☒	☐
AbbVie	☐	☐	☐	☒
Bausch Health	☐	☐	☒	☐
Boehringer Ingelheim	☐	☐	☒	☐
Janssen	☐	☐	☒	☐
LEO Pharma	☐	☐	☒	☐

Novartis	☐	☐	☒	☐
Pfizer	☐	☐	☒	☐