

CADTH REIMBURSEMENT REVIEW

Stakeholder Feedback on Draft Recommendation

DOSTARLIMAB (Jemperli)
(GlaxoSmithKline Inc.)

Indication: Dostarlimab in combination with carboplatin and paclitaxel for the treatment of adult patients with primary advanced or recurrent mismatch repair deficient (dMMR)/microsatellite instability-high (MSI-H) endometrial cancer who are candidates for systemic therapy.

April 18, 2024

Disclaimer: The views expressed in this submission are those of the submitting organization or individual. As such, they are independent of CADTH and do not necessarily represent or reflect the view of CADTH. No endorsement by CADTH is intended or should be inferred.

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CADTH does use reasonable care to prevent disclosure of personal information in posted material; however, it is ultimately the submitter's responsibility to ensure no identifying personal information or personal health information is included in the submission. The name of the submitting stakeholder group and all conflicts of interest information from individuals who contributed to the content are included in the posted submission.

CADTH Reimbursement Review Feedback on Draft Recommendation

Stakeholder information	
CADTH project number	PC0325
Brand name (generic)	Jemperli (Dostarlimab)
Indication(s)	In combination with platinum-containing chemotherapy for the treatment of adult patients with primary advanced or recurrent mismatch repair deficient (dMMR)/microsatellite instability-high (MSI-H) endometrial cancer.
Organization	Ontario Health (Cancer Care Ontario) Gynecological Cancer Drug Advisory Committee
Contact information ^a	Name: Dr. Sarah Ferguson
Stakeholder agreement with the draft recommendation	
1. Does the stakeholder agree with the committee's recommendation.	Yes <input checked="" type="checkbox"/>
	No <input type="checkbox"/>
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 Gyne DAC agrees with the recommendations. This is a gap in treatment options for this group of patients.	
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 <input type="checkbox"/>
	No <input type="checkbox"/>
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 <input checked="" type="checkbox"/>
	No <input type="checkbox"/>
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 <input checked="" type="checkbox"/>
	No <input type="checkbox"/>
If not, please provide details regarding the information that requires clarification.	
<ul style="list-style-type: none"> Allowing ECOG 2 is important. Acceptable chemotherapy regimens include platinum alone or in combination with taxane. In the event that there is toxicity that limits chemotherapy, dostarlimab alone is preferred over use of other non-platinum and non-taxane chemotherapy regimens. 	
5. If applicable, are the reimbursement conditions clearly stated and the rationale for the conditions provided in the recommendation?	Yes <input checked="" type="checkbox"/>
	No <input type="checkbox"/>
If not, please provide details regarding the information that requires clarification.	

The DAC would like it to be clarified that MMR status needs to be determined before starting dostarlimab.

^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	<i>Please state full name</i>			
Position	<i>Please state currently held position</i>			
Date	<i>Please add the date form was completed (DD-MM-YYYY)</i>			
<input type="checkbox"/>	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	<input type="checkbox"/>
			Yes	<input type="checkbox"/>
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	<input type="checkbox"/>
			Yes	<input type="checkbox"/>
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	<input type="checkbox"/>
			Yes	<input type="checkbox"/>
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
<i>Add company name</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<i>Add company name</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<i>Add or remove rows as required</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

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	<input type="checkbox"/>
	Yes	<input checked="" type="checkbox"/>
If yes, please detail the help and who provided it. OH-CCO provided a secretariat function to the group.		
3. Did you receive help from outside your clinician group to collect or analyze any information used in this submission?	No	<input checked="" type="checkbox"/>
	Yes	<input type="checkbox"/>
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	<input type="checkbox"/>
	Yes	<input type="checkbox"/>
If yes, please list the clinicians who contributed input and whose declarations have not changed: <ul style="list-style-type: none"> Dr. Sarah Ferguson Dr. Tiffany Zigras Dr. Orit Freedman Dr. Julie My Van Nguyen 		

C. New or Updated Conflict of Interest Declarations

New or Updated Declaration for Clinician 1	
Name	Dr. Stephen Welch
Position	Member, OH-CCO Gynecological Cancer Drug Advisory Committee
Date	09-04-2024

<input checked="" type="checkbox"/>	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.
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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
GSK	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<i>Add company name</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<i>Add or remove rows as required</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

New or Updated Declaration for Clinician 2

Name	Dr. Robert Grant
Position	Member, OH-CCO Gynecological Cancer Drug Advisory Committee
Date	09-04-2024

<input checked="" type="checkbox"/>	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.
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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
<i>Add company name</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<i>Add company name</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<i>Add or remove rows as required</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

New or Updated Declaration for Clinician 3

Name	Dr. Josee-Lyne Ethier
Position	Member, OH-CCO Gynecological Cancer Drug Advisory Committee
Date	09-04-2024

<input checked="" type="checkbox"/>	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.
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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
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	\$0 to 5,000	\$5,001 to 10,000	\$10,001 to 50,000	In Excess of \$50,000
<i>Add company name</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<i>Add company name</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<i>Add or remove rows as required</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

CADTH Reimbursement Review

Feedback on Draft Recommendation

Stakeholder information	
CADTH project number	PC0325
Name of the drug and Indication(s)	Dostarlimab in combination with carboplatin and paclitaxel for the treatment of adult patients with primary advanced or recurrent mismatch repair deficient (dMMR)/microsatellite instability-high (MSI-H) endometrial cancer who are candidates for systemic therapy.
Organization Providing Feedback	PAG
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 <input type="checkbox"/>
	Minor revisions: A change in reimbursement conditions is requested <input type="checkbox"/>
No Request for Reconsideration	Editorial revisions: Clarifications in recommendation text are requested <input checked="" type="checkbox"/>
	No requested revisions <input type="checkbox"/>
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.	
<ul style="list-style-type: none"> - Under Table 1 - Initiation, PAG suggests clarifying the disease stage in the sentence: "Patients must not have any of the following: 3.2 Prior therapy with an anti-PD-1, anti-PD-L1, or anti-PD-L2 agent." 	
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.

- Under Table 2 – Considerations for initiation of therapy (second question), PAG commented that there is a non-sponsored review in progress of nab-paclitaxel for use in a variety of solid tumors for patients who experience severe hypersensitivity to conventional taxanes, but it is still under review and may not be funded in all provinces. PAG asked whether single agent platinum would be acceptable for patients who cannot have ongoing taxane.

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. An algorithm is needed (rapid algorithm) 2.
2. Please specify other implementation questions or issues that should be addressed by CADTH
1. 2.
3. Please specify questions or issues that should be addressed by CAPCA. (oncology only)
1. 2.
Support strategy
4. 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	PC0325
Brand name (generic)	JEMPERLI (Dostarlimab)
Indication(s)	Dostarlimab in combination with carboplatin and paclitaxel for the treatment of adult patients with primary advanced or recurrent mismatch repair deficient (dMMR)/microsatellite instability-high (MSI-H) endometrial cancer who are candidates for systemic therapy.
Organization	GlaxoSmithKline Inc.
Contact information ^a	[REDACTED]
Stakeholder agreement with the draft recommendation	
1. Does the stakeholder agree with the committee's recommendation.	Yes <input checked="" type="checkbox"/>
	No <input type="checkbox"/>
Please explain why the stakeholder agrees or disagrees with the draft recommendation. Whenever possible, please identify the specific text from the recommendation and rationale.	
GSK is overall pleased with the draft recommendation and agrees with the criteria for reimbursement based on the submitted evidence.	
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 <input checked="" type="checkbox"/>
	No <input type="checkbox"/>
N/A	
Clarity of the draft recommendation	
3. Are the reasons for the recommendation clearly stated?	Yes <input checked="" type="checkbox"/>
	No <input type="checkbox"/>
N/A	
4. Have the implementation issues been clearly articulated and adequately addressed in the recommendation?	Yes <input type="checkbox"/>
	No <input checked="" type="checkbox"/>
<p>Table 2, Pg 10, Row 1, Response c):</p> <p>“While pERC acknowledged the clinical experts’ response, the committee supported using the chemotherapy regimens studied in the RUBY Part 1 trial at treatment initiation but noted that patients who develop contraindications to a chemotherapy regimen may continue with nab-paclitaxel instead of paclitaxel and/or cisplatin instead of carboplatin.” GSK would like to request that the language above be modified to “...patients who develop contraindications to a chemotherapy regimen may continue with an alternative chemotherapy such as docetaxel, nab-</p>	

paclitaxel, liposomal doxorubicin, and cisplatin.” This is to reflect alternative chemotherapy use in clinical practice, as outlined in provincial treatment guidelines.^{1,2}

Table 2, Pg 10, Row 2, Response b):

“pERC noted that there is insufficient evidence to support using single agent dostarlimab in patients who experience disease relapse less than 6 months from neoadjuvant or adjuvant systemic therapy.” GSK would like to request that the language above be modified to reflect that sufficient clinical evidence exists to support using single agent dostarlimab in this patient population (i.e. GARNET), and clarify that pERC did not recommend that dostarlimab monotherapy be reimbursed. In the preceding paragraph to this statement, it notes that the clinical experts consulted by CADTH consider patients who have disease relapse less than 6 months may be eligible for treatment with a single agent PD-1 inhibitor, with reference made to the GARNET study. On pg 11, it was also stated that the clinical experts consulted by CADTH would offer dostarlimab monotherapy to patients who are unable to tolerate chemotherapy, based on evidence that single agent PD-1 inhibitors have demonstrated excellent responses among patients with primary advanced and recurrent dMMR endometrial cancer.

5. If applicable, are the reimbursement conditions clearly stated and the rationale for the conditions provided in the recommendation?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>

Table 1, Pg 4, Implementation Guidance for Reimbursement Condition #1:

“MMR status needs to be determined before treatment.” GSK would like to request that this language be modified to “MMR/MSI status needs to be determined before treatment.” In clinical practice, clinicians may conduct MSI status testing prior to testing for MMR status.

Table 1, Pg 5, Reimbursement Condition #7:

“Dostarlimab + carboplatin-paclitaxel should only be reimbursed when administered in combination.” GSK would like to clarify that dostarlimab would be reimbursed as monotherapy following the first 6 cycles with carboplatin-paclitaxel.

^a CADTH may contact this person if comments require clarification.

References

1. BC Cancer Agency Endometrium. Accessed July 17, 2023. <http://www.bccancer.bc.ca/health-professionals/clinical-resources/cancer-management-manual/gynecology/endometrium#Management-Endometrium>.
2. Alberta Health Services. Clinical Practice Guideline Gyne-002 Version 5. 2015. July 17, 2023. <https://www.albertahealthservices.ca/assets/info/hp/cancer/if-hp-cancer-guide-gyne002-endometrial.pdf>