



Canada's Drug Agency  
L'Agence des médicaments du Canada

## CDA-AMC REIMBURSEMENT REVIEW

# Stakeholder Feedback on Draft Recommendation

**Enzalutamide**

(non-sponsored review)

**Indication:** For the treatment of patients with non-metastatic castration-sensitive prostate cancer (nmCSPC) with biochemical recurrence at high risk of metastasis (high-risk BCR)

**Oct 31, 2024**

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

By filing with CDA-AMC, the submitting organization or individual agrees to the full disclosure of the information. CDA-AMC does not edit the content of the submissions.

CDA-AMC 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	PX0366
Brand name (generic)	enzalutamide
Indication(s)	For the treatment of patients with non-metastatic castration-sensitive prostate cancer (nmCSPC) with biochemical recurrence at high risk of metastasis (high-risk BCR)
Organization	Ontario Health (Cancer Care Ontario) Genitourinary Cancer Drug Advisory Committee ("GU DAC")
Contact information <sup>a</sup>	Name: Dr. Girish Kulkarni
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"/>
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"/>
Clarity of the draft recommendation	
3. Are the reasons for the recommendation clearly stated?	Yes <input checked="" type="checkbox"/>
	No <input type="checkbox"/>
4. Have the implementation issues been clearly articulated and adequately addressed in the recommendation?	Yes <input checked="" type="checkbox"/>
	No <input type="checkbox"/>
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"/>
The GU DAC's comments only pertain to the Draft Recommendation document.	

<sup>a</sup> 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	<input type="checkbox"/>
	Yes	<input checked="" type="checkbox"/>
OH (CCO) provided a secretariat function to the group.		
2. 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		
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	<input checked="" 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"> <li>Dr. Girish Kulkarni</li> <li>Dr. Chris Morash</li> </ul>		

### C. New or Updated Conflict of Interest Declarations

New or Updated Declaration for Clinician 1	
Name	Dr. Urban Emmenegger
Position	Member, OH (CCO) GU DAC
Date	27-October-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.
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
Astellas (correction from what was declared during the input)	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

#### New or Updated Declaration for Clinician 2

<b>Name</b>	Dr. Reta Barua
<b>Position</b>	Member, OH (CCO) GU DAC
<b>Date</b>	25-October-2024
<input checked="" type="checkbox"/>	<b>I hereby certify</b> 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
Janssen	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

#### New or Updated Declaration for Clinician 3

<b>Name</b>	Dr. Akmal Ghafoor
<b>Position</b>	Member, OH (CCO) GU DAC
<b>Date</b>	21-October-2024
<input checked="" type="checkbox"/>	<b>I hereby certify</b> 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
Janssen	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

## CADTH Reimbursement Review

### Feedback on Draft Recommendation

Stakeholder information	
CADTH project number	PX0366
Name of the drug and Indication(s)	Enzalutamide For the treatment of patients with non-metastatic castration-sensitive prostate cancer (nmCSPC) with biochemical recurrence at high risk of metastasis (high-risk BCR)
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"> <li>- In Table 2, under Initiation, the sentence should include the right indication under review: “Enzalutamide with or without ADT should be reimbursed in patients who meet the criteria for <b>non-metastatic castration-sensitive prostate cancer (nmCSPC) with biochemical recurrence at high risk of metastasis (high-risk BCR).</b>”</li> <li>- In Table 2, under Initiation, PAG suggests adding “and” such as: 1. High risk is defined as PSA doubling time of 9 months or less, <b>and</b> Screening PSA level</li> </ul>	

<ul style="list-style-type: none"> <li>- In Table 2, under Initiation, PAG suggests adding “or” for the two possible PSA screening levels such as: 1ng/mL or higher in prior RP (with or without post-operative RT) patients, or at least 2ng/mL above nadir in prior RT</li> </ul>
<p><b>c) Implementation guidance</b></p> <p>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.</p> <ul style="list-style-type: none"> <li>- In the DPI table, for the first question, PAG suggests adding LHRH antagonists <b>and agonists</b> in the sentence: “As per the clinical expert, all LHRH antagonists can be considered interchangeable in terms of efficacy.” Not all provinces fund LHRH antagonists.</li> </ul>

## 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.

<p><b>Algorithm and implementation questions</b></p> <p><b>1. Please specify sequencing questions or issues that should be addressed by CADTH (oncology only)</b></p> <ol style="list-style-type: none"> <li>1. An update to the algorithm is needed (rapid algorithm).</li> <li>2.</li> </ol> <p><b>2. Please specify other implementation questions or issues that should be addressed by CADTH</b></p> <ol style="list-style-type: none"> <li>1.</li> <li>2.</li> </ol>
<p><b>Support strategy</b></p> <p><b>3. Do you have any preferences or suggestions on how CADTH should address these issues?</b></p> <p>May include implementation advice panel, evidence review, provisional algorithm (oncology), etc.</p>

## CADTH Reimbursement Review Feedback on Draft Recommendation

Stakeholder information		
CADTH project number	PX0366-000	
Brand name (generic)	Enzalutamide	
Indication(s)	For the treatment of patients with non-metastatic castration-sensitive prostate cancer (nmCSPC) with biochemical recurrence at high risk of metastasis (high-risk BCR)	
Organization	Astellas Pharma Canada, Inc.	
Contact information <sup>a</sup>	Name: [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"/>
<p>Astellas Pharma Canada, Inc agrees with the recommendation. Astellas noted two points of correction:</p> <p><b>Re:</b> page. 7 final bullet "FMEC noted that because enzalutamide is only available as a capsule formulation where gelatin (pork) may be an included ingredient...".</p> <p><b>Astellas Response:</b> We would like to note that the current capsule formulation of enzalutamide does not include pork as an ingredient.</p> <p><b>Re:</b> page 27, para 4 "defined by a PSA doubling time of months or less"</p> <p><b>Astellas Response:</b> This appears to be a typo. The number 9 is missing. The statement should read "defined by a PSA doubling time of 9 months or less".</p>		
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 checked="" type="checkbox"/>
	No	<input type="checkbox"/>
N/A		
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"/>
N/A		

<sup>a</sup> CADTH may contact this person if comments require clarification.