CADTH

CADTH REIMBURSEMENT REVIEW

# Stakeholder Feedback on Draft Recommendation

**relugolix (Orgovyx)**

(Sumitomo Pharma Canada, Inc.)

**Indication:** Advanced prostate cancer

**May 16, 2024**

# CADTH Reimbursement Review
# Feedback on Draft Recommendation

| Stakeholder information | |
|---|---|
| CADTH project number | PC0342 |
| Brand name (generic) | Orgovyx (relugolix) |
| Indication(s) | For treatment of adults with advanced prostate cancer |
| Organization | OH (CCO) Genitourinary Cancer Drug Advisory Committee |
| Contact information[a] | Name: Dr. Girish Kulkarni |

## 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 GU DAC believes that relugolix should be available regardless of whether they are candidates for chemotherapy, radiation therapy, or surgical therapy. This should be given in the same indication as any other form of ADT, with the same considerations of reimbursement.
- Despite progression, an ADT (which includes relugolix) should be continued in all lines of therapy as per current standard of care.
- The GU DAC felt strongly that this is another form of ADT. As long as the price is similar, this should use the same indication and funding mechanisms as any form of injectable ADT.
- The funding stream should be similar to how other ADTs are currently funded.

## 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?
Please see above.

## Clarity of the draft recommendation

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

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

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

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

The GU DAC agrees that any strong drug-drug interactions need to be considered seriously, but at the discretion of physician and pharmacist. However, the GU DAC disagrees with the comment that relugolix should be restricted on which combination ARAT to use, or with radiation therapy. It should be used in the same context as any other ADT.

Similar to how clinicians may switch between injectable ADTs for various reasons (i.e. painful IM/SC injections), oral relugolix should be included as an alternate ADT option, under the current standard of care, based on clinical judgement.

| **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.

- The GU DAC believes that relugolix should be available regardless of whether they are candidates for chemotherapy, radiation therapy, or surgical therapy. This should be given in the same indication as any other form of ADT, with the same considerations of reimbursement.

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

## Appendix 2. Conflict of Interest Declarations for Clinician Groups

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

| A. Assistance with Providing the Feedback | | |
|---|---|---|
| **2. Did you receive help from outside your clinician group to complete this submission?** | No | ☐ |
| | Yes | ☒ |
| If yes, please detail the help and who provided it.<br>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 | ☒ |
| | 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:<br>• Dr. Girish Kulkarni<br>• Dr. Aly-Khan Lalani<br>• Dr. Chris Morash<br>• Dr. Sebastien Hotte<br>• Dr. Urban Emmenegger | | |

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

| New or Updated Declaration for Clinician 1 | |
|---|---|
| **Name** | Dr. Christina Canil |
| **Position** | Member, OH(CCO) GU Cancer Drug Advisory Committee |
| **Date** | 08-05-2024 |
| ☒ | **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** |
| *Add company name* | ☐ | ☐ | ☐ | ☐ |
| *Add company name* | ☐ | ☐ | ☐ | ☐ |

| New or Updated Declaration for Clinician 2 | |
|---|---|
| **Name** | Dr. Reeta Barua |
| **Position** | Member, OH(CCO) GU Cancer Drug Advisory Committee |
| **Date** | 08-05-2024 |
| ☒ | **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** |
| *Add company name* | ☐ | ☐ | ☐ | ☐ |
| *Add company name* | ☐ | ☐ | ☐ | ☐ |

# CADTH Reimbursement Review

# Feedback on Draft Recommendation

| Stakeholder information | |
|---|---|
| CADTH project number | PC0342 |
| Name of the drug and Indication(s) | Relugolix For the treatment of adult patients with advanced prostate cancer |
| Organization Providing Feedback | PAG |

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

| **2. Change in recommendation category or conditions**<br>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**<br>Complete this section if editorial revisions are requested for the following elements |
|---|
| **a) Recommendation rationale** |
| Please provide details regarding the information that requires clarification. |
| **b) Reimbursement conditions and related reasons** |
| Please provide details regarding the information that requires clarification. |
| **c) Implementation guidance** |
| Please provide high-level details regarding the information that requires clarification. You can provide specific comments in the draft recommendation found in the next section. Additional implementation questions can be raised here. |

PAG requested clarification on the disease setting in the main recommendation statement and in Table 1: can “advanced prostate cancer” be clarified in terms of metastatic vs. non-metastatic disease, and castration-sensitive vs. castration-resistant disease?

PAG requested clarification on the drug(s) included in this recommendation: is the recommendation for relugolix to be used only when patients are on ADT alone (as per Discussion Points); or with either ADT alone or in combination with “enzalutamide specifically in the context of metastatic castration-resistant prostate cancer” if patients transform from mCSPC to castration-resistant disease while on relugolix (as per trial criteria)?

PAG requested clarification on Care provision issues in Table 2: “pERC agreed with the clinical experts and noted limited evidence on efficacy of relugolix as part of an intensification therapy or in combination with radiation therapy for advanced prostate cancer”, and PAG is asking for pERC’s position as to whether relugolix should not be combined with apalutamide and abiraterone.

# 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 update to the algorithm is needed (rapid algorithm).<br>2. |
| **2. Please specify other implementation questions or issues that should be addressed by CADTH** |
| 1.<br>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. |