

CADTH REIMBURSEMENT REVIEW

Stakeholder Feedback on Draft Recommendation

ospemifene (Osphena)
(Duchesnay Inc.)

Indication: Dyspareunia, vaginal dryness

April 29, 2022

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.

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

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 | SR0709 |
| Name of the drug and Indication(s) | Ospemifene (Osphena) for postmenopausal women for the treatment of moderate to severe dyspareunia and/or vaginal dryness, symptoms of vulvar and vaginal atrophy, a component of genitourinary syndrome of menopause. |
| 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 | <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 type="checkbox"/> |
| | No requested revisions | <input checked="" 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.

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. |