Canada's Drug Agency
L'Agence des médicaments du Canada
Drugs. Health Technologies and Systems. Médicaments, technologies de la santé et systèmes.

# Feedback on Draft Recommendation

| Interested party information | |
|---|---|
| Project number | PC0400 |
| Brand name (generic) | Verzenio (abemaciclib) |
| Indication(s) | For the treatment of hormone receptor (HR)- positive, human epidermal growth factor receptor (HER2)- negative advanced or metastatic breast cancer, in combination with an aromatase inhibitor (AI) in postmenopausal women as initial endocrine-based therapy |
| Organization | REAL Breast Cancer Alliance of Canada |
| Contact information[a] | Name: Dr. Mita Manna |

| Interested party agreement with the draft recommendation | | |
|---|---|---|
| **1. Does the interested party agree with the committee's recommendation.** | Yes | ☒ |
| | No | ☐ |

**The proposed reimbursement conditions in Table 1 are consistent with the MONARCH 3 clinical trial and align with both current clinical practice and the evidence outlined in our submission.**

**Initiation criteria:**
We support the initiation criteria outlined in table 1 (items 1, 2, 3.1, 3.2 and 3.3), which recommend reimbursement for patients with previously untreated HR-positive, HER2-negative advanced or metastatic disease. This aligns with the MONARCH 3 trial population and is reflected in Section 5.2 of the REAL Alliance submission, which recommends the use of abemaciclib plus AI "*in endocrine-sensitive patients with HR+/HER2– advanced or metastatic breast cancer who had no prior systemic therapy in the advanced setting.*" Although ECOG performance status is not explicitly mentioned in our submission, we endorse the use of MONARCH 3 criteria, which included patients with ECOG 0–1. As such, we consider the performance status condition appropriate and implicitly supported.

**Discontinuation criteria:**
With respect to discontinuation (Table 1, items 4.1 and 4.2), we support the recommendation that reimbursement should cease upon disease progression or the development of intolerable side effects. This is consistent with both the product monograph and standard clinical practice. In Section 5.4 of our submission, we state clearly that:
"*Abemaciclib + AI combination therapy should be discontinued at the first sign of disease progression or in the case of persistent toxicity, as per the product monograph.*"

**Prescribing criteria:**
Finally, we also support the prescribing condition that abemaciclib should be prescribed by clinicians with expertise in managing advanced breast cancer (table 1, item 5). This is directly aligned with Section 5.5 of our submission, which states: *Oncologists with experience in treating breast cancer patients are required for the initial treatment recommendation and early monitoring of abemaciclib + AI combination therapy*.

**Feasibility of adoption:**
While the economic feasibility of adoption of abemaciclib plus NSAI has not been addressed yet (table 1, item 7), we urge CDA to consider that the proposed reimbursement of abemaciclib plus NSAI does not expand the eligible treatment population, but rather introduces an additional treatment option within an existing first-line standard of care (section 5.2 from our submission). From a feasibility perspective, we believe this provides clinicians with flexibility to match treatment to individual patient needs — particularly in cases where an alternative to ribociclib may be more appropriate — without altering the scope of overall system utilization.

| Expert committee consideration of the input | | |
|---|---|---|
| **2. Does the recommendation demonstrate that the committee has considered the input that your organization provided?** | Yes | ☒ |
| | No | ☐ |
| 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 | ☒ |
| | 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 | ☒ |
| Overall, we are aligned with the proposed conditions for reimbursement. However, we wish to clarify one point regarding the feasibility and adoption for the eligible treatment population (table 1, item 7). The inclusion of abemaciclib plus NSAI would not broaden the patient population currently eligible for first-line CDK4/6 inhibitor therapy; rather, it would add an additional therapeutic option within the established standard of care. This approach would give clinicians greater flexibility to individualize treatment — for example, when ribociclib may not be the most appropriate choice — while maintaining the same scope of system utilization and resource demands. | | |
| **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] CDA-AMC 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 CDA-AMC 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.
- CDA-AMC may contact your group with further questions, as needed.
- Please see the *Procedures for 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 | ☐ |
| 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 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. Jean-Francois Boileau<br>• Dr. Nathaniel Bouganim<br>• Dr. Christine Brezden-Masley<br>• Dr. Jeffrey Cao<br>• Dr. Stephen Chia<br>• Dr. Scott Edwards<br>• Dr. Karen Gelmon<br>• Dr. Nayyer Iqbal<br>• Dr. Anil Abraham Joy<br>• Dr. Kara Laing<br>• Dr. Nathalie Levasseur<br>• Dr. Mita Manna<br>• Dr. Callista Phillips<br>• Dr. Maged Salem<br>• Dr. Sandeep Sehdev<br>• Dr. Christine Simmons | | |

**C. New or Updated Conflict of Interest Declarations**
**NONE**