Clinician Input Template for CADTH pan-Canadian Oncology Drug Review Program

*Before completing this template, be sure to* [*register*](https://drugreviewsadmin.cadth.ca/Landing/Register/Register.aspx?Lang=EN) *with the pCODR program. Please visit* [*www.cadth.ca/pcodr/registration*](http://www.cadth.ca/pcodr/registration) *for information about the registration process.*

1. **About the Registered Clinician**

|  |  |
| --- | --- |
| Name of Registered Clinician |  |
| Title |  |
| Disease Specialty (if applicable) |  |
| Province |  |
| Organization Membership (if applicable, national or provincial) |  |
| Email |  |
| Telephone Number |  |

If this is a joint clinician input submission, please indicate the organization this submission is on behalf of, as well as list the names of the other clinicians and disease site specialty (if applicable). Please note that all clinicians listed must also register with CADTH and complete conflict of interest declaration forms.

|  |
| --- |
|  |

**Confirmation of Authorship**

I declare that I am the author of this submission and I confirm that no other parties have written or participated in the writing of the submission, except for those abovenamed in this joint submission (if applicable).

|  |  |  |
| --- | --- | --- |
|  |  |  |
| Signature |  | Date (YYYY/MM/DD) |

1. **About the Drug and Indication Under Review**

|  |  |
| --- | --- |
| CADTH pCODR Project Number | pCODR 10225 |
| Generic Drug Name (Brand Name) | Avelumab (Bavencio) |
| Indication | Avelumab for the first-line maintenance treatment of patients with locally advanced or metastatic urothelial carcinoma (UC) whose disease has not progressed with first-line platinum-based induction chemotherapy. |
| Funding Request | Same as indication |
| Trial(s) Being Submitted to pCODRa | JAVELIN Bladder 100 study ([NCT02603432](https://clinicaltrials.gov/ct2/show/NCT02603432))  |
| Health Canada Status | Pending  |
| FDA | Approved (06-30-2020) |
| European Medicines Agency Status | Pending  |
| Practice Guidelinesa | [NCCN](https://www.nccn.org/professionals/physician_gls/pdf/nscl.pdf) |
| Provincial Funding of Current Treatments or Funding Algorithm | The standard first line treatment for patients with locally advanced or metastatic UC is platinum-based induction chemotherapy. Some patients who are not candidates for platinum chemotherapy may receive alternate chemotherapy (e.g., gemcitabine and paclitaxel). Pembrolizumab is currently funded in patients with relapsed disease following first-line therapy. There is currently no maintenance treatment following good response to induction chemotherapy; patients are being monitored and given best supportive care |

a Please note that access to some online publications require subscription.

1. **Key Questions for Clinician Input**

## 3.1 Current Treatment(s) for the Indication Under Review:

* If this is different than what is listed in the Provincial Funding of Current Treatments or Funding Algorithm on the previous page, identify the treatment(s) you would use.
* If more than one treatment is funded in your province, identify the treatment(s) that would be the most appropriate comparator for the drug under review.

|  |
| --- |
|  |

## 3.2 Eligible Patient Population

Describe the patients for whom you would use the new treatment. Examples can include, but are not limited to, the following questions:

* Does the patient population in the reimbursement request align with the need identified in your clinical practice? Is there an unmet need?
* Can the inclusion and exclusion criteria of the clinical trial be applied in clinical practice?
* Is there a subgroup of patients beyond the study population that you would like to use the new treatment in? Is there a subgroup of patients within the study population that the new treatment should be limited to?

|  |
| --- |
|  |

**IMPLEMENTATION QUESTIONS**

* **In some clinical** [**trials**](https://pubmed.ncbi.nlm.nih.gov/31553054/)**, avelumab is being administered as a flat 800 mg dose every 2 weeks. Is it reasonable to implement avelumab dosing as 10 mg/kg up to a cap of 800 mg every 2 weeks to minimize drug waste, in line with how nivolumab and pembrolizumab are currently implemented?**

|  |
| --- |
|  |

* **Is there any evidence to administer avelumab on a different schedule (e.g., every 4 weeks) for patient convenience and to minimize visits to the cancer treatment centre?**

|  |
| --- |
|  |

* **Is there evidence to inform whether avelumab maintenance can be administered to patients who are in response following non-platinum-based chemotherapy in the first-line setting for advanced bladder cancer?**

|  |
| --- |
|  |

## 3.3 Relevance to Clinical Practice

Do you have experience with using the treatment (through clinical trials, manufacturer’s access program, private drug insurance) under review?

[ ] Yes [ ] No

* How or when would you use the new treatment? Is there any population/subpopulation where you particularly want to use this drug?
* How is the new treatment different than currently available treatments with respect to efficacy, safety, and tolerability?
* Are there contraindications to using the new treatment? Are there contraindications to current treatments that would make the new treatment favourable?

Please note: Scientific published references are not required, as pCODR has access to current scientific literature through the manufacturer’s submission and a rigorous, independent literature search.

|  |
| --- |
|  |

**IMPLEMENTATION QUESTIONS**

* **What is an appropriate timeline to start avelumab maintenance therapy on a time-limited basis for patients who have already completed platinum-based chemotherapy at the time of implementation?**

|  |
| --- |
|  |

* **How frequently should patients be monitored for disease progression on maintenance?**

|  |
| --- |
|  |

##  3.4 Sequencing and Priority of Treatments

* Please describe how the new treatment could be sequenced with current treatment(s), if appropriate.
* In your opinion, in the event that the drug under review becomes available for funding in your jurisdiction, would the new treatment be a replacement of current treatment(s) or another option?

|  |
| --- |
|  |

**IMPLEMENTATION QUESTIONS**

* **What is the recommended therapy for patients who progress on avelumab?**

|  |
| --- |
|  |

* **Is there evidence on the use of pembrolizumab after progression on avelumab?**

|  |
| --- |
|  |

* **If a patient is intolerant to avelumab and must stop treatment, is there evidence and/or inclination to use pembrolizumab upon progression? If the reason for stopping is not intolerance or disease progression, is it more appropriate to re-start avelumab at the time of progression?**

|  |
| --- |
|  |

* **If subsequent anti-PD1 therapy is permitted, what would be the minimum progression free interval to qualify for such therapy? (e.g., patients who progress during or within 6 months of stopping avelumab would not be eligible for further anti-PD1 therapy).**

|  |
| --- |
|  |

* **Would you prefer to give maintenance therapy with avelumab or treatment in second line with pembrolizumab?**

|  |
| --- |
|  |

* **Under what circumstances should maintenance avelumab not be offered?**

|  |
| --- |
|  |

* **Is there an optimal duration of treatment with avelumab maintenance? How does a physician determine when to stop maintenance therapy?**

|  |
| --- |
|  |

* **Can patients take a treatment break after a number of cycles with stable disease, and if so, is there a minimum number of cycles that should be administered, and is there a timeframe after which patients can resume avelumab upon disease progression?**

|  |
| --- |
|  |

## 3.5 Companion Diagnostic Testing

* If companion diagnostic testing is required for the new drug, is the test available in your jurisdiction? Is it funded by your jurisdiction? What concerns, if any, do you have on the test and turnaround time for test results? Are there specific considerations to a testing algorithm that you think would be important to share with the pCODR Expert Review Committee?

|  |
| --- |
|  |

**Appendix A: pCODR Clinician Conflict of Interest Declarations**

**Please note: Each registered clinician must complete their own separate pCODR Clinician Conflict of Interest Declarations Template even if the submission is made jointly.**

|  |  |
| --- | --- |
| **Name of registered clinician:** |  |
| **Name of drug and indication under review:** |  |

**Conflict of Interest Declaration**

To maintain the objectivity and credibility of the pCODR process, all participants in the pCODR review process must disclose any conflicts of interest. A registered clinician must declare any potential conflicts of interest that may influence or have the appearance of influencing the information submitted. A conflict of interest declaration is requested for transparency — it does not negate or preclude the use of the clinician input.

Examples of conflicts of interest include, but are not limited to:

* financial support from the pharmaceutical industry or other entities (e.g., educational or research grants, honoraria, gifts, and salary)
* affiliations, or personal or commercial relationships with drug manufacturers or other interest groups.

**Section A: Payment Received**

1. Have you received any payments over the previous two years from any company or organization that may have a direct or indirect interest in the drug under review?

|  |
| --- |
|[ ]  Yes |
|[ ]  No |

 If no, please go to Section B.

1. What form of payment did you receive? (Check all that apply.)

|  |  |  |
| --- | --- | --- |
|[x]  Advisory role (e.g., advisory boards, health technology assessment submission advice)  |[ ]  Program or Operating Funding (e.g., website)  |  |
|[ ]  Conference attendance  |[ ]  Research/educational grants  |  |
|[ ]  Royalties |[ ]  Travel grants |  |
|[ ]  Gifts  |[ ]  Sponsorship of events |  |
|[ ]  Honoraria |[ ]  Other, please specify:  |  |

1. Please provide the names of companies and organizations, and the amounts of the payments, in the following table.

|  |  |  |
| --- | --- | --- |
| **Company** | **Nature or description of activities or interests** | **Check Appropriate Dollar Range** |
| **$0 to 5,000** | **$5,001 to 10,000** | **$10,001 to 50,000** | **In Excess of $50,000** |
|  |  | [ ]  | [ ]  | [ ]  | [ ]  |
|  |  | [ ]  | [ ]  | [ ]  | [ ]  |
|  |  | [ ]  | [ ]  | [ ]  | [ ]  |

**Section B: Holdings or Other Interests**

Have you received or are in possession of stocks or options of more than $10,000 (excluding mutual funds) for organizations that may have a direct or indirect interest in the drug under review? If yes, please list them in the following box.

|  |
| --- |
|  |

**Section C: Affiliations, Personal or Commercial Relationships**

Do you have personal or commercial relationships either with a drug or health technology manufacturer (including the manufacturer’s parent corporation, subsidiaries, affiliates, and associated corporations) or other interest groups? If yes, please provide the names of the companies and organizations, and outline the nature of these relationships, in the following box.

|  |
| --- |
|  |

|  |  |
| --- | --- |
| By checking this box, I hereby certify that the information that I have presented here is accurate and complete to the best of my knowledge. | [ ]  |

|  |  |  |  |
| --- | --- | --- | --- |
|  |  |  |  |
| Date |  | Name |  |