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

CDA-AMC REIMBURSEMENT REVIEW

Patient and Clinician Group Input

erdafitinib (Balversa)

(Janssen Inc.)

Indication: Erdafitinib is indicated for the treatment of adult patients with locally advanced unresectable or metastatic urothelial carcinoma (UC), harboring susceptible FGFR3 (fibroblast growth factor receptor) genetic alterations, with disease progression during or following at least one line of a programmed death receptor-1 (PD-1) or programmed death-ligand 1 (PD-L1) inhibitor therapy including within 12 months of neoadjuvant or adjuvant therapy. Treatment with BALVERSA® should be initiated following confirmation of a susceptible FGFR genetic alteration using a validated test.

June 28, 2024

This document compiles the input submitted by patient groups and clinician groups for the file under review. The information is used by CDA-AMC in all phases of the review, including the appraisal of evidence and interpretation of the results. The input submitted for each review is also included in the briefing materials that are sent to expert committee members prior to committee meetings.

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 views of CDA-AMC. No endorsement by CDA-AMC is intended or should be inferred.

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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 group and all conflicts of interest information from individuals who contributed to the content are included in the posted submission.

CADTH

Patient Input Template for CADTH Reimbursement Reviews

Name of Drug: erdafitinib (Balversa)
Indication: Adult patients with locally advanced unresectable or metastatic urothelial carcinoma (UC), harbouring susceptible fibroblast growth factor receptor (FGFR)3 genetic alterations, who have disease progression during or following at least one line of prior therapy including within 12 months of neoadjuvant or adjuvant therapy
Name of Patient Group: Bladder Cancer Canada
Author of Submission: Adam Waiser

1. About Your Patient Group

Bladder Cancer Canada (BCC) was formed in 2009 by two bladder cancer survivors who found that there was no one to talk to about their treatments, experiences and fears. Today, BCC is a registered national charity and the only organization in Canada serving those facing a bladder cancer diagnosis. Our objectives are to help bladder cancer patients and their support teams address the day-to-day issues of this disease; to increase awareness of bladder cancer among the general public and medical community; and to fund research which pursues the diagnosis, treatment and elimination of bladder cancer. www.bladdercancercanada.org

2. Information Gathering

Bladder Cancer Canada (BCC) collected the data for this submission from an online survey. The survey was initially posted in May-June 2024 and was subsequently reposted on September 25th. The survey asked questions about the impact of FGFR3 metastatic urothelial carcinoma on the lives of patients, the effect of current treatments and the patient experience with erdafitinib (Balversa). Potential respondents were identified through messages to the BCC mailing list. Messages were also posted on Facebook, LinkedIn and Twitter as well as the Cancer Connection and Cancer Survivors Network online discussion boards. Many of these posts were shared by the Bladder Cancer Advocacy Network and the World Bladder Cancer Patient Coalition. Nonetheless, BCC found it extremely difficult to identify patients with appropriate experience.

Four people completed the online survey – two in May and two in September. All four had locally advanced unresectable or metastatic urothelial carcinoma with an FGFR3 mutation. However, only two had treatment experience with Balversa. All four respondents are from Canada.

1 person agreed to participate in a telephone interview to elaborate on their survey responses. They had treatment experience with Balversa.

3. Disease Experience

Patient A was diagnosed prior to 2016, Patients B & C were diagnosed in 2022 and Patient D was diagnosed in 2021.

Patient A is receiving their second treatment. Patient B is receiving their third treatment or higher. Patient C was watching and waiting following treatment when the completed the survey in May. Patient D was receiving their second treatment when they completed the survey in May. However, they are now deceased.

The most commonly reported cancer symptoms were: fatigue (75%, n=4) as well as insomnia, neuropathy and decreased mobility (all 50%).

4. Experiences With Currently Available Treatments

Respondents had treatment experience with enfortumab vedotin, gemcitabine, cisplatin, pembrolizumab, carboplatin, docetaxel, doxorubicin, avalumab and pendrolasium.

Respondents were asked to rate their agreement with the statement “My current therapies are able to manage my cancer symptoms” on a scale of 1 (strongly disagree) to 10 (strongly agree). The average score was 4 (n=3), suggesting that current therapies do not adequately manage the respondents’ symptoms. Patient B indicated that it was too soon to comment. Patient C said “Radical cystectomy was thought to be almost curative since there was no sign of spread but I have now had four instances of metastatic disease treated with radiation and little reassurance that I won’t continue to have more.”

The most commonly reported side effects of these treatments were fatigue (75%, n=4) as well as neuropathy and hair loss (50% each).

Patient A reported that they had difficulty accessing treatment due to the travel time.

5. Improved Outcomes

When respondents were asked whether they would be willing to tolerate new side effects from drugs that can control disease progression or improve overall survival on a scale of 1 (will not tolerate side effects) to 10 (will tolerate significant side effects), the average score was 6.25 (n=4), Interestingly, the two respondents with Balversa treatment experience gave lower scores of 4 each, compared to scores of 7 and 10 for the two patients without.

6. Experience With Drug Under Review

Patients A and B were treated with Balversa following at least one line of a programmed death receptor-1 (PD-1) or programmed death-ligand 1 (PD-L1) inhibitor therapy including within 12 months of neoadjuvant or adjuvant therapy

Patient A was treated with doxorubicin, carboplatin and dacetaxel in addition to Balversa. They completed their full course of treatment.

Patient B was treated with gemcitabine, cisplatin, avalumab and enfortumab vedotin prior to receiving Balversa. They have been receiving Balversa for 6 weeks, beginning with a 4mg dose and then increasing to 6mg.

Treatment

On a scale of 1 (much worse) to 5 (much better), respondents were asked to rate how their life had changed on Balversa compared to other therapies that they had received in the following categories:

- Metastatic cancer symptoms
- Drug side effects
- Maintaining quality of life
- Controlling disease progression
- Preventing recurrence

Both respondents scored every category as a 3 except for Patient B who rated Maintaining Quality of Life as a 4, suggesting that Balversa has not made a major difference with either respondent. However, Patient A did indicate that Balversa had helped to manage their insomnia.

Side Effects

Patient A only reported one side effect from Balversa – dysgeusia, while Patient B reported dry mouth, nausea and leg pain.

When asked to rate the tolerability of the side effects of Balversa on a scale of 1 (completely tolerable) to 10 (completely intolerable), Patient A gave a 9 and Patient B gave a 3. Patient B commented “Better than expected in terms of side effects.”

Oral Therapy

Both respondents indicated that taking Balversa orally made their treatment easier. Patient B commented “I like the freedom of it.”

7. Companion Diagnostic Test

n/a

8. Anything Else?

When asked if they would recommend Balversa to other patients with bladder cancer, both respondents said that they would.

Appendix: Patient Group Conflict of Interest Declaration

To maintain the objectivity and credibility of the CADTH reimbursement review process, all participants in the drug review processes must disclose any real, potential, or perceived conflicts of interest. This Patient Group Conflict of Interest Declaration is required for participation. Declarations made do not negate or preclude the use of the patient group input. CADTH may contact your group with further questions, as needed.

1. Did you receive help from outside your patient group to complete this submission? If yes, please detail the help and who provided it.

Adam Waiser, an independent consultant, prepared this submission with the assistance and oversight of Bladder Cancer Canada staff.

2. Did you receive help from outside your patient group to collect or analyze data used in this submission? If yes, please detail the help and who provided it.

Adam Waiser, an independent consultant, created the clinician surveys, oversaw survey distribution and collection, and analyzed the data for this submission with the assistance and oversight of Bladder Cancer Canada staff.

3. List any companies or organizations that have provided your group with financial payment over the past 2 years AND who may have direct or indirect interest in the drug under review.

Table 1: Financial Disclosures

Check Appropriate Dollar Range With an X. Add additional rows if necessary.

Company	$0 to 5,000	$5,001 to 10,000	$10,001 to 50,000	In Excess of $50,000
None				

I hereby certify that I have the authority to disclose all relevant information with respect to any matter involving this patient group with a company, organization, or entity that may place this patient group in a real, potential, or perceived conflict of interest situation.

Name: Michelle Colero
Position: Executive Director
Patient Group: Bladder Cancer Canada
Date: October 16, 2024

CADTH

CADTH Reimbursement Review

Clinician Group Input

CADTH Project Number: PC0375
Generic Drug Name (Brand Name): erdafitinib
Indication: For the treatment of adult patients with locally advanced unresectable or metastatic urothelial carcinoma (UC), harboring susceptible FGFR3 (fibroblast growth factor receptor) genetic alterations, with disease progression during or following at least one line of a programmed death receptor-1 (PD-1) or programmed death-ligand 1 (PD-L1) inhibitor therapy including within 12 months of neoadjuvant or adjuvant therapy. Treatment with BALVERSA® should be initiated following confirmation of a susceptible FGFR genetic alteration using a validated test.
Name of Clinician Group: Ontario Health (Cancer Care Ontario) Genitourinary Cancer Drug Advisory Committee ("GU DAC")
Author of Submission: Dr. Girish Kulkarni

1. About Your Clinician Group

OH(CCO)'s Drug Advisory Committees provide timely evidence-based clinical and health system guidance on drug-related issues in support of CCO's mandate, including the Provincial Drug Reimbursement Programs (PDRP) and the Systemic Treatment Program.

2. Information Gathering

Information was gathered by videocall and finalized through email..

3. Current Treatments and Treatment Goals

Current treatment options are:

- if a patient is post-ICI or chemotherapy, or the combination, they are eligible for enfortumab vedotin

The goal is to improve overall survival.

4. Treatment Gaps (unmet needs)

4.1. Considering the treatment goals in Section 3, please describe goals (needs) that are not being met by currently available treatments.

We need a treatment for patients with genomic alterations. FGFR testing is reimbursed in Ontario and this treatment works for this alteration. So this would be the first targeted therapy identified for this patient population based on molecular testing.

5. Place in Therapy

5.1. How would the drug under review fit into the current treatment paradigm?

Patients who are post ICI, or have a contraindication with an ICI, with FGFR mutations/alterations would be eligible for this treatment.

5.2. Which patients would be best suited for treatment with the drug under review? Which patients would be least suitable for treatment with the drug under review?

Patients who are post ICI, or have a contraindication with an ICI, with FGFR mutations/alterations are best-suited.

5.3 What outcomes are used to determine whether a patient is responding to treatment in clinical practice? How often should treatment response be assessed?

Conventional imaging (CT scan of chest/abdomen/pelvis) as per physician discretion.

5.4 What factors should be considered when deciding to discontinue treatment with the drug under review?

Unacceptable toxicity or clinically significant disease progression.

5.5 What settings are appropriate for treatment with [drug under review]? Is a specialist required to diagnose, treat, and monitor patients who might receive [drug under review]?

Outpatient setting under the advisement of a medical oncologist.

6. Additional Information

In Ontario, there is reflex testing in T3/T4 N+ disease in the localized setting. FGFR testing is also available in the metastatic setting.

7. Conflict of Interest Declarations

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 clinician group input. CADTH may contact your group with further questions, as needed. Please see the *Procedures for CADTH Drug Reimbursement Reviews* (section 6.3) for further details.

1. Did you receive help from outside your clinician group to complete this submission? If yes, please detail the help and who provided it.

   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? If yes, please detail the help and who provided it.

   <Enter Response Here>

3. 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 this is required for each clinician who contributed to the input — please add more tables as needed (copy and paste). It is preferred for all declarations to be included in a single document.**

4. 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 this is required for <u>each clinician</u> who contributed to the input — please add more tables as needed (copy and paste). It is preferred for all declarations to be included in a single document.**

Declaration for Clinician 1

Name: Dr. Girish Kulkarni
Position: Lead, OH (CCO) GU DAC
Date: 19-06-2024

☒ **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.

Table 1: Conflict of Interest Declaration for Clinician 1

	Check appropriate dollar range*			
Company	**$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				
Add or remove rows as required				

* Place an X in the appropriate dollar range cells for each company.

Declaration for Clinician 2

Name: Dr. Aly-Khan Lalani
Position: Member, OH (CCO) GU DAC
Date: 21-06-2024

☒ 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.

Table 2: Conflict of Interest Declaration for Clinician 2

	Check appropriate dollar range*			
Company	**$0 to $5,000**	**$5,001 to $10,000**	**$10,001 to $50,000**	**In excess of $50,000**
Janssen		X		
Add company name				
Add or remove rows as required				

* Place an X in the appropriate dollar range cells for each company.

Declaration for Clinician 3

Name: Dr. Sebastien Hotte
Position: Member, OH (CCO) GU DAC
Date: 27-06-2024

☒ 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.

Table 3: Conflict of Interest Declaration for Clinician 3

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		X		
Add company name				
Add or remove rows as required				

* Place an X in the appropriate dollar range cells for each company.

Declaration for Clinician 4

Name: Dr. Urban Emmenegger
Position: Member, OH (CCO) GU DAC
Date: 27-06-2024

☒ 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.

Table 4: Conflict of Interest Declaration for Clinician 4

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		X		
Add company name				
Add or remove rows as required				

* Place an X in the appropriate dollar range cells for each company.

Declaration for Clinician 5

Name: Dr. Christina Canil
Position: Member, OH (CCO) GU DAC
Date: 26-06-2024

☒ 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.

Table 5: Conflict of Interest Declaration for Clinician 5

	Check appropriate dollar range*			
Company	**$0 to $5,000**	**$5,001 to $10,000**	**$10,001 to $50,000**	**In excess of $50,000**
Janssen		X		
Add company name				
Add or remove rows as required				

* Place an X in the appropriate dollar range cells for each company.

Declaration for Clinician 6

Name: Dr. Chris Morash
Position: Member, OH (CCO) GU DAC
Date: 21-06-2024

☒ 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.

Table 5: Conflict of Interest Declaration for Clinician 6

	Check appropriate dollar range*			
Company	**$0 to $5,000**	**$5,001 to $10,000**	**$10,001 to $50,000**	**In excess of $50,000**
Janssen		X		
Add company name				
Add or remove rows as required				

* Place an X in the appropriate dollar range cells for each company.

Declaration for Clinician 7

Name: Dr. Akmal Ghafoor
Position: Member, OH (CCO) GU DAC
Date: 21-06-2024

☒ 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.

Table 5: Conflict of Interest Declaration for Clinician 7

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				
Add or remove rows as required				

* Place an X in the appropriate dollar range cells for each company.