

## CADTH Reimbursement Review

# Patient Input

ENFORTUMAB VEDOTIN (TBC)  
(Seagen Canada Inc.)

**Indication:** Locally advanced or metastatic urothelial carcinoma

**CADTH received patient input from:**

Bladder Cancer Canada

July 16, 2021

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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 personal information is included in the submission. The name of the submitting patient group and all conflict of interest information are included in the posted patient group submission; however, the name of the author, including the name of an individual patient or caregiver submitting the patient input, are not posted.

## CADTH Reimbursement Review Patient Input Template

Name of the Drug and Indication	Enfortumab vedotin for the treatment of patients with locally advanced or metastatic urothelial cancer (mUC) who have previously received a programmed death receptor-1 (PD-1) or programmed death-ligand 1 (PD-L1) inhibitor and who: have received a platinum-containing chemotherapy in the neoadjuvant/adjuvant, locally advanced or metastatic setting or are not eligible for cisplatin-containing chemotherapy
Name of the Patient Group	Bladder Cancer Canada
Author of the Submission	[REDACTED]

### 1. About Your Patient Group

**BLADDER CANCER CANADA** (BCC) is the first and only Canadian patient advocacy organization dedicated to bladder cancer issues.

The story of Bladder Cancer Canada began with two people who have bladder cancer – David Guttman and Jack Moon. Their medical teams tended to the disease in their bodies, but they realized nourishment for their inner beings was missing – and was just as critical to their recovery. They needed other bladder cancer patients to talk to about their fears and uncertainty. Someone to help them find up-to-date information about diagnosis, treatment options and prognosis. At that time, there was no one to turn to. So, in 2009, they formed BCC to fill the void.

Today, BCC is a nationally-registered Canadian charity. Supported by a Medical Advisory Board and a Medical Research Board consisting of the top bladder cancer specialists across Canada, its mission aims to help bladder cancer patients and their support teams address the day-to-day issues of this disease; increase awareness among the general public and medical community; and fund research into the diagnosis, treatment and elimination of the disease. BCC's vision is patient support, awareness and research to create a world where bladder cancer is just a memory.

Connect with Bladder Cancer Canada at [www.bladdercancercanada.org](http://www.bladdercancercanada.org).

### 2. Information Gathering

The information was gathered through an online survey and telephone interviews. All of the data was contributed anonymously.

Bladder Cancer Canada (BCC) developed and designed a 20-minute online survey that was disseminated in English only. Recruitment was undertaken by BCC through social media, e-newsletters and other online platforms, as well as direct email to physicians, patients and caregivers. The online survey was open between May 27 and June 11, 2021. All of the 38 patients and 6 caregivers who completed the survey reported being diagnosed or a caregiver to someone diagnosed with Stage II or

higher muscle-invasive bladder cancer. One-third of patients said they were living with locally advanced or metastatic bladder cancer, and two-thirds of caregivers reported caring for someone with advanced or metastatic disease. The same percentage of patients (40%) reported either having or not having previously received platinum-based chemotherapy. Of those who had received platinum-based chemotherapy, 44% said their cancer did not progress (i.e. it stabilized or improved), while 22% said that their cancer did progress after receiving chemotherapy. The majority of survey respondents were from Canada, with a small number from the U.S.

Telephone interviews were conducted in June 2021 with two patients from Canada who had experience on enfortumab vedotin.

### 3. Disease Experience

While some survey respondents reported that having bladder cancer has had a minimal impact on their day-to-day lives, many patients and caregivers mentioned that fatigue, lack of sleep, and loss of strength and stamina were problematic, but manageable to a greater or lesser extent. The most commonly mentioned impacts on day-to-day life were related to continence issues, including frequent need for urination and loss of control, urostomy and catheter management, and urinary tract infections. One caregiver said that due to frequent “accidents,” she and her husband have become less social. Some patients and caregivers also mentioned that day-to-day activities take more time and planning, and can even be uncomfortable for some – such as walking, sitting, driving, sleeping, getting dressed and wearing clothing. Caregivers mentioned that they were constantly worried for their loved ones and were no longer able to plan anything ahead of time. One caregiver said they had become the sole earner, as her loved one was no longer able to work, and another provided in-home care to her husband, helping to manage his chronic pain caused by bladder cancer. Some patients reported that their mental health has been impacted by living with bladder cancer, leading to a loss of confidence, avoidance of leaving home/going out, loss of employment and fear of looking for another job, and reduced intimacy. It was also noted by some respondents that the COVID-19 pandemic has exacerbated the day-to-day impacts of living with bladder cancer. And finally, financial impacts were mentioned related to the costs of catheter and urostomy supplies that are not covered by some provincial governments – in some cases putting additional strain on already limited financial resources.

- *“My biggest peeve is that Pharmacare WILL NOT pay for my catheters. They will pay for all other ostomy supplies, BUT NOT CATHETERS!! No one should have to pay to pee!!”*
- *“Urostomy supplies strain my already limited financial resources.”*
- *“Everything takes more time and planning. Clothes are uncomfortable. Bending is uncomfortable.”*
- *“I completely lost my confidence avoid going anywhere, lost my job and don't dare to apply for another as I need to go to empty my bag.”*
- *“When my husband was first diagnosed, day-to-day tasks were hard. Between all the appointments and COVID restrictions it was terrible. Chemo was hard, and I wanted to be close by but was unable to. Now, he is on Immunotherapy every 6 weeks and doing well.”*

When asked about the impact of bladder cancer on their quality of life, the responses ranged from “not much” to “I have no life.” One caregiver said their “life has been shattered.” Fatigue was the most commonly reported symptom of bladder cancer by both patients and caregivers, followed by blood in the urine, pain in the abdomen and bones, decreased mobility and difficulty/pain when urinating. Recovery from surgery was difficult for many respondents, having a major impact on quality of life for months to years following the surgery. Pain – extreme in some cases – was mentioned by patients and caregivers alike as being a very difficult aspect of bladder cancer to manage. Many people cited frequent urinary tract infections as having a significant and sustained impact on their quality of life, and in some cases life-threatening, when the infections led to hospitalization due to sepsis or kidney problems. One patient whose ureters were both blocked by tumours underwent surgery to insert bilateral nephrostomy tubes and bags through their back. Side effects from treatment – such as chemotherapy and immunotherapy –

were also mentioned as impacting patients' quality of life, leaving them to cope with nausea, fatigue, pain, a weakened immune system and reduced mobility – or causing them to discontinue treatment altogether.

- *“Were at a stop presently. We were going to retire and enjoy our grandkids. We feel numb now, our life has been shattered.”*
- *“During 5 years, I was always having UTIs and had to rush to hospital every time. My quality of life was very difficult. I had to stay home just in case and I had problems with my kidney every time I had a UTI.”*
- *“Fear and stress can get me down. Many doctors' appointments and scans are a continual reminder the cancer could reappear elsewhere.”*

#### 4. Experiences With Currently Available Treatments

Regarding patients' response to platinum-based chemotherapy, 39% of respondents said they had previously received this form of treatment and among them, 44% reported that their bladder cancer did not progress, while 22% said that it did progress after receiving platinum-based chemotherapy. Of the currently available pharmaceutical treatments for bladder cancer, survey respondents specifically mentioned having received one or more of the following: Platinol (cisplatin) – 47%; Gemzar (gemcitabine) – 18%; Keytruda (pembrolizumab) – 16%; and Paraplatin (carboplatin) – 7%. Imfinzi (durvalumab), Adriamycin/Rubex (doxorubicin), and Trexall (methotrexate) were each mentioned by 3% of patients. Other treatments mentioned by survey respondents include Bacillus Calmette-Guerin (BCG) and vinblastine.

In addition to pharmaceutical interventions, respondents also mentioned receiving radiation therapy and surgery, including TURBT (transurethral resection of bladder tumour) and full/partial cystectomy, and some reported that they were being monitored and had not yet received any treatment for their bladder cancer. The extent and duration of efficacy of the various bladder cancer treatment modalities and combinations varied widely among survey respondents. Some reported that their cancer was gone following chemotherapy alone, or with radiation and TURBT (tri-modal therapy), and others have found success with immunotherapy, including in reducing metastases. For some patients, bladder removal surgery (full/partial cystectomy) was successful in eliminating the cancer, while others required additional treatment following surgery. A few patients shared that a full cystectomy was not successful in stopping tumour growth and that other forms of treatment were not able to stop the cancer from metastasizing. Others expressed frustration with having to undergo various treatments with significant side effects, only to end up having to have their bladder removed after all. One caregiver felt that a standard of care for the treatment of bladder cancer was needed across the country.

When asked what side effects patients experienced from treatments for bladder cancer, the following were mentioned by patients/caregivers: fatigue (67%/100%), constipation (48%/67%), low blood cell count (39%/67%), loss of appetite (36%/50%), neuropathy (27%/33%), nausea (27%/67%), hair loss (24%/33%), insomnia (21%/17%), diarrhea (18%/17%), mouth sores (6%/17%), and vomiting (3%/17%), as well as skin problems, shortness of breath, hearing loss/tinnitus, and incontinence. Surgery was mentioned by many respondents as being extremely difficult and involving a lengthy and very painful recovery. People reported being able to manage side effects of treatment by resting, “waiting it out,” taking naps/sleeping more, taking medications for symptom management (including opioids for pain), leading a more sedentary lifestyle, taking time off work, and by having a positive and a supportive home life.

The majority of respondents said they have had no difficulties accessing treatment for bladder cancer, however, some mentioned they did have difficulties due to: the travel distance to access treatment (8%); the cost of treatment (5%); the treatment being unavailable in Canada (5%); not having access to a physician (5%); and requiring time off work to receive treatment (3%). One patient mentioned that if they hadn't been able to take early retirement, they would have had to quit their job due to their treatment regimen. Additionally, the COVID-19 pandemic has made it difficult for some patients to reach their

doctors and one caregiver reported that their loved one's surgery was cancelled and then rescheduled a few weeks later due to COVID.

With respect to the financial impact of undergoing treatment for bladder cancer, just over two-thirds of patients and caregivers indicated they hadn't experienced any financial challenges. Of those who said they had experienced financial challenges as a result of being treated for bladder cancer, costs related to reduced income due to work absence, travel, parking, accommodations, medications, and homecare were mentioned. One caregiver noted that having Short Term Disability benefits was helpful while her husband was receiving chemotherapy and unable to work. In addition to some patients in certain provinces having to cover some of the costs of urostomy and catheter supplies (as mentioned in Section 3), one patient added that paying out-of-pocket for a costly diagnostic CT scan because of long wait-times at public facilities in their province.

- *“Surgical bladder removal unsuccessful as the tumour had enveloped the left femoral artery and was too risky to try surgery. Next tried immunotherapy, but the drug used boosted my immune system, causing a flare up of my rheumatoid arthritis symptoms, so that was discontinued. I then had six radiation treatments which, as evidenced by two subsequent CT Scans, has stopped the tumour growth, so far. Another treatment was explored but my tumour didn't have a certain mutation and so I didn't qualify for it.”*
- *“My cancer is gone, but the residual loss of kidney function is not good. I am not a candidate for at home dialysis if my kidney function goes lower because of my Indiana pouch.”*
- *“During radiation treatments, I had to urinate every hour or so. Lack of sleep is my main problem. During my two chemo cycles, I had absolutely no energy and could barely walk across the street. TURBTs were painful, and the catheter is very uncomfortable.”*

## 5. Improved Outcomes

When asked what improvements patients and caregivers would like to see if enfortumab vedotin was accessible to them as a treatment for bladder cancer, they mentioned: slowing or stopping the disease from progressing, recurring and spreading; a reduction in pain; fewer/no infections; reduced fatigue, increased energy level/strength; improved mental health; reduced impairment of sexual functionality; avoidance of surgery (cystectomy); improved continence/urination control; to go into remission/be cured; and overall, patients and caregivers hoped for fewer/less severe side effects than experienced with bladder cancer treatments currently in use.

Assuming that the desired improvements were provided through treatment with enfortumab vedotin, respondents were asked how their day-to-day life and quality of life as patients/caregivers would be different. People mentioned they would be able to go for a walk and no longer fear leaving the house, and that they would be able to help around the house (i.e. cutting the grass, meal preparation) and participate in family activities. They also mentioned being able to get a longer and continuous night's sleep, drive for longer periods of time, and travel to visit family. Additionally, respondents said that their outlook on life would be more positive and they would be able to plan for the future – with one person “life would improve immensely.” One patient also noted that “if [enfortumab vedotin] can help more patients avoid surgery, it's well worth the cost, as surgery (cystectomy) is quite life-changing.”

- *“I would expect an increase in physical strength and a decrease in fatigue and shortness of breath. I would hope to be able to go on walks with my wife, participate in family activities, and travel to visit family (assuming Covid is under control or eliminated).”*
- *“I'd have more mobility and be able to do pretty much what I'd like, including the ability to drive for up to two-four hours at a time. Increased amount of continuous sleep would be nice (not having to urinate every 1-2 hours).”*

- *“Any new drug or advance in treatment of bladder cancer will directly affect me as a caregiver. It would hopefully give me more time with my husband, affect his quality of life and ease my state of mind.”*

## 6. Experience With Drug Under Review

Two patients were interviewed regarding their experiences with enfortumab vedotin. Both live in Canada and accessed the treatment through a clinical trial, and both have been on treatment for more than two years. One of the two patients first learned about the treatment from a family member in the U.S. and then contacted her physician to find out if there were any clinical trials in Canada that she might qualify for.

By way of comparison with other treatments, the patients interviewed said that past treatments they had received had left them feeling nauseous, tired and weak. One patient noted that while on other treatments, she often had “bad days” when all she wanted to do was sit all day, or stay in bed. And on two occasions, the fatigue and weakness from her previous treatments was so extreme that friends from England flew to Canada to help her husband take care of her, because he was overwhelmed. One patient also experienced vision problems from one treatment which temporarily prevented him from performing his job.

With respect to any disadvantages of treatment with enfortumab vedotin, one of the two patients interviewed said that the only side effect she could think of was itchy skin, described as “more of a nuisance than anything else,” which she manages with Benadryl, as needed. The other patient interviewed mentioned hair loss, alterations to sense of taste, nausea and skin sores which he noted were temporary and resolved over time. This same patient also said that he continues to experience numbness and tingling in his hands due to neuropathy and some gastrointestinal (GI) upset from time to time; however, he feels these side effects haven’t been as bad as those experienced on other treatments. He manages them by reducing his hours at work as needed for the neuropathy, and by taking an antacid to address any GI issues.

Also as compared with other treatments for bladder cancer, the benefits of enfortumab vedotin that were mentioned by the patients interviewed included a shorter treatment schedule, shorter time in hospital for each treatment, and fewer side effects. One patient commented that enfortumab vedotin is “very easy on the body,” and both remarked that their energy levels were much improved on enfortumab vedotin, as compared with the extreme fatigue they experienced on other treatments.

When asked what key values about enfortumab vedotin have been important to them as patients, they said that the treatment has made a “huge difference” in their life and has given them their “life back again” – allowing them to resume the activities that they enjoy, such as cooking, gardening, taking short road trips, and playing guitar in a rock band. One patient recalled that when he was first diagnosed, he had to make a choice to live or to die – and he chose to live. Of all of the treatments he’s been on, he says that enfortumab vedotin is “by far the best” – the treatment shrunk his tumour (he has had a complete response to therapy) and it has helped him survive bladder cancer thus far.

## 7. Companion Diagnostic Test

N/A

## 8. Anything Else?

Based on the interviews conducted and some of the survey responses, it is important to patients to have publicly funded access to enfortumab vedotin. One patient commented that all the other treatments he tried before enfortumab vedotin were a waste – both to him and to the healthcare system in terms of their expense. He suggested that the savings gained from not using an ineffective treatment on patients could go towards funding enfortumab vedotin. This patient also pointed out that because the treatment has allowed him to live longer and keep working, he is able to continue paying his taxes.

- *“My bladder has been removed. However, having lived with bladder cancer for 10 years, I would hope that all current and future Bladder cancer patients would have access to Padcev [enfortumab vedotin] and the cost be covered under the applicable government program. As a patient I was focussed on being positive. As a caregiver, my wife was under significant stress and she felt helpless.”*

## 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.

Advocacy Solutions, experts in healthcare advocacy, provided best practices for data collection, consultation and discussions with our patient group.

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.

Advocacy Solutions collected the responses from our patient group and provided analysis on the results.

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.

Company	Check Appropriate Dollar Range			
	\$0 to 5,000	\$5,001 to 10,000	\$10,001 to 50,000	In Excess of \$50,000

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, Bladder Cancer Canada  
 Patient Group: Bladder Cancer Patients & Caregivers  
 Date: July 12, 2021



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
EMD Serono (Indirect)	x			
Pfizer Canada (Indirect)	x			
Verity Pharmaceuticals (Indirect)	x			
Merck Canada (Indirect)			x	
Ferring Canada (Indirect)			x	
Astra Zenica (Indirect)			x	
Bristol Myers Squibb (Indirect)			x	
Seagen (Indirect as the funding was from the pat-ed fund)			x	