

## CADTH Reimbursement Review

# Patient Input

**sacituzumab govitecan (TBC)**  
(Gilead Sciences Canada, Inc.)

**Indication:** Locally advanced or metastatic triple-negative breast cancer

**CADTH received patient input from:**

Canadian Breast Cancer Network  
Rethink Breast Cancer

**July 23, 2021**

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## CADTH Reimbursement Review Patient Input

<b>Name of the Drug and Indication</b>	Sacituzumab govitecan ( [REDACTED] ) for the treatment of patients with triple-negative, locally advanced/metastatic breast cancer who have received two prior lines of therapy for metastatic disease.
<b>Name of the Patient Group</b>	Canadian Breast Cancer Network
<b>Author of the Submission</b>	[REDACTED]
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### 1. About Your Patient Group

The Canadian Breast Cancer Network (CBCN) is a leading, patient-directed, national health charity committed to ensuring the best quality of care for all Canadians affected by breast cancer through the promotion of information, education and advocacy activities. [www.cbcn.ca](http://www.cbcn.ca)

As a member of the Canadian Cancer Action Network, the Canadian Breast Cancer Network is committed to adhering to the Code of Conduct Governing Corporate Funding.

### 2. Information Gathering

Information for this submission was collected via:

**CBCN's 2017 [Lived Experience Breast Cancer Patient Survey](#):** An online survey was distributed in English and French to patients living with breast cancer. No patients surveyed had direct experience with the treatment under review. Survey questions comprised of a combination of scoring options and free form commentary. Patients were contacted through the membership databases of CBCN and other patient organizations.

#### **Patient Respondents Profile:**

157 Canadian metastatic patients participated in the survey. In this submission, CBCN specifically utilizes the data provided by the 14 patients who identified as having metastatic triple negative breast cancer (mTNBC).

The respondents all identified as female and all spoke English as a first-language. The majority of respondents were from Ontario (6) and British Columbia (2). The rest of the respondents were from New Brunswick (1), Alberta (1), Quebec (1), Nova Scotia (1), Saskatchewan (1) and Newfoundland and Labrador (1).

Most of the respondents (5) were between the ages of 50-59 when they were diagnosed with metastatic breast cancer, 4 respondents were in the 40-49 age range, 3 were between 30-39 years, and 2 were between 60-69 years of age.

All but 1 respondent was in a relationship. 13 of the mTNBC patients had children, with the majority (7) having children 20 years or older. 4 had children between the ages of 13-19, 3 had children 2-5 years of age, and 3 had children between 6-12 years old.

**CBCN's 2012 [Lived Experience of Metastatic Breast Cancer Patients and Caregivers Survey Report](#):** An online survey, conducted in collaboration with ReThink Breast Cancer, was distributed to patients living with metastatic breast cancer (mBC) and their caregivers. No patients surveyed had experience with the treatment under review. Survey questions comprised of a combination of scoring options and free form commentary. Patients were contacted through the membership databases of CBCN and other patient organizations.

**Key informant interviews:** A phone interview were conducted in June 2021 with a Canadian metastatic breast cancer patients living with metastatic triple negative breast cancer that had direct experience with the treatment under review.

**Printed sources:** A review was conducted of current studies and grey literature to identify issues and experiences that are commonly shared among many women living with breast cancer.

### 3. Disease Experience

Metastatic breast cancer is the spread of cancerous cell growth to areas of the body other than where the cancer first formed, and is often more severe. It is most commonly spread to the bones, but can include the lungs, liver, brain and skin. Current treatment options for metastatic breast cancer are only effective at prolonging progression-free disease, and most cases of advanced disease will progress and symptoms will worsen. Patients with a diagnosis of metastatic breast cancer understand the limitations of current treatment options and seek to live their remaining months and years with the best possible quality of life that they can achieve.

Triple negative breast cancer (TNBC) is an aggressive form of breast cancer whose growth is not driven by estrogen, progesterone, or by the overexpression of HER2 (human proteins epidermal growth factor receptor). While anyone can be diagnosed with triple negative breast cancer, this subtype of breast cancer has been found to be

higher in young people, Black and Hispanic women, and those with a BRCA1 mutation.<sup>1</sup> Individuals in Canada, and in general, who are diagnosed with TNBC have a poor prognosis and poor survival outcomes. According to the American Cancer Society, the 5-year survival rate is 65% for regional mTNBC and 12% for distant mTNBC. This is compared to the 5-year survival rate for localized TNBC.<sup>2</sup>

In our 2017 Survey, the majority of respondents experienced metastases to their bones, liver and lungs. 12% of metastatic patients reported metastases to their brain while 20% reported metastases to other body parts. Of the 14 patients who indicated that they are living with mTNBC, the majority of respondents (10) experienced metastases to their lungs. This was followed by metastases to other parts of their bodies (6), their bones (5), their liver (3) and their brain (2).

### **The Physical Impact of Metastatic Breast Cancer**

How the disease presents itself through symptoms, how it progresses, and how it is experienced varies by patient, but many effects of metastatic breast cancer represent a significant or debilitating impact on their quality of life. In our 2012 Lived Experience of Metastatic Breast Cancer Patients and Caregivers Survey Report (2012 Survey), patients were asked what impact cancer-related symptoms had on their quality of life:

- 54% of patients reported that fatigue resulted in a significant or debilitating impact, and 40% reported some or moderate impact;
- 39% of patients reported that insomnia resulted in a significant or debilitating impact, and 46% reported some or moderate impact;
- 37% of patients reported that pain resulted in a significant or debilitating impact, and 44% reported some or moderate impact.

These results were further reinforced in our 2017 Lived Experience Breast Cancer Patient Survey (2017 Survey).

### **The Social Impact of Metastatic Breast Cancer**

The impact of this disease spreads across all aspects of a patient's life, restricting an individual's employment and career, ability to care for children and dependents, and their ability to be social and meaningfully participate in their community. When asked in the 2012 Survey what kind of impact living with metastatic breast cancer has had on their quality of life:

- Among those who were employed, 71% of patients identified significant restrictions to their ability to work;
- Among those with children or dependents, 21% identified significant restrictions and 53% reported some or moderate restrictions to their caregiving responsibilities;

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<sup>1</sup> Triple-Negative Breast Cancer. *Breastcancer.org*. Accessed June 28, 2021.  
<https://www.breastcancer.org/symptoms/types/triple-negative>

<sup>2</sup> Triple-negative Breast Cancer. *American Cancer Society*. Accessed June 28, 2021.  
<https://www.cancer.org/cancer/breast-cancer/understanding-a-breast-cancer-diagnosis/types-of-breast-cancer/triple-negative.html>

- 49% of patients identified significant restrictions and 38% identified some or moderate restrictions to their ability to exercise;
- 42% of patients identified significant restrictions and 42% identified some or moderate restrictions to their ability to pursue hobbies and personal interests;
- 41% of patients identified significant restrictions and 41% identified some or moderate restrictions to their ability to participate in social events and activities;
- 22% of patients identified significant restrictions and 52% identified some or moderate restrictions to their ability to spend time with loved ones.

Other experiences identified by patients included: guilt, the feeling of being a burden on caregivers, fear of death, poor body image, not knowing what functionality will be lost, fear of the impact of cancer and the loss of a parent on children, not knowing what will happen to children, the loss of support of loved ones, as well as marital stress/loss of fidelity and affection from husband.

#### 4. Experiences With Currently Available Treatments

##### The Goals of Current Therapy

As with all treatment for metastatic breast cancer, the goal of treatment for metastatic triple negative breast cancer is to control disease progression (extending life) and to manage cancer-related symptoms (extending or stabilizing quality of life). Treatment options for mBC and their effectiveness vary among type of cancer, location of cancer, and how symptoms are experienced.

Patients diagnosed with mTNBC have very limited treatment options. Targeted therapies that treat HR-positive and HER2-positive breast cancers are usually ineffective in treating TNBC. Because of the lack of effective treatment options for mTNBC, patients with this subtype of metastatic breast cancer face much lower overall survival (OS) rates than patients with other subtypes of metastatic breast cancer.

Currently, treatment for TNBC is very limited and usually involves chemotherapy, surgery and radiation. In the case of mTNBC however, the standard of care is single-agent chemotherapy. Unfortunately, as the disease continues to progress and treatment stops responding, individuals must move to second- and third-line treatments, making their treatment options even more limited as they require newer lines of treatment.

While immunotherapy can be helpful as a first-line treatment, single-agent chemotherapy is the standard treatment beyond first-line therapies but it is associated with low response rates (<20%) and short median progression-free survival (2-3 months).<sup>3</sup> Eribulin is usually used for previously treated mTNBC but its PFS is low (>3 months).<sup>3</sup> In addition to this, chemotherapy in general has a very high toxicity profile and is often associated with significant adverse events.

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<sup>3</sup> Bardia, A., et al. Sacituzumab Govitecan in Metastatic Triple-Negative Breast Cancer. *N Engl J Med.* 384, 1529-41 (2021). (2016). <https://doi.org/10.1056/NEJMoa2028485>

All of the 14 mTNBC patients had been or were currently being treated with chemotherapy, 11 patients previously had surgery, 12 patients had or were receiving radiation therapy and 2 patients had or were currently receiving hormone therapy.

### **Key Factors for Decision-Making Around Treatment**

Respondents in our 2017 Survey indicated that the following key factors influenced their decision-making around treatments:

1. Effectiveness of the treatment – how well the treatment stabilized their disease and delayed progression of their disease.
2. Prolonging life without sacrificing quality of life – being able to maintain productive, active lives with minimal disruption to daily routines.
3. Side effect management – minimizing risk while stabilizing their disease.
4. Cost and accessibility of treatments – affordability and ease of accessing treatments.

### **Treatment efficacy:**

When asked how important progression-free survival was in considering treatments, the mTNBC patients in our 2017 Survey revealed that efficacy of the treatment is an important consideration to their decision-making. 69% of the 13 mTNBC who responded to the question indicated that progression-free survival of less than 3 months was important or very important. 86% of the 13 mTNBC who responded to the question indicated that progression-free survival of 3-5 months was important or very important. Of all of the 14 mTNBC in our 2017 Survey, 85% indicated that progression-free survival of 6 months or longer very important. When asked about overall survival, 85% of all mTNBC patients indicated that overall survival was very important when considering treatment options.

Metastatic patients in our 2017 Study also spoke on the importance of treatment effectiveness in their decision-making anecdotally:

*“The most important factors for me are progression free survival and quality of life.” – mBC patient respondent*

*“Quality of life, efficacy of the drug to stabilize my TNBC” – mTNBC patient respondent*

*“Anything to prolong my survival and maintain quality of life.” – mBC patient respondent*

*“Survival is of utmost importance to me.” – mBC patient respondent*

### **Quality of life:**

Quality of life was routinely cited by patients as a key factor in making treatment decisions. In our 2017 Survey, 93% of the mTNBC patients revealed that quality of life was important or very important to them when considering treatment options.

More specifically, 50%, 93% and 57% of mTNBC patients indicated that minimal side effects, mobility, and productivity, respectively, were important or very important considerations when making decisions regarding treatment options.

This concern was reiterated anecdotally:

*“Making sure I have some quality of life so I can [spend] as much time with my kids and family I don’t want them to watch me suffer” – mTNBC patient respondent*

*“Trying to balance the most effective treatment regime with the least impact on my day to day living/quality of life. Maintaining a certain level of independence is important to me.” – mTNBC patient respondent*

*“Definitely the balance of quality of life vs side effects with the [effectiveness].” – mTNBC patient respondent*

#### **Patient willingness to tolerate treatment side effects:**

In our 2012 Metastatic Patient and Caregiver Survey, the responses to what level of side effects and how much impact on one’s quality of life would be worth extending progression-free disease by six months was shown to be determined at the personal level.

When asked to rate how much impact different symptoms of cancer and cancer treatment would be considered tolerable:

- Almost two-thirds of patients indicated that when it comes to **fatigue, nausea, depression, problems with concentration, memory loss, diarrhea and insomnia**, some or a moderate impact on one’s quality of life would be considered acceptable, and approximately one quarter of patients indicated that a strong or debilitating impact would be considered acceptable.
- 70% of patients indicated that when it comes to **pain**, some or a moderate impact on one’s quality of life would be considered acceptable, and 27% of patients indicated that a strong or debilitating impact would be considered acceptable.

Similar responses were also found in our 2017 Survey. The majority of mTNBC respondents who responded to the question on acceptable side effects (13) indicated that **pain, fatigue, nausea, insomnia, lack of concentration, memory loss, diarrhea, and hair loss** were somewhat acceptable or very acceptable symptoms in exchange for 6 months or less of benefits from breast cancer treatment. The majority of mTNBC respondents indicated that **depression** as a symptom in exchange of 6 months or less of benefits from breast cancer treatment was somewhat acceptable (9 respondents). When it came to the symptom of **vomiting**, 10 mTNBC (the majority) indicated that it would not be acceptable (2 said it would be somewhat acceptable).

### **The financial burden of treating and managing breast cancer:**

The financial burden associated with living with advanced breast cancer extends far beyond any loss of income during a temporary or permanent absence from employment. In addition to the loss of income during illness, metastatic breast cancer patients can incur substantial costs associated with treatment and disease management. Research on the financial impact of breast cancer on patients identified the following:<sup>4</sup>

- 80% of breast cancer patients report a financial impact due to their illness.
- 44% of patients have used their savings, and 27% have taken on debt to cover costs.

These findings were consistent with the responses in our 2012 Survey:

- Nearly one-third of patients indicated that the **cost of medication, the cost of alternative treatments (i.e. massage, physiotherapy, etc.) to manage symptoms and side effects, and the time required to travel to treatment** had a significant or debilitating impact on their quality of life.
- 24% of patients indicated that the **costs associated with travel** had a significant or debilitating impact on their quality of life, and 41% of patients indicated that it had some or moderate impact on their quality of life.

In our 2017 Survey, mTNBC patients reported that their diagnosis had some (57%) or a very large (43%) impact on their finances. In addition to this, 79% of mTNBC indicated that the **time required to travel to treatment** had some or a significant impact of their quality of life. 71% reported the same in regard to the **cost of other treatments** (i.e. massage, physiotherapy, etc.) and 79% reported the same in regard to **costs associated with travel**.

The financial impacts of a metastatic breast cancer diagnosed was also reiterated anecdotally:

*“Many of the next step treatments are very expensive [and not covered by government programs] and it is a HUGE struggle to get [coverage]. [...] When dealing with an incurable disease the last thing you want to have to do is spend time on a letter writing campaign to argue about whether or not you should receive the drugs [recommended by your physician]. At about \$1500.00 a week, I don't know many who can afford that.” – mBC patient respondent*

*“Always a concern as you never know if the next drug will be covered or how long it takes to get approval from private coverage. Many times it delays treatment and this weighs on one's mind.” – mTNBC patient respondent*

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<sup>4</sup> Janet Dunbrack, Breast Cancer: Economic Impact and Labour Force Re-entry. Canadian Breast Cancer Network, 2010



*“I wanted to try [immunotherapy], but it is [\$]7500.00 every 3 weeks not covered by private insurance, now will probably have to go on chemo again, and the last ones were very hard on me causing toxicity and having to get blood transfusions.” – mTNBC patient respondent*

*“Just because I am not in the lowest income bracket does not mean I don't need assistance. I am excluded from all programs I have tried to access.” – mTNBC patient respondent*

Other financial barriers that metastatic breast cancer patients mentioned include: not qualifying for insurance at work, inability to change employers due to loss of insurance, and the prohibitive cost of new treatment options.

### **Patient Access to Local Resources and Supports During Treatment**

When living with cancer, many patients experience significant barriers and challenges around availability of health care services and quality childcare in their community. In response to the 2012 Survey questions about the availability of supports such as childcare, transportation and alternative treatments in their community:

- Among patients with children or other dependents, 53% indicated that there is minimal or no access **to appropriate care for their loved ones** when they are experiencing debilitating symptoms related to their cancer, and 40% identified barriers to accessing quality care during cancer treatment.

Similar results were found in our 2017 Survey among mTNBC with children at the time of their diagnosis:

- 7 patients reported that finding **appropriate care for their children/dependents when experiencing side effects** of cancer treatments was not accessible
- 7 patients indicated that finding **appropriate care for their children/dependents during cancer treatment** was not accessible

Among all mTNBC patients from our 2017 Survey, 43% indicated that finding symptom management options in or around their community was not accessible and 36% indicated that it was somewhat accessible.

### **Patient Willingness to Tolerate Risk**

When asked in the 2012 Survey about their willingness to tolerate risk with a new treatment:

- 34% of respondents were willing to accept serious risk with treatment if it would control the disease
- 45% of respondents were willing to accept some risk with treatment
- 21% of respondents were very concerned and felt less comfortable with serious risks with treatment

### **Need for Personal Choice**

The open ended question and the key informant interviews showed is that it is imperative that women with metastatic breast cancer have access to, and the option of

what drugs they take. Most patients are well aware of the adverse effects of treatment up front and they want to make a personal choice that works for them. 57% percent of mTNBC patients in our 2017 Survey expressed being very comfortable in treatment decisions. Metastatic breast cancer patients expressed the need for personal choice and autonomy in our 2012 Survey as well as in the 2017 Survey:

*“I think patients (ESPECIALLY young patients) should be given more decision making power in terms of access to radical treatments to control disease. [...] With two small [children] I am determined to access any treatment that can extend my life and I hate struggling with doctors for this access.” – 2012 Survey*  
*“I believe that I would prefer to tolerate severe restrictions in the quality of my life, if it meant that I would be able to have a longer period without progression.” – 2012 Survey mBC patient respondent*

*“It would be nice to have more choices and more information about them. I was lucky to get on a clinical trial perhaps because my oncologist was a research oncologist and involved in many. While I knew friend and acquaintances that had Stage IV BC and never informed of clinical trials, and sadly several did not survive the disease.” – 2017 Survey mBC patient respondent*

*“I am frustrated that ALL the treatment choices aren't given to me... I am told what I am taking next with no option or discussion on other options. My oncologist has assured me there are many treatments available, but have never shared which, so I have to turn to Facebook groups for guidance.” – 2017 Survey mTNBC patient respondent*

## 5. Improved Outcomes

For metastatic patients, extension of progression-free survival (PFS) is of critical concern. Like any other treatment for metastatic breast cancer, patients have an expectation that sacituzumab govitecan (██████████) will extend their progression-free survival with good quality of life when first- and second-line therapies stop working.

The phase 3 ASCENT trial evaluated and compared sacituzumab govitecan with the treatment of physician's choice of a single-agent chemotherapy (eribulin, vinorelbine, capecitabine, or gemcitabine) in patients with relapsed or refractory metastatic triple-negative breast cancer.<sup>3</sup>

For patients without brain metastases, Phase 3 of the ASCENT trial showed a median PFS of 5.6 months for sacituzumab govitecan and a median PFS of 1.7 months for the comparison group. Median overall survival (OS) was 12.1 months with sacituzumab govitecan and 6.7 months with chemotherapy. For the full study population (those with or without brain metastases), median PFS was 4.8 months with sacituzumab govitecan compared to a median PFS of 1.7 months with chemotherapy. Median overall survival (OS) for sacituzumab govitecan was 11.8 months and 6.9 months with chemotherapy.

Around 20% of patients who are diagnosed with TNBC are 65 years and old.<sup>5</sup> These individuals are also less fit for chemotherapy because of higher comorbidity rates, higher use of medications, and pre-existing frailty or functional loss.<sup>5</sup> As a result, older patients are more likely to receive less aggressive treatment for TNBC. To assess safety and efficacy outcomes of patients 65 years and older, a post-hoc subgroup analysis of phase 3 of the ASCENT data looked at patients 65 years and older without known brain metastases at baseline.<sup>5</sup> This subgroup analysis found that patients 65 years and older who received sacituzumab govitecan had significant survival and clinical benefits compared to those in the control group who received the treatment of the physician's choice. For those 65 years and older, median PFS was 7.1 months compared to 2.4 months and median OS was 15.3 months compared to 8.2 months.

### **Adverse Effects**

The phase 3 data from the ASCENT trial showed a few adverse effects in patients. Commonly reported side effects of any grade were: neutropenia, diarrhea, nausea, alopecia, fatigue, and anemia. Commonly reported side effects of grade 3 or higher were: neutropenia, leukopenia, diarrhea, anemia, and febrile neutropenia. 39 patients (15%) treated with sacituzumab govitecan reported serious adverse events.

In the subgroup analysis of the ASCENT trial, the safety profile of sacituzumab govitecan in patients 65 years and older was found to be comparable and as manageable as that among patients younger than 65 years old.<sup>5</sup> Treatment discontinuation due to adverse events was 2% in both groups and there were no treatment-related deaths for either groups. While dose reductions happened more within patients 65 years and older compared to patients younger than 65, these rates were similar between sacituzumab govitecan and the treatment of physician's choice in the control group. Despite dose reductions, there was no considerable impact on efficacy of sacituzumab govitecan.

### **Impact of Treatment Options to Patients**

By delaying the progression of the disease, this treatment can relieve cancer-related symptoms, and improve a patient's quality of life. When living with no or with minimal cancer-related symptoms, and with minimal side effects from treatment, patients are able to reduce the impact of cancer on their ability to care for children and dependents, continue with their employment and earn income, spend time with loved ones and participate in their life in a meaningful way by engaging in social activities, travelling, maintaining friendships, and pursuing personal interests.

### **Value to Patients**

The value to patients of extending the time that their cancer is progression-free cannot be overestimated. Patients living with metastatic breast cancer are aware that their advanced disease will progress with worsening symptoms until death, and embrace

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<sup>5</sup> Kalinsky, K., et al. Outcomes in Patients Aged  $\geq 65$  Years in the Phase 3 ASCENT Study of Sacituzumab Govitecan in Metastatic Triple-Negative Breast Cancer. *J Clin Onc.* 39 (2021). [https://doi.org/10.1200/JCO.2021.39.15\\_suppl.1011](https://doi.org/10.1200/JCO.2021.39.15_suppl.1011)

opportunities to try new treatments, even if benefits may be as little as a six month extension of progression-free disease. It is also very important for patients to have good quality of life when receiving treatment for metastatic disease. Patients that we speak to on a regular basis acknowledge the importance to have the energy to attend their children's activities and to spend time with family and friends.

## 6. Experience With Drug Under Review

### **Patient Profile:**

CBCN connected with the only Canadian patient who has experience with the treatment.

The patient is 37 years old and was diagnosed in November 2019. She was first diagnosed with stage III triple negative breast cancer which is now stage IV, triple negative breast cancer. She is able to access this treatment because of her oncologist. She has been previously been treated with an immunotherapy, AC chemotherapy, taxol, cisplatin, capecitabine, atezolizumab, and abraxane. She also had a double mastectomy and underwent 25 rounds of radiation.

### **The Impact of the Treatment on the Disease**

With having been on a variety of treatments, the patient we interviewed expressed personal satisfaction with the treatment. She expressed that [REDACTED] has been both impactful in treating her cancer and has been the treatment with the most manageable side effects.

*“It’s the first thing that’s made any difference in my cancer at all since I was on AC chemo. The AC chemo shrunk my cancer, but then when I switched over to Taxol and cisplatin, my tumour grew back, and they continued chemotherapy and I went right into surgery to remove the tumour, because it was no longer responding. And then after the removal, I had a clean PET scan, and then I did radiation. And then while I was on capecitabine, it came back. And atezo and abraxane did nothing. And when I went on to [REDACTED], I had lymph nodes in my neck and chest that had cancer in them. I had a spot on my lung and my liver, and I had bone metastases. And after doing three cycles of [REDACTED], all of my lymph node involvement was gone. All of my bone metastases were gone. My lung spot was gone. The only thing left was my liver spot.”*

Not only was [REDACTED] helpful in treating her cancer, but after initial treatment with [REDACTED], the pain the patient felt in association to her bone metastases and her difficulty breathing due to the cancer on her lungs subsided.

*“I was in an incredible amount of pain from the bone metastases specifically, and I was having trouble breathing from the lung spot when I started [REDACTED]. And during the first cycle—I can’t remember if it was the first treatment or the*

*second treatment, but I'm pretty sure it was the first treatment—my bone pain and my breathing difficulties were gone.”*

### **Assessing Risks Associated with the Treatment**

The patient that we interviewed shared that the side effects that she experienced from [REDACTED] were very minor. The side effects from [REDACTED] included hair loss, nausea, and headaches, which she emphasized were very minimal and more than manageable.

*“They're all fine. They're all acceptable. I think they're all within a realm of normal, manageable side effects.”*

To address the headaches and nausea, she was able to take over-the-counter medications and take them on an as-needed basis. The patient found the side effects of [REDACTED] to be much more tolerable than those she experienced while on other treatments.

*“I take Tylenol for headaches if I need to. And I have some anti-nauseas that I take if I get nauseous. But it's really on an as-needed basis, whereas with other therapies, I was taking them daily to make sure the side effects didn't start, whereas with [REDACTED], the side effects I find are quite minor. So if I feel a little bit nauseous or a little bit headachy, I can take an over-the-counter medication and it's enough to cut down the side effect, whereas with the other ones I was taking very heavy prescription medications daily.”*

### **Alternatives to the Treatment**

The patient was able to access [REDACTED] through her oncologist and she acknowledged that most other metastatic triple negative breast cancer patients do not have access to this treatment.

*“I feel incredibly lucky. I speak to a lot of other women, especially young women like me, some even younger, that have the same Stage IV triple negative diagnosis as I do, and they were unable to get this treatment.”*

She sought out this treatment because everything else she had tried up to this point had not been working and was advised by her oncologist that this would give her the best chance. Prior to her oncologist getting involved, she had already begun seeing an oncologist in the United States to start therapy there due to a lack of alternatives in Canada.

*“Everything else I tried wasn't working. And it was what my oncologist said would give me the best chance. There were other therapies available in the United States, but really there weren't any other good therapies available to me in Canada.”*

Without access to this treatment, the patient we interviewed stated that she would have looked to get therapy in the United States and paid out-of-pocket. While she had this potential alternative, she acknowledged that she is privileged to have the financial means to do so and recognized that many other patients do not have the same means or access as she does.

*“There’s actually not many options left available in Canada. I would probably be paying out-of-pocket for something in the United States. And I’m only really lucky enough to be able to do that because I have the financial means to do it, and I live close enough to the United States border that I can drive down for treatment. I talked to another patient who has the same cancer as me and that lives in Edmonton, and she can’t drive down to the States. So she had to fly down and is living there at great expense to her.”*

In terms of how [REDACTED] compared to other treatments that she had been on, the patient we interviewed found it to be the most preferable option, especially due to the difficult side effects from the alternatives.

*“It’s actually one of the most manageable ones. I actually found I got the most life-impacting side effects when I went on capecitabine. And when I was on AC chemo, obviously that’s quite a difficult chemotherapy. There was a lot of nausea and that sort of thing. This one, it’s not so bad. I don’t have to take as many other drugs to manage the side effects.”*

*“Infusions are every couple of weeks so it’s not hard to do the treatment.”*

### **The Social and Financial Impact of the Treatment**

In terms of the social impacts of [REDACTED], the patient that we interviewed discussed that being on this treatment has allowed her to live a well-rounded life and uphold a good quality of life, rating her quality of life while taking this treatment as an “eight out of ten”.

*“I’ve been able to do a lot more while on [REDACTED] than I have with other therapies.”*

It has also had a positive impact on not just her life, but her family’s as well.

*“It has had a hugely positive impact on our family. It’s been a huge relief to everyone in my family to have a treatment that actually works and to be able to have me functional and to be able to be happy while on treatment instead of in [bed] and in pain.”*

While her mother lives with her and her husband to assist with childcare responsibilities, she has been able to actively participate in this as compared to other treatments.

*“My husband and my mother live with us to help with my son. But I definitely have more ability and more energy to do things than I did with other therapies.”*

In terms of the financial impacts of this treatment, the patient that we interviewed expressed that without being able to access this treatment, she would have been paying out-of-pocket and travelling to the United States to get treated. With this treatment being the only one that seems to be really helping her, the patient that we interviewed expressed the need for patients like her to have access to ████████ in Canada.

*“I think that absolutely it should be acceptable here in Canada and that it should be funded by the government so that people who have Stage IV triple negative breast cancer have a chance at prolonging their lives. There’s a lot of additional therapies available for people who are hormone positive or HER2 positive. But there isn’t really a lot that is available that is effective for people that have triple negative.”*

Overall, the patient we interviewed expressed that she is really happy to be able to access a treatment that is effective in treating her cancer while allowing her a good quality of life.

*“It’s saving my life. It’s saving my life. It’s giving me more time with my son, who’s only three. It’s the only thing that made any difference in my cancer.”*

**7. Companion Diagnostic Test**  
**Not applicable**

**8. Anything Else?**  
**Not applicable**

## Appendix: Patient Group Conflict of Interest Declaration

To maintain the objectivity and credibility of the CADTH CDR and pCODR programs, 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.

CBCN did connect with the manufacturer, Gilead, to identify clinicians that could connect us with patients with experience on the treatment.

All other research, interviews and outreach to patients was conducted independently by the Canadian Breast Cancer Network, as was the compilation of information and data for the writing of this submission.

As a member of the Canadian Cancer Action Network, the Canadian Breast Cancer Network is committed to adhering to the Code of Conduct Governing Corporate Funding.

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.  
No. The Canadian Breast Cancer Network compiled and wrote this submission independently.
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
Gilead			X	

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: Bukun Adegbembo

Position: Coordinator of Health Policy and Digital Communications



Patient Group: Canadian Breast Cancer Network (CBCN)  
Date: June 22, 2021

## Patient Input Template for CADTH CDR and pCODR Programs

Name of the Drug and Indication	██████████ (sacituzumab govitecan) is indicated for the treatment of adult patients with unresectable locally advanced or metastatic triple-negative breast cancer (mTNBC) who have received at least two prior therapies, including at least one prior therapy for locally advanced or metastatic disease.
Name of the Patient Group	Rethink Breast Cancer
Author of the Submission	██████████
Name of the Primary Contact for This Submission	██████████
Email	██
Telephone Number	██████████

### 1. About Your Patient Group

If you have not yet registered with CADTH, describe the purpose of your organization. Include a link to your website.

Rethink Breast Canada’s mission is to empower young people worldwide who are concerned about and affected by breast cancer through education, support and advocacy. Since 2001, we have been building community for young women with breast cancer and providing support and resources to help them live the best quality of life. Because up to 30% of all breast cancers become metastatic, Rethink Breast Cancer has always worked closely with young MBC patients—who, sadly, leave our community far soon. We represent the voice of young people with breast cancer and strive to ensure their needs and values are heard and considered in all aspects of breast cancer treatment and care at all stages of their breast cancer experience. [www.rethinkbreastcancer.com](http://www.rethinkbreastcancer.com)

### 2. Information Gathering

CADTH is interested in hearing from a wide range of patients and caregivers in this patient input submission. Describe how you gathered the perspectives: for example, by interviews, focus groups, or survey; personal experience; or a combination of these. Where possible, include **when** the data were gathered; if data were gathered in **Canada** or elsewhere; demographics of the respondents; and **how many** patients, caregivers, and individuals with experience with the drug in review contributed insights. We will use this background to better understand the context of the perspectives shared.

Online patient surveys were conducted between June 19 and July 10, 2021. The surveys asked questions about the impact of breast cancer on the lives of patients, the effect of current treatments and their willingness to accept side effects for improved health outcomes. The survey also included questions directed to patients with [REDACTED] treatment experience. Potential respondents were identified through messages posted to Rethink's Young Women's Network and Instagram channel as well as through Facebook and Twitter. Messages were also posted on the Cancer Connection, BreastCancer.org and Cancer Survivors Network online discussion forums.

A total of 30 people completed the patient survey. Of these respondents, 6 are from Canada (representing Alberta, British Columbia, Manitoba and Ontario), 22 are from the United States, 1 is from the United Kingdom and 1 is from Antigua and Barbuda.

### **3. Disease Experience**

CADTH involves clinical experts in every review to explain disease progression and treatment goals. Here we are interested in understanding the illness from a patient's perspective. Describe how the disease impacts patients' and caregivers' day-to-day life and quality of life. Are there any aspects of the illness that are more important to control than others?

All 30 respondents have been diagnosed with metastatic triple-negative breast cancer (mTNBC).

4 respondents were diagnosed in 2020, 9 were diagnosed in 2019, 4 were diagnosed in 2018, 6 were diagnosed in 2017, 3 were diagnosed between 2016, and 4 were diagnosed in 2015 or earlier.

9 respondents were originally diagnosed with mTNBC, while 21 had disease progression following their initial diagnosis.

10 respondents have brain metastases.

22 respondents are currently receiving third-line treatment or higher, 3 are receiving second-line treatment, 2 are receiving first-line treatment, 2 are receiving treatment after recurrence and 1 has had no evidence of disease for between six months and two years.

### **4. Experiences With Currently Available Treatments**

CADTH examines the clinical benefit and cost-effectiveness of new drugs compared with currently available treatments. We can use this information to evaluate how well the drug under review might address gaps if current therapies fall short for patients and caregivers.

Describe how well patients and caregivers are managing their illnesses with currently available treatments (please specify treatments). Consider benefits seen, and side effects experienced and their management. Also consider any difficulties accessing treatment (cost, travel to clinic, time off work) and receiving treatment (swallowing pills, infusion lines).

All 30 respondents provided information about the treatments they have received since their diagnosis. Over half of respondents were treated with paclitaxel, capecitabine, doxorubicin, nab-paclitaxel and atezolizumab.

Treatments Received	n	Treatments Received	n
Taxol (paclitaxel)	20	Taxotere (docetaxel)	6
Xeloda (capecitabine)	20	Lynparza (olaparib)	4
Adriamycin (doxorubicin)	19	Radiation	2
Abraxane (nab-paclitaxel)	17	Cisplatin	2
Tecentriq (atezolizumab)	16	Epirubicin	2
Gemzar (gemcitabine)	13	Navelbine (vinorelbine)	1
Paraplatin (carboplatin)	11	Opdivo (nivolumab)	1
Cytosan (cyclophosphamide)	10	Kadcyla (trastuzumab emtansine)	1
Halaven (eribulin)	7	Herceptin (trastuzumab)	1
Keytruda (pembrolizumab)	7	Kisqali (ribociclib)	1

Most respondents have undergone multiple lines of treatment and reported a wide range of outcomes and side effects. Their description of the side effects of previous treatments tended to be more severe than those reported in other surveys conducted by Rethink Breast Cancer for previous submissions. Many respondents reported hospitalizations due to the side effects of previous therapies. Xeloda was often identified as especially difficult to tolerate.

Fatigue was the most commonly reported side effect of previous treatments (97%, n=30), followed by loss of appetite (77%), nausea (70%), constipation (67%), diarrhea (60%) and headache (57%).

Hand and foot syndrome, nausea and fatigue were identified as the most difficult to tolerate side effects of these treatments.

## 5. Improved Outcomes

CADTH is interested in patients' views on what outcomes we should consider when evaluating new therapies. What improvements would patients and caregivers like to see in a new treatment that is not achieved in currently available treatments? How might daily life and quality of life for patients, caregivers, and families be different if the new treatment provided those desired improvements? What trade-offs do patients, families, and caregivers consider when choosing therapy?

Rethink Breast Cancer asked patients to evaluate the importance of different outcomes for their breast cancer treatment on a scale of 1 (not important) to 5 (very important). All outcomes were rated over 4.4, but controlling disease progression, preventing recurrence and overall survival were considered the most important patient values. Preventing recurrence was rated higher by these respondents than respondents to surveys for previous submissions, likely reflecting their longer treatment history.

Importance of outcome	1 - not important	2	3	4	5 – very important	Average
Controlling disease progression	0.00% 0	0.00% 0	0.00% 0	3.33% 1	96.67% 29	4.97 30
Reducing symptoms	3.45% 1	6.90% 2	6.90% 2	10.34% 3	72.41% 21	4.41 29

Maintaining quality of life	0.00% 0	0.00% 0	6.67% 2	10.00% 3	83.33% 25	4.77 30
Managing side effects	0.00% 0	3.33% 1	3.33% 1	23.33% 7	70.00% 21	4.60 30
Preventing recurrence	0.00% 0	0.00% 0	0.00% 0	3.33% 1	96.67% 29	4.97 30
Overall survival	0.00% 0	0.00% 0	0.00% 0	3.33% 1	96.67% 29	4.97 30

Comments:

- I am in treatment to LIVE; therefore I have to take a few side effects with a grain of salt sometimes.
- I want to be around for my husband and my 2 kids. It breaks my heart to think of them experiencing milestones without me there to cheer them on.

**6. Experience With Drug Under Review**

CADTH will carefully review the relevant scientific literature and clinical studies. We would like to hear from patients about their individual experiences with the new drug. This can help reviewers better understand how the drug under review meets the needs and preferences of patients, caregivers, and families.

How did patients have access to the drug under review (for example, clinical trials, private insurance)? Compared to any previous therapies patients have used, what were the benefits experienced? What were the disadvantages? How did the benefits and disadvantages impact the lives of patients, caregivers, and families? Consider side effects and if they were tolerated or how they were managed. Was the drug easier to use than previous therapies? If so, how? Are there subgroups of patients within this disease state for whom this drug is particularly helpful? In what ways?

20 respondents match the full indication for this review – they were treated as a breast cancer patient with [REDACTED], they received at least two lines of treatment for breast cancer before [REDACTED], and they received at least one line of treatment for metastatic breast cancer before receiving [REDACTED]. 1 of these respondents is from Canada; the other 19 are from the United States. 4 of the respondents in this group agreed to participate in telephone interviews with staff members to discuss their treatment experience and elaborate on their feedback.

**Patient Experience**

5 respondents had received [REDACTED] for less than 3 months, 8 respondents had received it for 3-6 months, and 7 respondents had received it for 6-12 months.

15 respondents were still receiving [REDACTED] at the time of the survey, while 5 stopped receiving it because it did not control their cancer.

**Quality of Life**

Patients were asked to rate the change to their quality of life on [REDACTED] compared to other treatments they had received on a scale of 1 (much worse) to 5 (much better). Patients indicated improvements in every area except for the ability to work where the effect was neutral. Stronger positive changes were noted for metastatic cancer symptoms, controlling disease, overall survival and preventing recurrence. It should be noted that the latter three categories were rated as the most important patient values in section 5.

Change to quality of life on [REDACTED]	1 – much worse	2	3	4	5 – much better	n/a	Average
Controlling disease	5.00% 1	0.00% 0	15.00% 3	20.00% 4	45.00% 9	15.00% 3	4.20 17
Metastatic cancer symptoms	0.00% 0	0.00% 0	20.00% 4	40.00% 8	40.00% 8	0.00% 0	4.20 20
Drug side effects	10.53% 2	10.53% 2	31.58% 6	26.32% 5	15.79% 3	5.26% 1	3.28 19
Maintaining quality of life	0.00% 0	5.00% 1	30.00% 6	35.00% 7	30.00% 6	0.00% 0	3.90 20
Preventing recurrence	5.00% 1	0.00% 0	5.00% 1	25.00% 5	25.00% 5	40.00% 8	4.08 12
Overall survival	5.00% 1	0.00% 0	15.00% 3	20.00% 4	40.00% 8	20.00% 4	4.13 16
Ability to work	0.00% 0	10.00% 2	10.00% 2	10.00% 2	0.00% 0	70.00% 14	3.00 6
Ability to sleep	0.00% 0	15.00% 3	30.00% 6	30.00% 6	15.00% 3	10.00% 2	3.50 18
Ability to drive	0.00% 0	5.00% 1	30.00% 6	30.00% 6	15.00% 3	20.00% 4	3.69 16
Ability to perform household chores	5.00% 1	0.00% 0	35.00% 7	30.00% 6	25.00% 5	5.00% 1	3.74 19
Ability to care for children	0.00% 0	5.00% 1	10.00% 2	10.00% 2	20.00% 4	55.00% 11	4.00 9

Comments:

- Some days I just have to sleep; some days I can't really leave because of my stomach, and then other days, I'm moving around; I have grandkids and they spend time with me, and I just keep going like nothing else is going on in my life
- Most days I feel normal, whereas before I wasn't feeling normal
- I remember it was crazy how [REDACTED] worked immediately

**Symptom Relief**

7 respondents indicated that [REDACTED] had helped to relieve some of the symptoms associated with mTNBC. Jacksonian marches, bone pain and neuropathy were all identified as specific cancer symptoms that improved during treatment with [REDACTED].

Comments include:

- I haven't had any brain episodes since starting [REDACTED] which is huge because those were affecting my day-to-day life because if it happened the right side, then I couldn't speak, on the left side, I couldn't walk
- I knew pretty much from the start back in November that it was helping because my bone pain ... it disappeared - I had no pain
- Because [REDACTED] is really working, my pain kind of went away, so it really helped my quality of life
- I definitely think its decreasing [my brain mets] which has given me less symptoms and allowed me to have a better quality of life

**Side Effects**



A majority of patients experienced fatigue (79%, n=19), alopecia (74%), diarrhea (68%) and neutropenia (59%) as side effects from [REDACTED].

When asked how much they could tolerate the side effects associated with [REDACTED] on a scale of 1 (completely intolerable) to 10 (completely tolerable), the average score was 8.05. Only two respondents gave a score lower than 5.

Rating	Responses	Rating	Responses
1	0.00% 0	6	0.00% 0
2	0.00% 0	7	5.26% 1
3	10.53% 2	8	21.05% 4
4	0.00% 0	9	15.79% 4
5	10.53% 2	10	36.84% 7

Comments:

- The only serious side effect was the neutropenia. All the others are tolerable or manageable with medication.
- The diarrhea gets annoying, but if it continues to extend my life, I'll take it.
- All had their own challenges, but [REDACTED] was the easiest by far
- [REDACTED] was the easiest for side effects.

Patients also emphasized that they were willing and able to tolerate these side effects for the medical benefits provided:

- It's not easy but cancer is rough
- I can deal with an occasional day of not feeling well in my tummy for keeping my cancer at bay

Many respondents also noted that they were able to manage the side effects with the use of other drugs.

## 7. Companion Diagnostic Test

If the drug in review has a companion diagnostic, please comment. Companion diagnostics are laboratory tests that provide information essential for the safe and effective use of particular therapeutic drugs. They work by detecting specific biomarkers that predict more favourable responses to certain drugs. In practice, companion diagnostics can identify patients who are likely to benefit or experience harms from particular therapies, or monitor clinical responses to optimally guide treatment adjustments.

What are patient and caregiver experiences with the biomarker testing (companion diagnostic) associated with regarding the drug under review?

Consider:

- Access to testing: for example, proximity to testing facility, availability of appointment.
- Testing: for example, how was the test done? Did testing delay the treatment from beginning? Were there any adverse effects associated with testing?
- Cost of testing: Who paid for testing? If the cost was out of pocket, what was the impact of having to pay? Were there travel costs involved?

- How patients and caregivers feel about testing: for example, understanding why the test happened, coping with anxiety while waiting for the test result, uncertainty about making a decision given the test result.

## 8. Biosimilar

If the drug in review is a biosimilar (also known as a subsequent entry biologic), please outline any expectations or concerns held by patients, caregivers, and families about the biosimilar. If the biosimilar was less expensive than the brand name drug, what would the impact be for patients, caregivers, and families?

## 9. Anything Else?

Is there anything else specifically related to this drug review that CADTH reviewers or the expert committee should know?

When asked if they would recommend ████████ to other patients with breast cancer, all 20 respondents said that they would.

Asked to elaborate, comments included:

- It was great! Very tolerable and I felt “normal”
- I have made steady improvement. Less fatigue, more energy, regained appetite.
- I would absolutely recommended this drug to other patients with breast cancer. Everyone is different when it comes to what drugs they respond to, but I feel this drug is especially important for those who have failed multiple treatments prior to trying this
- I feel it is a great drug, especially for those with brain mets. As tolerable or more tolerable as other chemos I have been on. Neuropathy hit quick though and fatigue/insomnia is tough.
- It's working! Mets in lungs have disappeared, mets in liver and bones are shrinking.
- It is an absolute must
- This was the first medicine that got me clear – to NED – after just a couple of months, so it was really a blessing
- I'm in USA getting ████████, it is working for me and I hope every Canadian who is diagnosed with mTNBC has a chance to get this treatment.



## Appendix: Patient Group Conflict of Interest Declaration

To maintain the objectivity and credibility of the CADTH CDR and pCODR programs, 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.

We asked Gilead to provide us with information about the general characteristics of the drug and its benefits. We asked our Scientific Advisory Committee (medical oncologists) about this drug and its benefits and whether it addressed an unmet need. Adam Waiser is a freelance health technology assessment writer who we contracted to help us with writing this submission.

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.

We contracted Adam Waiser to help us develop the survey we used to collect the data used in this submission. All interviews were conducted by Rethink Breast Cancer staff. Adam Waiser helped us analyze the findings of our survey and interviews.

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
Gilead Sciences	X			

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: MJ DeCoteau  
Position: Executive Director  
Patient Group: Rethink Breast Cancer  
Date: July 21, 2021