CADTH

Patient Input Template for CADTH CDR and pCODR Programs

Name of the Drug and Indication	**Trodelvy (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	**Adam Waiser**
Name of the Primary Contact for This Submission	**MJ DeCoteau**
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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

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 Trodelvy 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
Cytoxan (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 Trodelvy, they received at least two lines of treatment for breast cancer before Trodelvy, and they received at least one line of treatment for metastatic breast cancer before receiving Trodelvy. 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 Trodelvy 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 Trodelvy 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 Trodelvy 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 Trodelvy	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 Trodelvy worked immediately

Symptom Relief

7 respondents indicated that Trodelvy 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 Trodelvy.

Comments include:

- I haven't had any brain episodes since starting Trodelvy 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 Trodelvy 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 Trodelvy.

When asked how much they could tolerate the side effects associated with Trodelvy 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 is it continues to extend my life, I'll take it.
- All had their own challenges, but Trodelvy was the easiest by far
- Trodelvy 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 Trodelvy 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 Trodelvy, 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