

## CADTH Reimbursement Review

# Patient Input

**VENETOCLAX (Venclexta)**

AbbVie Corporation

**Indication:** Acute myeloid leukemia

**CADTH received patient input from:**  
The Leukemia & Lymphoma Society of Canada

**February 12, 2021**

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## CADTH Drug Reimbursement Review Patient Input Template

Name of the Drug and Indication	Venetoclax and Cytarabine for acute myeloid leukemia
Name of the Patient Group	The Leukemia & Lymphoma Society of Canada
Author of the Submission	[REDACTED]
Name of the Primary Contact for This Submission	[REDACTED]
Email	[REDACTED]
Telephone Number	[REDACTED]

### 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.

#### The Leukemia and Lymphoma Society of Canada (LLSC)

The mission of LLSC is: Cure leukemia, lymphoma, Hodgkin's disease and myeloma, and improve the quality of life of Canadians affected by all of the 137 different types of blood cancer.

<http://www.bloodcancers.ca>

### 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.

Information was gathered through an on-line survey that was created by LLSC. The survey was created in both English and French, was made available to respondents on December 7, 2020 and closed on January 24, 2021.

Both English and French online surveys were created using Survey Monkey and promoted by LLSC through various social media channels and directly by email. The survey asked for input from those with experiences with the treatments for AML.

There were a total of 29 respondents to the survey. All of the respondents indicated that they were patients (persons with AML). None of the respondents had experience with venetoclax and cytarabine.

18 respondents identified as Female, 10 respondents identified as Male, and 1 respondent did not provide a gender.

All respondents identified that they live in Canada. The breakdown is as follows:

Ontario - 13

Quebec - 6

British Columbia - 6

Alberta - 4

The age range of the patients are as follows:

25-34 - 3

35-44 - 3

45-54 - 3

55-64 - 9

65-74 - 9

75-84 - 2

28 of the respondents provided the year that they were diagnosed with AML:

2021 – 1

2020 – 4

2019 – 7

2018 – 5

2017 – 5

2016 – 3

2015 – 2

2014 – 1

### 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?

25 respondents provided an answer when asked the open-ended question - "How do the symptoms associated with AML impact your quality of life (For example: Impact on daily life, impact on social life and relationships, etc.).

2 respondents indicated that they were now feeling no impact or back to normal. Among the remaining respondents, fatigue was mentioned most often along with impacts on social life:

- I no longer do many of the active activities I did before the AML like hiking and biking. I was also forced into early retirement. My dating life is over. I still tire easily. I lost the sight in my right eye.
- Pre-diagnosis, I was very, very active, holding three jobs that equalled a full pay cheque- librarian in the morning, massage therapist three afternoons, and teaching at a local university on the weekends. As I become 'sicker', I could barely walk across the room. The day I was diagnosed, I was wheeled up to the cancer ward from emergency and was there for five months. Everything in my life stopped cold turkey-employment, social life, relationships, etc. I made a complete personal 360 degree pivot to focus on my healing and living. Pre-Covid, I retired, got active with walking, travelled to visit my two sons and their families, participated in art workshops, and went out and about. In Covid, I keep doctors appointments, do my art, take safe, short walks. I have visitors-one at a time-and Skype and FaceTime with friends and family. I watch documentaries, am taking on-line Italian classes and history of religions. I also listen to a lot of excellent music and am politically active in my Province. I'm a different kind of 'busy'!
- Fear of being ill again if I relapse
- prior to diagnosis, symptoms were tiredness, sore gums, bruising. Once treatment started, symptoms were related to chemo. Nausea, bruising, internal bleeding.
- All levels are impacted. Changes your life completely.
- Changed my life completely. Can no longer do some of the things I did in the past. Still have lingering affects etc.
- Other than occasional fatigue and the fact that we're dealing with the COVID Pandemic I feel pretty good. No limits. Some side effects from cancer drugs.
- Lack of energy and lack of breath when not in treatment. Feeling sick while in treatment
- Fatigue
- Very straining on relationships. Difficult to make plans and look to the future
- Generally my life is great but experience daily issues like foggy brain, numbness in my feet, imbalances body aches, tiredness
- Can't return to work due to still being immunosuppressed post-stem cell transplant and on Sorafenib

- Daily activities Social life Weakness and pain in whole body Unable to perform daily household chores
- Well covid and my compromised immune system has caused me to be very socially isolated. I haven't seen some very important people in my life for almost 2 years at this point. Symptoms have also caused an impact to my physical fitness and being able to do things that I normally would
- fatigue affects my daily routine
- Fatigue, anxiety, shortness of breath
- The initial year was absolutely overwhelming, in terms of treatment and expenses. I had a stem cell transplant in June 2019 and am now recovering.
- Feel fatigued for no know reason
- It was hard
- Impact on travelling
- impact on daily life, medication, taste, fatigue, etc.
- Daily life house maintenance have and is Personal life conjugal and family friendly relations isolation Professional life career change questioning Vision of life
- Family, social, travel

When asked if there are any aspects or symptoms that are easier to control, 7 respondents said “no” and 3 respondents alluded to exercise as helping with fatigue (and other symptoms):

- “Exercise helps a lot with fatigue”
- “I find keeping active helps with many (symptoms)”
- “I think all of the symptoms are difficult, to be honest, but perhaps for me the easiest over time was recovering my energy. I used exercise.”

1 respondent said:

- There is NO CONTROL with AML. I learned that right away, in the emergency room!- and decided that I needed to embrace everything that came my way. The main aspect of AML, I found, was that it is a decision. The decision, that I was not alone in the event. The decision, that I am stronger than I know. The decision that my medical team knows what they are doing, the medications I am given are supporting my healing-everyone from the cleaners in my room to my specialist where supporting me. And, being able to ask for help makes a very inclusive group! And, the main decision, to stay in the here and now, to be present. To be now. The two times I had emotional melt downs in the hospital, was when I was thinking about the future, and when I was thinking about the past. Being in the ‘here and now’, makes a much easier journey and really helps the heart! There will be challenges and many victories.

Respondents also added the following comments on how the disease affects the quality of life of their family and friends:

- I need to take someone with me as an escort in case I run into trouble. I don't have the strength or stamina to work fast and complete a task - have to putter at it to conserve energy.
- My Father, when he was alive, had a difficult time understanding the I wouldn't just die from the cancer. His thinking process was very generational. My older son does extensive, deep research and is married to a nurse, so they support me with keeping in top of all things science. My younger son, is very sensitive to what I say and do and always aware of my health. They both assisted me with my recovery. We are all honest with each other and find that is very helpful in our relationships. My friends are also remarkable, giving time and activities to me if I ask for something of them. All my family and my friends, have said that they have learned a lot about themselves being able to go through this experience with me-together. We learned that our tomorrows have turned into today!
- They don't want to talk about any aspect of AML.
- During the year of treatment, they worked hard to support me, visit me in hospital, take me to appointments, arrange food, etc.
- It affects those in your immediate household since they will most probably be your primary caregivers. However, anyone that is close to you will be affected as well.
- Having had it, there is an element of fear for me and my family that it will return
- They are worried about me.
- I'm not working anymore. Decided early retirement to take better care of my health. My support system is strong,
- Mostly just putting up with me when I'm in treatment
- Future uncertainty is the most difficult
- They experience stress
- All good now but very upsetting during the chemo treatment and during the transplant
- They were worried for me.
- More attention now from my adult children
- Sad / scared
- It's very hard on them, because they are terrified that AML will be fatal for me. Psychological counselling has been essential.
- Badly
- Worry, insecurity, fear of dying

- Many worries, stress of the spouse when the affected person goes away alone, fear of the death of the spouse.
- Broken family balance Emotional affect with spouse Intimate relationship disturbed eg illness Interpersonal relationship changed r / e vision different life
- emotional for my children, relatives, friends

## 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).

Respondents identified a variety of frontline treatments they received for AML after diagnosis:

Chemotherapy – 24

Stem cell transplant / bone marrow transplant – 16

Drug Therapy – 6

Radiation Therapy – 5

Car T Therapy - 1

We asked respondents to describe both positive and negative experiences with frontline AML treatments:

- I just stayed positive, did as I was asked as far as treatment went. I did not stay in bed - but walk as much as I could and sat up all day. I had extra food like bananas and ginger ale brought in to keep my strength up. You need to eat even if you have trouble keeping food down. I ordered as bland food on the menu as I could find that was still nutritious.
- Positive: first chemotherapy treatment, the availability of various medicine regimes, bone marrow transplant, and blood transfusions. Negative: second chemotherapy treatment as I lost all my hair-all over my body-but also my fingernails and toenails and it was very difficult to walk as my feet were swollen, cracked and very sore. Also, for many months, post chemotherapy, I was constantly vomiting as I couldn't hold anyone down.
- There were a few set backs but on the whole was not as bad as I thought it would be. Biggest problem was minor damage to the heart muscle but an exercise program and medication helped repair that.

- Venetoclax treatment was way more tolerable and I was able to be more independent while on it. It got me into remission quickly and was able to get a transplant within 2 months. However my first transplant didn't work and I recently had another one which is showing more signs of working this time. The Chemo, transplant, radiation and drug therapies are all hard on the body and short term, long term effects are tough as well. The worst part is that these therapies can cause other illnesses.
- A long process that was difficult because I did not feel well. The period just before stem cell transplant I was very sick and felt awful.
- My diagnosis was very acute meaning happened within a week. My spleen ruptured and I was in a coma for 8 days. The Princess Margaret hospital staff and doctors were amazing and I was given the best care,
- I cannot say enough or give enough praise to the nurses in the Kamloops Cancer Clinic. Informative, knowledgeable and helpful all the way. They are angels among us.
- Chemo is the hardest thing I've ever had to endure
- Going through the treatment is not fun but meeting people made up for it whether it be fellow patients and doctors and nurses.
- I received excellent care and am very grateful to be a Canadian.
- Staff at both Kingston and Ottawa were outstanding
- The team at Princess Margaret was incredible! I wouldn't have been able to get through it without them.
- Vyxeos primary treatment 5 weeks of my life in hospital but blast counts dropped by more than 60%
- The most difficult experiences I had involved the stem cell transplant and the intensive chemotherapy. I became very ill and was hospitalized for several weeks. I would say that the other difficult experience was being diagnosed with AML and told I had one month to live, without treatment. I had hardly any symptoms and was absolutely shocked. We had to move to another city for treatment, as well. Everything happened so fast. The most positive experiences included my recovery thus far from AML, because of the stem cell transplant (1 year, 6 months of survival so far), and the incredible support of medical staff, friends, and family.
- I was very impressed with the treatment I received from all the nurses and Doctors
- Successful, Stem Cell Transplant
- Extraordinary hospital care at Charles-Lemoyne Hospital. Impeccable pre-transplant file in Maisonneuve-Rosemont but refusal of the transplant after 3rd chemo at HCL in 2016.
- Everything went well. The hardest part of my illness was being in a sick health system ...
- total isolation for 6 weeks, lasix drug very unpleasant and not always necessary, cumbersome pic line for bathing, on the other hand the medical staff was extraordinary, the long days in external chemo from 8 am to 6 pm in the evening very painful

- Side effects chemo difficult physically and psychologically Length with a semblance of normal life Vision change in life Difficulty returning to work Mental difficulty Affect at the cognitive level
- Positive, NLP and hypnosis have helped me stay calm inside and trust the treatment and the unknown.

Below are the AML treatment side effects that have impacted the quality of life of the respondents, listed in the number of classifications being identified as 5 (extremely large impact) or a 4 (large impact):

- Hair Loss (17)
- Weakness (15)
- Extreme Fatigue (14)
- Diarrhea (10)
- Infections (8)
- Anemia (8)
- Mouth sores (8)
- Nausea and vomiting (7)
- Fever (6)
- Low blood cell counts (6)
- Tingling Sensations (4)
- Constipation (2)
- Graft versus host disease (2)
- Lung, heart, kidney or nerve problems (2)
- Cough (1)
- Rashes (1)
- Shortness of breath (1)
- Psychological distress (1)

The side effects that were experienced from frontline AML treatment have impacted the respondents in the following ways, listed in the number of classifications being identified as 5 (extremely large impact) or a 4 (large impact):

- Change to physical activity (15)
- Anxiety (11)
- Mental health and overall happiness (11)
- Eating challenges (12)
- Social development (6)

- Educational development (6)

Respondents also shared some of the quality of life issues that were experienced due to AML and the treatment during frontline therapy:

- Now I use either a cane or walker when I am outside the home. I stay away from crowds to keep away from germs. I can only do things in a bright light to be able to see what I am doing. It is hard to exercise.
- The main challenge was the nausea and vomiting. I didn't seem to have much control over it and had my wonderful bucket always with me. I could be fast asleep and awake and vomit. It was tough to get a handle on that. I was super sensitive to smells, so, I couldn't smell the meals being served as I would vomit. My vomiting was events, kept occurring until I was bringing stomach acid, they were very rarely single events. The next challenge was stomach infections, which caused diarrhea. For a while, diarrhea was my new best friend, which was totally amazing, as I was barely keeping any food in my system! The losing my fingernails and toenails multiple times. It was painful when I fought them on a sheet or blanket. I got done coloured Band-aids and wrapped them around fingers, thumbs, and toenails and that really helped! The nerve pain, cracking of feet and sensitive swelling also was painful to walk, the nurses would put multiple layers of towels down for me to walk on. Very helpful. The hair, on my head, is a vanity thing. I had very thick, healthy, straight dark hair-after chemotherapy, I lost it...and it never grew back. I now have baby fine, very thin hair. The least on the front, top of my head. Sigh. As my younger son says, 'Mother! Who cares!?! You're alive!!!!' He is correct and I still miss my hair! I had 'heavy' dreams bordering on the edge of nightmares. During my recovery from my BMT, I did have nightmares and, subsequently PTS syndrome, which I received help for. Very excellent help.
- Extremely tired and little desire to be active. Difficulty eating and keeping it down. A few days of low hemoglobin and fluid on the lung that caused shortness of breath.
- Anxiety, Isolation ( the first time I was admitted for my transplant there were no visitors allowed due to covid) there were no support staff, psychologists there for assistance. It took me a long time to recovery from this trauma and still think about it.
- Cannot do the things I used to. Feel tired and no energy. Seem to have a chronic sore throat and headache.
- Fatigue makes it harder sometimes if I'm with family and I overdo it. Overall my experience hasn't been too bad since my transplant in July 2019.
- The most significant impact is being sick during treatment.
- As I've said before, future uncertainty is the largest hit to my quality of life

- Had to move to Vancouver for treatment for 9 months. 2 or 3 months total in hospitals. Daily out patient care. Kinda turns your life upside-down. I am fortunate though had my beautiful spouse with me.
- I am now recovering from treatment and hoping one day soon to return to work
- Weakness Weight loss, hair loss
- It was a very challenging experience to be locked down to a hospital room for 30 day increments, during the transplant this was a much better experience with a new, large, single room but going through treatment and sharing a hospital room while you are experiencing extreme symptoms of diarrhea, nausea, etc.. is a really negative impact to your quality of life. Additionally, I was re-hospitalized with an infection during covid and having to fight with hospital staff about sharing a room with someone who is having visitors that cough, sneeze, touch things, use the bathroom, etc.. was TERRIBLE. I was scared for my life every day given I had such a low immune system.
- isolation with no visitors when hospitalized for stem cell transplant
- Fatigue was the only major side affect
- Your whole world changes when you are diagnosed with AML. Suddenly, you confront your mortality. You feel extremely weak, you have to go into hospital for months, and you don't realize you MUST go into remission to have a stem cell transplant. There are so many hurdles and you are constantly dodging one bullet after another. And your body begins to break down, with infections and exhaustion and lack of appetite. It is so hard. Even after you have a stem cell transplant you worry about the cancer coming back. If you read academic articles online, the statistics on living for 5 years or more are very concerning. I have to confess that I have struggled with fear. Psychological counselling, meditation, love of family and friends, exercise -- these have all helped.
- The worst issue is that I have no more job and that the treatments made me lose a lot of concentration and I get exhausted easily
- Cognitive / emotional disorders. Physical affectation loss of energy / endurance. Tired Overload on family Feeling of guilt
- isolation since I was far from the family. I would have liked to have free WIFI in my room to create the remote connection and also to have access to meditations and film to pass the time. Keep the focus on inner happiness.

We asked respondents if they had any challenges accessing treatment for AML or healthcare services and to share any positive or negative experiences. 2 respondents simply responded “no”, indicating they had no challenges accessing treatment.

13 respondents reported generally positive experiences:

- No. PMH arrange a case worker for me and they took care of everything for me. PMH also made sure I got all the health care treatment I needed to get me into remission.

- No my oncologists have all been amazing and very on top of everything.
- Got in right away. The system worked great.
- No challenges. Smooth sailing and highly professional care right from the first appointment with the oncologist through the beginning and continuation of treatment
- No, the experience has been positive
- Very positive
- No, this experience really renewed my faith in the Canadian healthcare system
- very well taken care of by doctors and nurses
- Had no issues accessing anything.
- no. My oncologist/menotologist was very kind in his treatment of me as an inpatient for 5 weeks
- I had no challenges, two days after I was accessed with AML, I was in the hospital and they started me on chemo. I was very impressed with how efficient and how quickly the treatment was started.
- My experience was sudden and ended up being emergency life or death care so I was taken into Princess Margaret once diagnosed immediately because my spleen was enlarged and causing a lot of pain. Very pleased with the care I received.
- Before I was diagnosed, I went to several walk-in clinics because I was so tired and just felt 'off'. The doctors were helpful but did not do blood work. Finally, I so ill, not being able to walk that my friend, [REDACTED], took me to Foothills (Calgary) emergency and it was there, within six hours, they diagnosed me. Immediately after the diagnosis, I was wheeled up to the cancer ward and everything went a warp speed-or, at least, it felt like that! I constantly rave about the phenomenal, fabulous care I received at Foothills. My team that worked with me were supportive, empathetic, caring, honest, measured, funny, stern-when needed-, embracing, informative-all around STARS!!!! They answered all my questions, were helpful beyond belief, and seemed to love what they were doing!!!! I took advantage of everything that was offered to me while I was in the hospital-meditating, counselling, ministries, handouts, walking around the ward, talking to all the staff, having great rapport with the nurses, doctors and specialists. The negatives were usually some of the tests that were done, the treading of line from my neck to my arm and the extraction of the marrow from my hips. Honestly, when it was time to go home, I joked that I was going to find a small room, in the basement, and nit be any trouble, and stay! It was great to get home!

6 respondents reported negative experiences:

- I had to seek treatment in another province as I did not qualify for treatment in my home province

- All of my treatments occurred away from my home city, as it has with most patients. Living in Vancouver during my treatments for AML, away from family and friends was definitely hard., and expensive
- I received medical treatment immediately, and the quality was exceptional. What was missing, though, was psychological support. I asked for support groups, meditation groups, counselling, and the services were extremely meagre (in Kingston Hospital and Ottawa General Hospital .
- Yes! I had difficulty getting a room for consolidation treatment
- the treatment was very fast but a lack of information, I entered the hospital for 2 to 3 days but stayed for six weeks.
- Doctor thought everything was normal. Long referral period

## 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?

When asked what are the most important factors they consider when making decisions about a new cancer treatment, physician recommendation was most important to the respondents. The following is a list of the factors that were considered very important:

- Physician recommendation (19)
- Possible impact on disease (17)
- Quality of life (12)
- Closeness of home (9)
- Outpatient treatment (8)

Respondents shared their thoughts on improvements they would like to see in new treatments that are not available in current treatments:

- Treatment to maintain remission
- Would be nice is stem cell transplant was available in Edmonton instead of just Calgary.
- New treatments are constantly being offered for cancer patients. Less side effects,
- All the newest treatments should be made available to patients who are fighting for their lives
- Of course. A more targeted treatment with fewer side effects.
- Health CANADA Should cover costs

- The approach should be holistic. Food is very important. Collaboration with complementary medicines, mainly naturopathy.
- I would like to have more information on future treatments. I had a chemo treatment without graft .. One day I will have a relapse .. I want to have access to all possible treatments for me .. This is the most important .. The disease is behind me for now but I hope to have more possibilities in the future.
- the famous vaccine for acute myeloid leukemia
- Decrease in side effects
- Meditation, hypnosis, NLP support. Awareness support (thoughts, emotions and behaviors)

## 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? If applicable, please provide the sequencing of therapies that patients would have used prior to and after in relation to the new drug under review. Please also include a summary statement of the key values that are important to patients and caregivers with respect to the drug under review.

None of the respondents had experience with venetoclax and cytarabine.

## 7. Anything Else?

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

## Appendix: Patient Group Conflict of Interest Declaration

To maintain the objectivity and credibility of the CADTH drug 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.

**No**

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**

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
AbbVie				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: Indrek Koppel

Position: Manager, Advocacy & Partnerships

Patient Group: The Leukemia & Lymphoma Society of Canada (LLSC)

Date: February 9, 2021