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

CDA-AMC REIMBURSEMENT REVIEW

Patient and Clinician Group Input

pembrolizumab (Keytruda)

(Merck Canada Inc.)

Indication: Pembrolizumab (Keytruda) in combination with chemotherapy for the treatment of adult patients with primary advanced or recurrent endometrial carcinoma (EC), and then continued as monotherapy.

December 2, 2024

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

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Patient Input Template for CADTH Reimbursement Reviews

Name of Drug: Pembrolizumab
Indication: Pembrolizumab (Keytruda®) in combination with chemotherapy for the treatment of adult patients with primary advanced or recurrent endometrial carcinoma (EC), and then continued as monotherapy
Name of Patient Group: Colorectal Cancer Resource & Action Network (**CCRAN**) in collaboration with the Canadian Cancer Survivor Network (**CCSN**) and HPV Global Action
Author of Submission: Cassandra Macaulay, Chief Research Officer, CCRAN

1. About Your Patient Group

CCRAN is a national, not-for-profit patient advocacy group championing the health and wellbeing of Canadians touched by colorectal cancer and others at risk of developing the disease, by providing support, education and advocacy to help improve patient outcomes by way of longevity and quality of life. CCRAN has expanded its mandate to serve cancer patients outside of the colorectal cancer space through its health technology assessment (HTA) patient evidence submissions, educational events and advocacy initiatives. It collaborates with other tumour type patient advocacy groups to help achieve its expanded mandate because, collectively, it can achieve far more than it could working in silos. (www.ccran.org)

2. Information Gathering

To help capture the advanced and recurrent endometrial cancer patient perspective for this submission, CCRAN reached out to 14 Canadian gynecological oncology clinicians / NRG-GY018 trial investigators on **October 29th – 30th, 2024** via email to request their assistance in identifying endometrial cancer patients who had experience with the therapy under review, with follow up emails through to **November 25th**. The email contained a patient recruitment poster (**APPENDIX A**) which clinicians could share with patients or their caregivers who may be willing to participate in a telephone interview to provide their lived experience with the therapy under review, in addition to their cancer diagnosis, treatment journey and endometrial cancer journey in general. Outreach to a Canadian patient advocate occurred on **November 12th** and on **November 13th**, five (5) additional Canadian gynecological oncologists were reached out to using the same methodology. HPV Global Action engaged several Medical Advisors and additional partners in an effort to identify patients who had/have experience with the therapy under review. Clinician investigators commented that it was difficult to identify patients due to the blinded trial and gynecologic oncologists noted a lack of patients on the protocol due to an easier access pathway for another immunotherapy through compassionate programs.

Given the identified lack of access in Canada, CCRAN determined that in order to truly be able to inform this expert review committee with the patient's lived experience, a pivot to an international outreach campaign would be required. Thus, on **November 19th** CCRAN reached out to 16 U.S.-based NRG-GY018 trial investigators via email to request assistance. CCRAN also undertook an in-depth search of white literature, social media, and patient story blogs in an attempt to identify feedback regarding the disease experience and the therapeutic under review. Additional outreach to 2 U.S. & U.K.-based patient organizations in women's cancer (SHARE Cancer Support and Peaches Womb Cancer Trust, respectively) took place on **November 22nd** as well as the Society of Gynecologic Oncology on the same date.

A social media outreach campaign (**APPENDIX B**) was shared within CCRAN, CCSN, and HPV Global Action's networks, from **November 15th to November 22nd.** CCSN produced an endometrial cancer patient experiences survey, which was circulated by the collaborating patient groups from **October 9th through November 20th**, but unfortunately, no responses were received. Hence, earlier data from a previous endometrial cancer survey which was released on **October 26, 2023**, and closed on **November 8, 2023** (**APPENDIX C**) was utilized to inform this submission in respect of the disease experience and the experience with previously available treatments.

These extensive efforts resulted in one (1) telephone interview with a Canadian endometrial cancer patient who accessed the pembrolizumab through a combination of private pay and extended health benefits, and five (5) telephone or zoom interviews with international endometrial cancer patients who had experience with the therapeutic under review. The transcripts of these patient interviews can be found in **APPENDIX D.**

3. Disease Experience

As the only cancer type exclusively diagnosed in individuals assigned female at birth, gynecological cancers are plagued with inequities, including chronic underfunding in research and treatments (NYSTF, 2022; Nature, 2023), as described in a recent submission **(PC0366-001)**. This underinvestment is part of a broader issue affecting women's health in general (Nature, 2024). Within the umbrella of gynecological cancers, endometrial cancer is the most prevalent, primarily affecting post-menopausal women. The incidence of the disease is rising sharply (Baker-Rand & Kitson, 2024; CCS, 2024), likely in part due to our aging population and increasing comorbidities. Alarmingly, despite rapid advancements in the oncology space, endometrial cancer is one of the few cancers wherein mortality rates are actually *increasing* (ACS, 2024; CCS, 2024); further emphasizing the urgent need for our society, and this committee, to direct efforts and funding to research and treatment options for this pathology. The increasing rates of mortality may disproportionately impact women of colour, as evidence is demonstrating in the United States (ACS, 2024), though limited race-related health data in Canada complicates assessments in the Canadian context.

Early-stage endometrial cancer is typically treated with surgery, sometimes alongside chemotherapy, hormone therapy or radiation, and generally has a favourable prognosis. Recurrences occur in approximately 18 - 20% of endometrioid endometrial cancer cases, (Restaino et al, 2022; Siegenthaler et al, 2022), as was the case for **Patient B, Patient E,** and **Patient F**, who recurred at less than 6 months, 14 months, and 17-18 months, respectively. In cases of recurrent or advanced disease, treatment options are limited, the overall prognosis is quite dismal with a 5-year overall survival rate lower than 20% (Cao et al., 2023), and access to new therapeutics for the management of endometrial cancer has been rather stagnant for decades.

Symptoms of endometrial cancer often present as abnormal vaginal bleeding in the pre-menopausal female and any vaginal bleeding in the post-menopausal setting. In some cases, the bleeding can be quite severe, as was experienced by **Patient B,** who eventually required 8 blood transfusions to combat her blood loss**:** ***"…I was just bleeding constantly and absolutely flooding my sanitary napkins… I was basically hemorrhaging ridiculous amounts of blood."*** While abnormal vaginal bleeding is the most common symptom in both age groups, and experienced by more than 90% of women with endometrial cancer, individuals may also experience abnormal vaginal discharge, difficulty or pain with urination, pain during sexual intercourse, pelvic pain, or unexplained weight loss (MSK, nd).

Patient profiles further reveal the variability in endometrial cancer experiences:

Patient A was diagnosed with **stage IV MSI-H endometrial cancer** at age **33** after experiencing serious leg pain related to a lump in her groin.

Patient B was diagnosed with stage III **MSI-H** endometrial cancer at the age of **30** after experiencing significant and worsening vaginal bleeding and pain. She quickly **recurred with stage IV** disease and was determined to have Lynch Syndrome.

Patient C was diagnosed with endometrial cancer at the age of **83** after intermittent vaginal bleeding and is unaware of her staging and biomarker information, sharing ***"I don't ask the questions that frighten me!"*** This is her third primary cancer diagnosis in the past 2 years.

Patient D was recently diagnosed at the age of **53** with a **stage IIIc dMMR endometrial cancer.** She initially presented with vaginal discharge which was misdiagnosed before later experiencing abnormal vaginal bleeding.

Patient E was diagnosed with stage Ic **pMMR** endometrial cancer on Christmas Eve after odd urinary symptoms at the age of **62** and later **recurred with metastatic disease.**

Patient F was diagnosed at the age of **67** with stage Ia endometrial cancer after experiencing bleeding after intercourse. She **recurred with metastatic disease** and is unaware of her biomarker status.

Several interviewed patients spoke to an element of dismissal of their symptoms, either by their healthcare provider, or through-self dismissal:

"I didn't think of cancer at all" **– Patient A**, age 33

"[I had] no real traction with my doctor, who said 'sometimes women just bleed"' **– Patient B**, age 30, who was initially diagnosed with hyperplasia but not cancer, and eventually required 8 blood transfusions in the emergency department

"I ignored it until I couldn't anymore" **– Patient C**, who was busy managing two other primary cancer diagnoses

"The first time I saw the gyne they misdiagnosed me" **– Patient D**, who did not initially present with the typical abnormal vaginal bleeding

A diagnosis of cancer is almost universally distressing often triggering intense emotions, such as extreme fear, stress, anxiety, as well as shock, an emotion that was unanimously experienced by all interviewed patients. **Patient A** shared, through tears,

that she was "*alone in the emergency room… I was just in a state of shock"* when she learned that she had early-age onset cancer. **Patient B** described that she was shocked and scared when learning the news, also alone in the emergency department: *"It's absolutely really a terrifying diagnosis. My wife is in the navy and was at sea at the time."* **Patient E** vividly recalled how she felt upon learning she had recurred: *"I looked up the 5-year survival rate and it was 17% - to say I was devastated doesn't even begin to describe it. I was psychotically upset, it was a terrible emotional trauma."*

The intimate nature of being diagnosed with a gynecological cancer adds an additional element of distress for many. Stigma, shame, and blame can be felt by individuals experiencing endometrial cancer, as **Patient F** vulnerably explained*: "I had some sexual trauma growing up, [and receiving my diagnosis] felt like Catholic whip lash."* **Patient B** had been trying to conceive and believes this played a role in her advanced diagnosis: *"I was diagnosed after IVF, I had had quite a lot of HRT. My wife was going to give the eggs, and I was going to carry, so I got a lot of HRT which probably made it worse."*

In additional to the psychological trauma of receiving a cancer diagnosis, many women experience pain related to their cancer symptoms. **Patient A** experienced severe leg pain related to her metastatic lesion, which did not allow her to sleep, significantly limited her mobility, and required daily pain management medications. **Patient B** also experienced severe pain, in her abdomen, which required opioid pain management. In **Patient E's** case it was her metastatic recurrence which caused severe physical symptoms from the ascites caused by her peritoneal disease which presented rather abruptly while on vacation with her husband and son: *"I could not eat for 10 days. I literally would pinch off a piece of food the size of a grain of rice. I'm not kidding."* Her recurrence was diagnosed in the emergency department in the city in which she was vacationing, and she shared her harrowing journey home after an unthinkable end to her family vacation: *"I could not walk to get my flight… I couldn't breathe, I was just praying I survived the flight back. And I went right from the flight to the hospital and became an in-patient at [my cancer center]."*

Interviewed patients also shared the distress caused by delays and siloes within the healthcare system, which appears from the patient input collected, to be a consistent concern with the disease experience across jurisdictions:

"I had to fight to get the MRI, they didn't have enough techs. And then I had to fight to see the oncologist. It was about a month between the date of diagnosis and getting to my oncologist. So, there was a delay, and that was with me calling every day to see if there was a cancellation." **– Patient A** (treated in Canada)

"In the [emergency department] no one wanted to take the lead, and then one doctor took my notes home, looked at all my case, and booked me for my investigations." **– Patient B** (treated in Scotland)

"The waiting factor is really bad, it's not good if women have to wait." **– Patient E** (treated in the USA)

Upon learning their diagnosis, those patients who were experiencing pain identified pain management as the immediate concern to be controlled. For patients not acutely experiencing pain, longevity and robust treatment options were prioritized by patients:

"Cancer is cancer. You just want it out of your body." **– Patient C**

"Well, the most important aspect for me is I want my life to be as long as possible because I have a family, and I want to be here with them." **– Patient E**

The burden of cancer extends to the family and friends, as well as the social, community, and professional connections of the individual diagnosed with cancer. One caregiver who completed the endometrial cancer patient survey shared the issues they encountered as a caregiver to an endometrial cancer patient, namely: emotional drain, anxiety/worry, inability to plan ahead, feeling isolated, and feelings of helplessness. **Patient A** tearfully shared how her cancer has impacted her parents: *"They had to move quickly very to Toronto to help me with everything, I was in a lot of pain and couldn't move very much. It was tough…I can imagine how tough it was for them. By the time my parents reached me I was immobile, and my mom had to find us a place to live. My dad was working overseas, and he resigned to come back to Canada. They sold their place and they came to Toronto to help me. I'm their only child so I can imagine how tough it could be for them."* **Patient B** experienced 'cancer ghosting' from some of her friends, who stepped away when they didn't know how to support a friend who had cancer in her 30s, and she shared that these friendships were damaging irrevocably. She had other friends who stepped up to support her, and she felt that they struggled in silence, hiding their emotions from her. For **Patient E**, the emotional turmoil of her diagnosis negatively impacted her marriage, as she felt her husband didn't understand what she was going through or how to help her cope: *"It definitely has affected my husband; this will make me cry. He's been very supportive in every practical way imaginable. But he struggles to know how to support me emotionally… I was kind of a wreck and was accusatory towards him and took it out on him…. I didn't feel I was getting what I wanted from him, and he was trying to do everything he could. It did affect our marriage."*

4. Experiences With Currently Available Treatments

Though there are therapeutics for the treatment of endometrial cancer currently under funding review with CDA, these therapeutic protocols have not yet received a funding recommendation and are not currently accessible through our publicly-funded healthcare system, nor is there any assurance of such in the future, and thus, the author implores the committee to review this funding decision through the lens of *the current treatment landscape* for advanced or recurrent endometrial cancer patients in Canada.

Endometrial cancer survey respondents accessed a variety of treatment options, including radiation therapy, surgical resection, targeted therapy, hormonal therapy, immunotherapy, chemotherapy, and complementary medicines. These patients experienced various symptoms, including **neuropathy, fatigue, dryness, itching, tightening and/or burning in the vagina, changes in sexual functioning, fluid retention, nausea, constipation, and 'chemo brain'**, as illustrated in **Figure 1.** Respondents described chemotherapy as ***"tough; much nausea and constipation"*** noting it ***"affects my thinking, loss of stamina, fatigue".***

Patient-Reported Side Effects of Currently Available Treatments

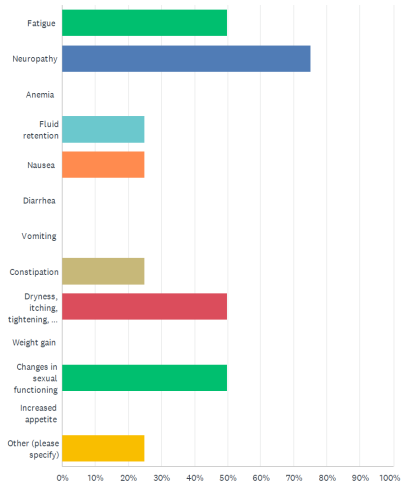


Figure 1

Patient B shared her experience with adjuvant chemotherapy following her initial diagnosis: ***"Chemotherapy was really tough. I think the biggest things were really debilitating fatigue for the first 4 days. It's like time stops moving, I couldn't sleep because of the steroids…. I'd have awful fatigue and I couldn't do anything but lay down, but I also couldn't sleep. I almost couldn't sit up I was so tired, it was exhausting and painful. Like an awful purgatory."*** The nausea experienced while undergoing chemotherapy treatment can impact many far-reaching facets of one's life, beyond what many can imagine. For **Patient B**, a vegan, the nausea was so intense she found that she had to eat chicken to maintain the protein she so desperately needed in her diet while minimizing her fiber intake, which made her feel ***"ethically uncomfortable"***, but she felt she had no choice to be able to tolerate her treatment.

Interviewed patients accessed the therapeutic protocol as first line systemic treatment upon being diagnosed with advanced or recurrent disease, thus experiences with surgical and radiotherapeutic interventions are described in the text below.

Patients B & E underwent radiation therapy / brachytherapy, and **Patient F** was referred for brachytherapy, but ultimately was not treated following a traumatic experience unique to the intimate nature of treating gynecologic cancer: ***"I strongly did not want radiation. I was referred for brachytherapy and they did it backwards - they read the CT after they did the extensive fitting for brachytherapy and pelvic therapy. It turned out that I had a couple of lymph nodes that had been affected. Like, read the damn scans before you spread my legs and do the fittings."*** **Patient B** experienced quite distressing diarrhea as a result of her pelvic radiation, sharing ***"a couple of times when we were going for walks in nature I would just have to run off and go in the woods."***

With the exception of **Patient A**, all patients underwent a hysterectomy. **Patient B** additionally underwent a Hartmann's procedure, leaving her with a colostomy. For **Patient D,** she found that ***"The surgery was kind of tough. I had bedrest for the first month after and that was a little bit more than I thought it was going to be. Just not being able to get up out of bed normally… I wasn't able to work for several months."*** **Patient C's** hysterectomy left her with some incontinence, but she articulated that the impacts would have been greater if she experienced a hysterectomy at a younger age: ***"At this age [83], it's a different mindset than if you are having children or having sexual relations. It's a very different mindset now than if you are sexually active with your partner."*** Indeed, both **Patient B** and **Patient F** spoke to the impact of their treatments on their sexual health:

"The brachytherapy caused some narrowing in my vagina, and the shortening of the vagina from surgery as well caused some issues with sexual functioning, which I think is quite important." **– Patient B**

"[My hysterectomy] certainly has impacted my want for a sex life. I just didn't feel that great." **– Patient F**

All too often, the significant effects of treatment on sexual health and functioning are dismissed or inadequately addressed in both clinical care and research (Agrawal, 2022; Barcellini et al., 2022). Interestingly, but perhaps unsurprisingly, female patients are less likely to be asked about sexual health than male patients, and particularly so if they are beyond child-bearing age

(Agrawal, 2022), as is often the case for endometrial cancer patients. Once again, this highlights one of the many inequities faced by women experiencing endometrial cancer.

5. Improved Outcomes

When asked what improvements they would like to see in cancer treatment (**Q33**), interviewed patients had quite a lot to contribute. They spoke about their desires to see the time from drug development to access decreased, to know that additional lines of therapy available if they should exhaust first-line treatment, their hopes for the development of treatments given by oral administration, improved access to targeted therapeutics rather than cytotoxic chemotherapeutics, increasing funding for endometrial cancer drug research, tumour-agnostic access to biomarker-informed therapeutics, the importance of connecting with patient organizations, and increased patient education and empowerment. Two responses, in particular, stood out as salient points to be considered for this review:

"Ideally, I think in Canada we have one of the most stringent medical programs and our oncologists have to go through so much to be where they're at. I think we should trust them. If the oncologist has recommended a treatment, that should be the therapy that's covered. In the small circle that I'm a part of, I meet other people who have cancer and they're trying to access drugs that are proven to work and they just can't access it…If the oncologist has recommended a therapy, I think that therapy should be provided to the patient." **- Patient A**

"I would like there not to be fake disqualifying criteria based on factors that may not be the whole picture, for example the pMMR status. If I had lived in certain places, I wouldn't [have been able to access this therapeutic] and I'd be screwed. For me that's important." **– Patient E**

Additionally, when survey respondents were asked which issues they would hope a new treatment would address, 60% of endometrial cancer patients ranked ***"prolong life"*** as the most important issue. The therapeutic protocol under review has demonstrated significantly longer progression free survival outcomes, quite remarkably in the dMMR patient population, and quite meaningfully in the pMMR patient population (Eskander et al, 2023), whose treatment options are so very limited. The therapeutic under review clearly offers the ability to prolong life for many, as is so very much desired by patients.

6. Experience With Drug Under Review

Patient A added the pembrolizumab to her chemotherapy treatment in August 2023 (on her 3rd infusion cycle, after a delay related to funding) and was still on pembrolizumab as a monotherapy at the time of the interview. Pembrolizumab was recommended by her oncologist who shared with her that there ***"were 2 new research studies published in February showing immunotherapy added to chemo shows improved outcomes and she thought I should do it."*** The patient then stated: ***"I trust her, and I looked up the results and knew I had to fight to get the immunotherapy added to the combination."*** Despite the therapeutic protocol being recommended to improve outcomes and extend her longevity and prescribed by her oncologist, this young patient experienced significant challenges in an effort to access the drug that she believed would extend her life: ***"My oncologist applied to Cancer Care Ontario and my file was rejected and they wouldn't provide funding. I reached out to Merck myself and learned that they didn't have a compassionate program outside of the US. The PMH reimbursement specialist confirmed this as well. There's no way of getting any funding for this drug and the drug company is not providing compassionate access. There was no clinical trial open."*** Ultimately, she has and continues to access her therapy through self-pay, with her extended health benefits paying a portion – which for many, would be unattainable.

Patient B received pembrolizumab as a monotherapy after being previously treated with paclitaxel and carboplatin just 6 months prior at the time of her initial diagnosis. She took the therapy from June 2021 to June 2023 and remains no evidence of disease despite a significant metastatic disease burden at the time of her recurrence: ***"I am in remission as far as I know, for the last 18 months. I had clear scans after about 6 months."***

Patient C declined the combination. At 83 years old, she ***"knew [she] was not going on chemo"*** but is doing remarkably well on her pembrolizumab monotherapy, which she has been on since January 2024.

Patient D began pembrolizumab in combination with chemo in April 2024, completing 6 cycles of the combination therapy and has been on the pembrolizumab monotherapy since August 2024.

Patient E began pembrolizumab in combination with chemo in June 2024, completing 6 cycles of the combination therapy and 2 cycles of the pembrolizumab monotherapy.

Patient F began pembrolizumab in combination with chemo in April 2024 and will take one more cycle of combination therapy before moving to the monotherapy.

Remarkably, **all patients experienced a robust response** to pembrolizumab +/- chemotherapy, as was evidenced radiographically, biochemically and/or clinically. **Patient A** has had her pain significantly reduced – her top priority upon diagnosis as the pain prior to treatment had been completely debilitating. When asked whether she felt the therapeutic protocol improved her cancer symptoms, she shared: ***"Yes, I don't even know if I would be alive if I didn't have the therapies. The tumour was growing so quickly. I went from no pain killers [prior to diagnosis] to high doses within a few months and I went from walking [prior to diagnosis] and by the time I started chemo, I was somewhat confined to a wheelchair. Now I can walk fine, I can walk for 2 hours, or more!"*** She further shared that progressive disease regression has been evident on her bloodwork and imaging, and her menstrual cycle has even resumed: ***"The drug is doing what we want it to do!"*** **Patient B**, as described above, has had no signs of disease for the past almost 3 years and is 18-months post-treatment. **Patient C** quite simply shared, ***"I go every 6 months for imaging – so far, so good"***, **Patient D** who did not have any evidence of macroscopic disease following her resection has seen progressive decrease in her CA-125 marker each cycle of therapy, and **Patient F** has received a clear PET scan since beginning treatment. When **Patient E**, who was extremely symptomatic from severe ascites and feeling like she was ***"going to die any second"***, was asked whether she felt the therapeutic relieved her cancer symptoms, she responded with an emphatic ***"Oh my goodness I can't emphasize this enough, 100% and more! … they kept asking me about the fluids and feeling my belly and it was gone."*** She went on to share that her imaging is clear and her ***"Signatera has been at a 0 since the second or third round of therapy - they say I'm in remission."***

As would be expected the interviewed patients generally reported more side effects and a lower quality of life while taking the combination therapy for the short duration of time, followed by fewer side effects and an improved quality of life while taking the pembrolizumab monotherapy. The short duration of initial treatment of pembrolizumab in combination with chemotherapy lends itself to increased tolerability and limits the impact of cumulative effects, particularly when framed against long-standing chemotherapeutic treatment as is the current standard of care in the pMMR setting. For the balance of the treatment regimen, patients are treated with a precision immunotherapeutic which is highly efficacious while maintaining a lower side effect profile when compared to its cytotoxic chemotherapeutic counterparts.

During the initial combination treatment of paclitaxel, carboplatin, and pembrolizumab, patients reported severe fatigue, neuropathy, allergic reactions, hair loss, neutropenia, and 'chemo brain'. An additional adverse event of internal bleeding was reported by **Patient A**, related to a drug interaction between the chemotherapy and prescribed pain killers. An average rating of **8 out of 10** was provided by interviewed patients in respect of their quality of life while on the treatment combination, with significant individual variability, ranging from ***"5 or 6 – I wouldn't be able to work for sure"*** [**Patient A**] to ***"12 out of 10"*** by a **Patient E** who experienced no physical adverse effects throughout either phase of her treatment. She had achieved a significant weight loss and focused on achieving a healthy lifestyle in the period between her initial diagnosis and her recurrence, and shared she felt physically better now than she did before cancer.

Side effects reported by patients while on pembrolizumab monotherapy included hyperthyroidism, hypothyroidism, joint pain, fatigue, diarrhea, skin changes, and worsening allergies / asthma. Patients generally reported these side effects to be quite tolerable and manageable and perceived a notable difference when moving from the combination therapy to the monotherapy, for which patients provided a remarkable average rating of **9.5 out of 10** in respect of quality of life.

"With the chemo, there was just a lot of fatigue and some days I couldn't get out of bed, I couldn't do the normal things, I couldn't go for a walk…. With the Keytruda I don't feel like it's draining my energy, it's just the allergies. Everything is starting to get better – my hair is growing back, which contributes to my quality of life and I just feel better." **- Patient D**

"With the pembro it's just very easy on me. It's half an hour infusion, you're in and out of the hospital very quickly, other than the thyroid issue which is a very easy fix, the joint pain wasn't bad, it goes away with walking, other than that the fatigue is really nothing compared to chemo. I can still go and travel while I'm on pembro." **– Patient A**

"Keytruda is a dream. It's a short 30 minutes infusion and for me, no side effects. My husband and I both LOVE it. The chemo, I'm glad I got it, it was a long day, but it is what it is, and I would do it again in a heartbeat." **- Patient E**

With minimal adverse effects of treatment and a short infusion time, pembrolizumab significantly improves quality of life for endometrial cancer patients, permitting them to engage in meaningful activities in their lives: *"It was life changing for me, I wouldn't be here if I hadn't had IO and I wouldn't be here if I had more chemo, it's quality of life, but it's survival as well."* **[Patient B]. Patient B** & **Patient D** both, quite remarkably, were able to work while undergoing their systemic treatment, improving their financial stability, sense of fulfillment, and contributing to society. **Patient B** was not only able to work but, was also able to progress and advance in her career, receiving promotions both during and after treatment. **Patient E** is able to enjoy and participate in her life as a grandmother and even schedules her pembrolizumab infusions in the morning so that she is able to babysit in the afternoon given the infusion time is so short and she feels well afterwards. She excitedly shared with the author that her third grandchild is on the way. **Patient A**, as well, shared that her treatment regimen minimally impacts her life: *"With the pembro, it's just a quick drip, just 30 minutes. I could have pembro and then go shopping right after if I wanted to. It just feels like a regular IV of liquid."* **Patients A, B** & **E** have been able to travel, which is an incredibly rewarding experience, for the body, soul, and mind, not only permitting patients to fulfill life goals they might not have otherwise had the opportunity to do, but also to provide a *"cancer vacation"* and an opportunity to enjoy life outside the weight of being a cancer patient. **Patient E** shared that she has been able to maintain her intimate relationship with her husband throughout treatment and **Patient B** shared that she was able to go out and socialize with friends and family and spend time *"doing meaningful life things, whereas with chemo I was really withdrawn and in the hospital every day, I was absolutely shattered."* **Patient C** puts the benefits in simple terms: *"I breathe every day."*

In addition to improving quality of life, the therapeutic under review provides a durable, and long-lasting response for many, which is clearly important to patients and their loved ones, according to survey respondents and interviewed patients who echoed the importance and significance of potentially being able to achieve long-term response, or a no evidence of disease status. In **Patient B** word's: *"I'm doing yoga training at the moment, and I am hoping to do yoga retreats for people with cancer. When I was first diagnosed, I wouldn't have dreamed to plan that far in advance."*

When asked if they felt it was worth accessing the therapeutic, patients shared enthusiastic responses:

"I think it's one of the few treatments that extends life without negatively impacting quality of life. I think we've all seen the research for that, it has the possibility of having a long-term disease control. So, I think it's extremely important. I think the data speaks for itself. IO is game-changing. Yes, it was worth it." **– Patient A**

"Really 100%, wow I would not be here… It saved my life, and I'm living a normal life, and we're going to New Zealand in 3 weeks…. I'm here and I'm able to engage in a meaningful life and do all the things that are important to me. If I hadn't had this drug, I wouldn't be here to tell you about it. It's worked better than I imagined, it's doing its job, it's incredible. It sounds a bit cheesy but, pembro has allowed me to thrive, with limitations, for the most part for the last 3.5 years with cancer, stage 4 endometrial cancer." **– Patient B**

"I'm alive! [laughs]" **– Patient C**

"Yes, I do. Because I've had a good response to it, and it just seems to be working for me…. I mean I don't know what it would have been like if I didn't take it." **– Patient D**

"Oh my goodness – huh – I couldn't even begin to describe how much…. It saved my life. Period. I can't imagine what my situation would be without it. It's giving me time with my family and all these memories created. It's definitely extended my life and made my life wonderful. I'm so grateful." **– Patient E**

7. Anything Else?

There is a significant and urgent unmet need for additional precision therapeutics in the management of advanced or recurrent endometrial cancer in Canada. This unmet need is particularly dire for the MSS/pMMR endometrial cancer patient population wherein systemic treatment options have not advanced for decades. **Patient E,** who faced a grim prognosis after recurring with extensive metastatic disease, but now has been told she is in remission, shared *"I'm so glad they didn't exclude me because*

I am pMMR." To further illustrate the unmet clinical need, the author shares a quote from a Canadian gynecological medical oncologist, which was referenced in a recent submission (**PC0381-000**):

"I maintain there is a huge unmet need for the MMRp and MSS endometrial cancer patient population. These patients do not have good, effective treatments once platinum resistance sets in. End of story. And significant loss of quantity and quality of life especially in women in their 50s and 60s who are primary caregivers to their children and parents and are contributing members of society and are still gainfully employed should be a primary concern. Making up about 70% of endometrial cancer patient population is the MMRp/MSS molecular subtypes and discussions should be left to the clinician and patient, with respect to the tolerance, toxicities, and efficacy of [immunotherapeutics] because these issues are discussed during the patient/oncologist consultation."

Patient C spoke eloquently and from her heart when reflecting on the importance of accessing the therapeutic protocol from her perspective as an individual with the lived experience: ***"There is nothing more wonderful and powerful than anything that keeps a person alive. Whatever drug keeps you alive, that person needs to be able to access it, period. Whether they can afford it or not, keeping people alive has no price tag."***

When asked if the therapeutic protocol should be made available to all patients who qualify for it, interviewed endometrial cancer patients responded with passionate pleas for access in Canada:

"You know I think it should be made available to all patients, period. From what I can see, in the US it's approved for everyone dMMR and pMMR - some pMMR will respond and who are we to say that they don't deserve a shot." **- Patient A**

"Yeah, I would based on my experience. I definitely think, yeah, it's been life-saving, life-changing for me. It can mean the difference between living well and not being here." **- Patient B**

"It should be made available not to all patients who qualify for it, but everyone who needs it." **- Patient C**

"Yeah absolutely…. I think it would be very beneficial in Canada for everyone to have access." **- Patient D**

"Oh absolutely! Strongly. I feel it would be devastating not to. Very detrimental and cost more money in the long run when they debilitate and can't function and end up slowly dying in a nursing home costing money." **- Patient E**

"I can say that I'm alive and my PET scan read clear, so clearly something's working. I would advise any country to have the opportunity to get it if it's found to be helpful, and it has." **- Patient F**

A positive funding recommendation for pembrolizumab in combination with chemotherapy would represent progress, and hope, in a cancer type that is under-supported and has derived little benefit from the advancements stemming from the new era of precision medicine within the Canadian treatment landscape. Furthermore, as referenced in **PC0366-001,** gynecological cancers, impacting only those assigned female at birth, receive disparate funding and research, while women uniquely face the challenge and societal burden of being primary caregivers. Gynecologic cancers are plagued by inequities in respect of support, funding, and research advancement. Providing access to this drug will help to reduce this disparity, marking a step towards closing the gap in funding and equity for women's health in Canada. Women facing cancer often times carry the psychological and mental burden of continuing their responsibilities as mothers, grandmothers, and wives, in addition to any paid professional obligations, while also battling a devastating disease. When endometrial cancer patients are able to access therapeutics which are effective and convenient, with minimal side effects, such as pembrolizumab in combination with chemotherapy, it is not only the patient who benefits, but the many individuals she cares for, ultimately reducing the burden of cancer at a societal level. The gynecological medical oncologist referenced in the patient input submission **PC0381-000** articulates this so well based on their extensive clinical experience:

"There are two groups: the older group who are not well so they are trying to balance their own needs and trying to take care of their own spouses who are themselves not well because they have underlying conditions. And a younger patient group who are taking care of their parents and taking care of their own kids, so the stress of both ends is really difficult, the disruption is unbelievable. Women being the primary caretaker is unbelievable when they themselves are diagnosed with a critical illness. It is quite drastic. This is every conversation I have. It is unique taking care of women. I hear: 'How am I supposed to do this?'!!"

Pembrolizumab in combination with chemotherapy is an effective therapy, which is easy to administer and is well-tolerated by patients, providing women with the ability to re-engage in their lives, their communities, their families, and their work, and in some, look forward to a time beyond cancer. The value and the benefits of this therapy are well in alignment with the perspectives, values, and hopes presented by patients as captured in this submission. Thus, **we strongly implore this committee to provide a positive funding recommendation for this therapeutic protocol in Canada.**

Appendix: Patient Group Conflict of Interest Declaration

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

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

   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 2 years AND who may have direct or indirect interest in the drug under review.

Table 1: Financial Disclosures

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

Company	$0 to 5,000	$5,001 to 10,000	$10,001 to 50,000	In Excess of $50,000
Merck				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: **Filomena Servidio-Italiano**
Position: **President & CEO**
Patient Group: **Colorectal Cancer Resource & Action Network (CCRAN)**
Date: **December 2, 2024**

DO YOU HAVE ENDOMETRIAL CANCER?

Have you taken Pembrolizumab (Keytrudd®)?

Pembrolizumab in combination with chemotherapy is currently under a funding review in Canada for the treatment of primary advanced or recurrent endometrial cancer, regardless of MMR or MSI status.

We really need your help!

By participating in a 45-minute phone interview, you can share valuable insights from your cancer journey and experience with the therapeutic protocol under review. Your perspective will help to inform the patient input submission which will have a meaningful impact on the funding recommendation in Canada.

Make your voice heard! Your input could help get this therapy funded in Canada.

1 833-792-2726 ext. 1001 cassandra.m@ccran.org

CANADIAN CANCER SURVIVOR NETWORK / RÉSEAU CANADIEN DES SURVIVANTS DU CANCER

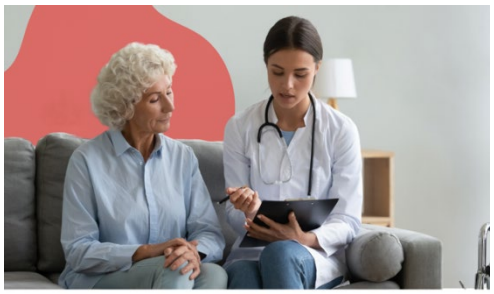
CCRAN Colorectal Cancer Resource & Action Network / RISCC Réseau d'informations et soutien pour le cancer colorectal

A PATIENT-FOCUSED ORGANIZATION

hpv global action / vph action globale

Pembrolizumab (Keytruda®) Patient Input Submission

Communications Toolkit



Suggested caption for social media posts:

Are you an endometrial cancer patient (or caregiver on their behalf)? Have you received pembrolizumab (Keytruda®)?

The Colorectal Cancer Resource & Action Network, Canadian Cancer Survivor Network and HPV Global Action are looking for endometrial cancer patients or their caregivers to share their experience with pembrolizumab (Keytruda®) in combination with chemotherapy.

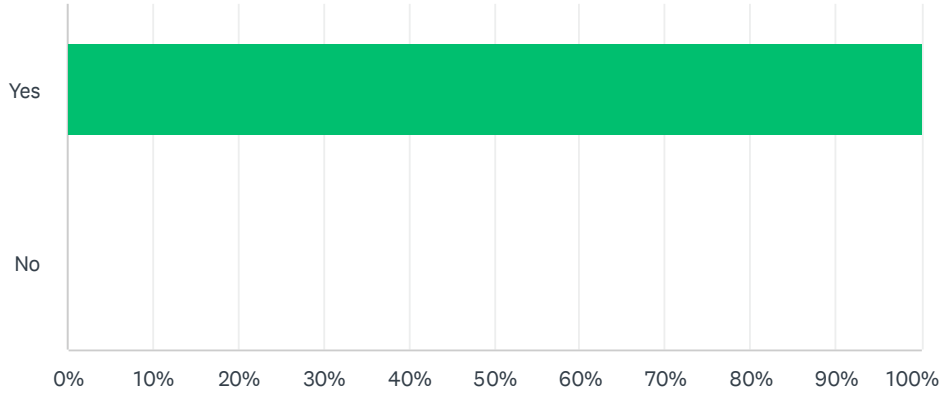
This therapeutic protocol is currently under funding review in Canada. Your input will help inform a collective patient input submission and may make this therapy more accessible for patients across the country. Connect with CCRAN [tag: @ccranorg] today to share your story via a telephone interview: cassandra.m@ccran.org or 1 833-792-2726 ext. 1001.

Your input will be kept anonymous. Let's make a difference together!

#CCRAN #EndometrialCancer #Cancer #CancerTreatment#ShareYourStory #Pembrolizumab #Pembro #Keytruda#PatientSupport #HealthcareCanada #CancerCare#PatientAdvocacy #CancerResearch #PatientVoices #Hope#MedicalAdvocacy #GyneCancer

Q1 Are you a resident of Canada?

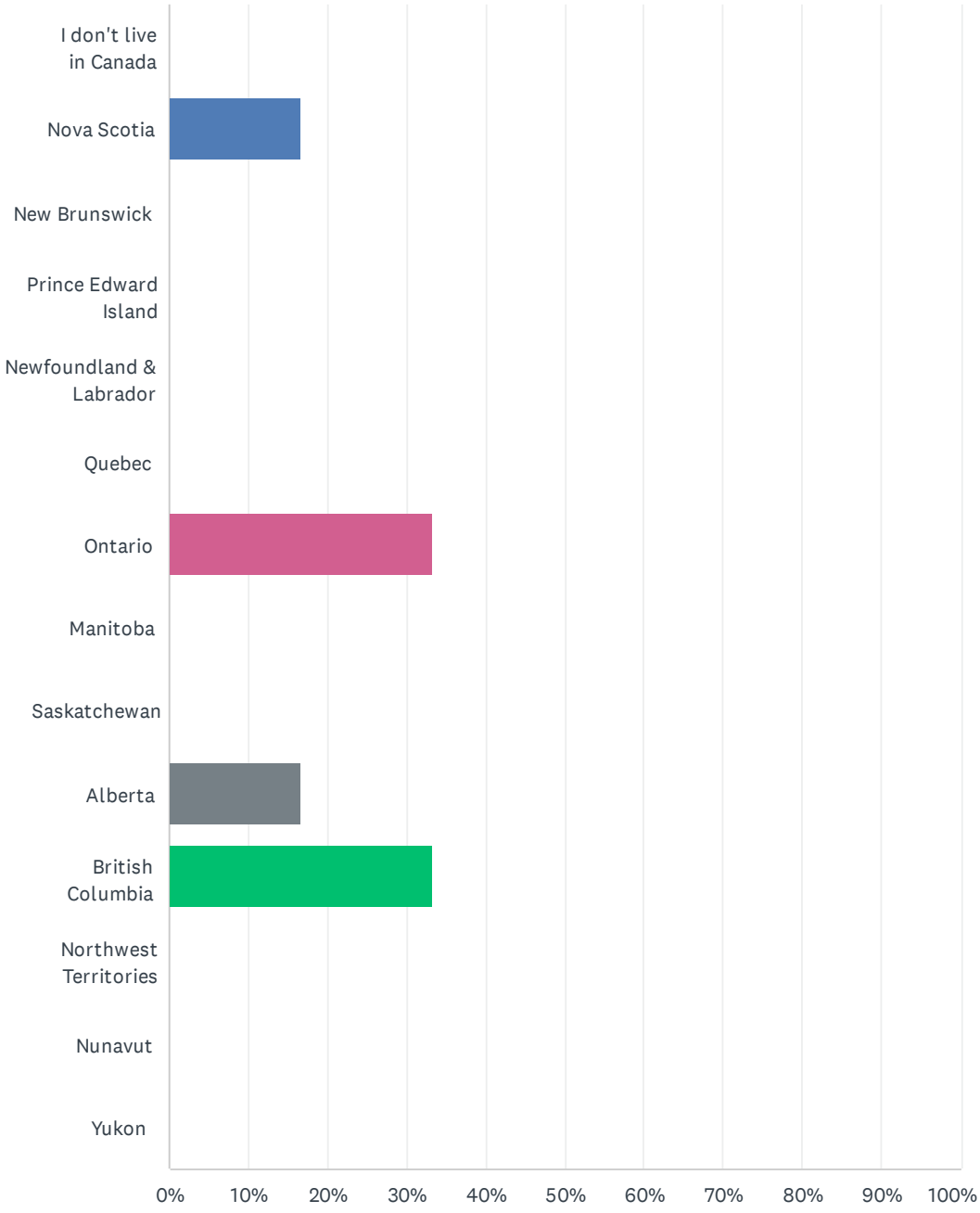
Answered: 6 Skipped: 0



ANSWER CHOICES	RESPONSES	
Yes	100.00%	6
No	0.00%	0
TOTAL		6

Q2 If you are a resident of Canada, in which province or territory do you reside?

Answered: 6 Skipped: 0



ANSWER CHOICES	RESPONSES	
I don't live in Canada	0.00%	0
Nova Scotia	16.67%	1
New Brunswick	0.00%	0
Prince Edward Island	0.00%	0
Newfoundland & Labrador	0.00%	0
Quebec	0.00%	0
Ontario	33.33%	2
Manitoba	0.00%	0
Saskatchewan	0.00%	0
Alberta	16.67%	1
British Columbia	33.33%	2
Northwest Territories	0.00%	0
Nunavut	0.00%	0
Yukon	0.00%	0
TOTAL		6

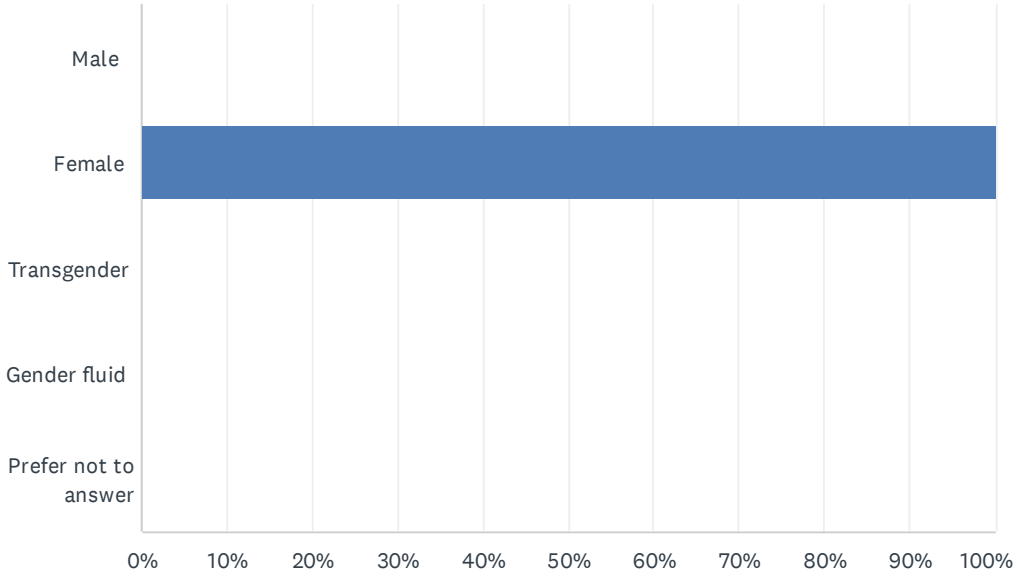
Q3 If not a resident of Canada, in which country do you live?

Answered: 0 Skipped: 6

#	RESPONSES	DATE
	There are no responses.	

Q4 What gender do you identify as?

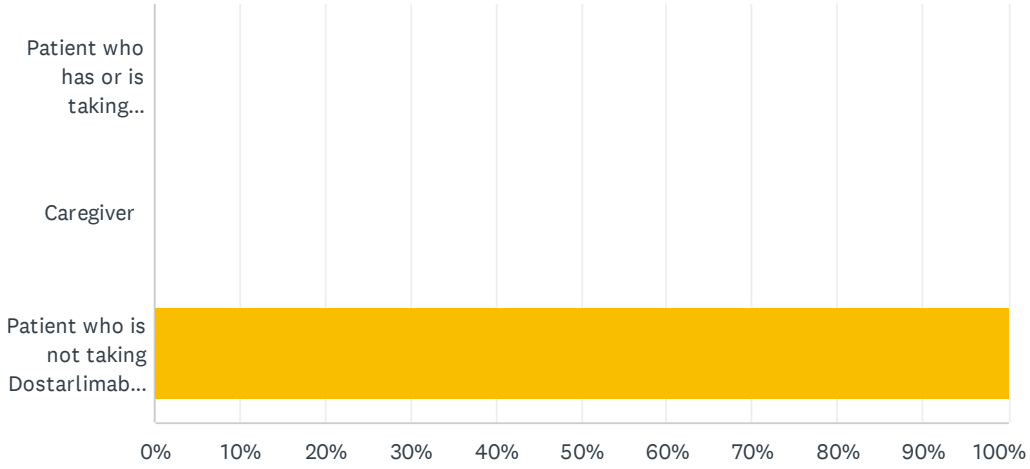
Answered: 6 Skipped: 0



ANSWER CHOICES	RESPONSES	
Male	0.00%	0
Female	100.00%	6
Transgender	0.00%	0
Gender fluid	0.00%	0
Prefer not to answer	0.00%	0
TOTAL		6

Q5 Are you a patient or a caregiver?

Answered: 6 Skipped: 0

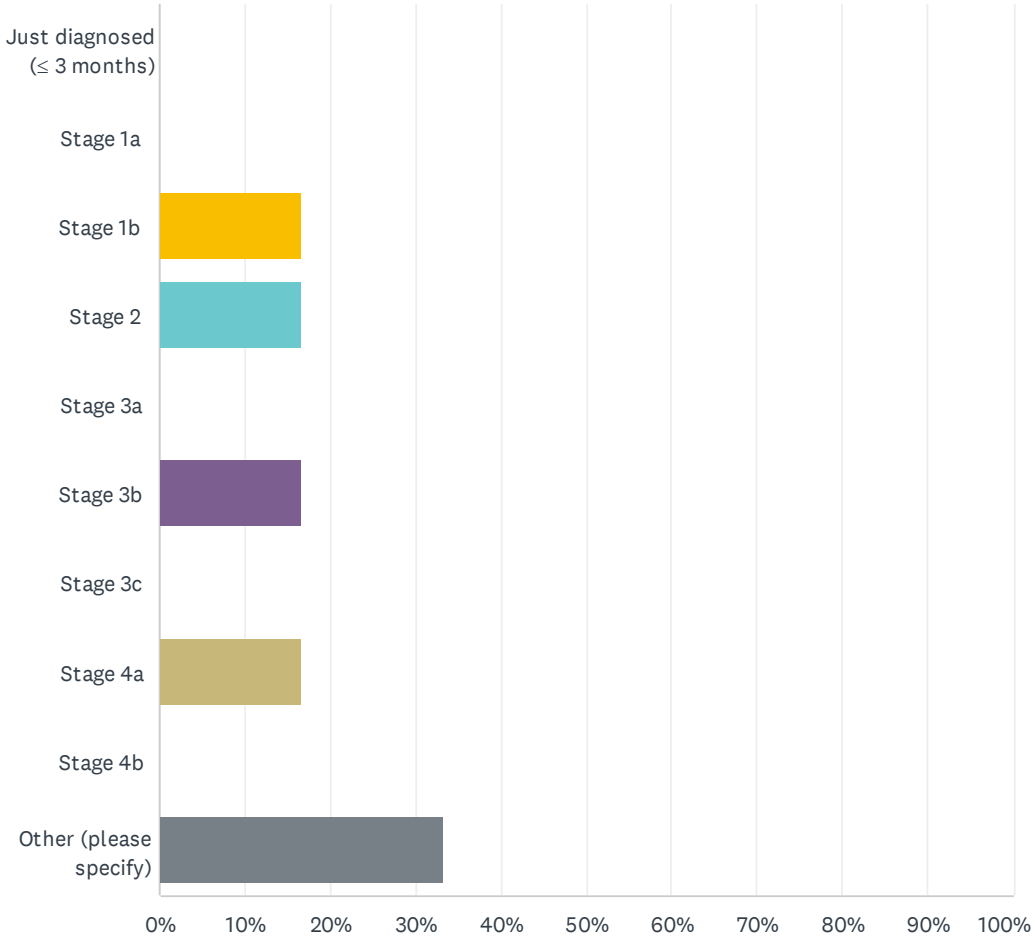


ANSWER CHOICES	RESPONSES	
Patient who has or is taking Dostarlimab	0.00%	0
Caregiver	0.00%	0
Patient who is not taking Dostarlimab (please specify treatment)	100.00%	6
TOTAL		6

#	PATIENT WHO IS NOT TAKING DOSTARLIMAB (PLEASE SPECIFY TREATMENT)	DATE
1	I am NED and on no drugs	10/31/2023 7:15 PM
2	niraparib	10/29/2023 3:29 PM
3	Exmethestane	10/29/2023 1:28 PM
4	none in remission	10/28/2023 2:53 PM
5	Had taxol/carboplatin	10/28/2023 11:57 AM
6	Hysterectomy and brachytherapy	10/28/2023 11:55 AM

Q6 What is the stage of your endometrial cancer?

Answered: 6 Skipped: 0

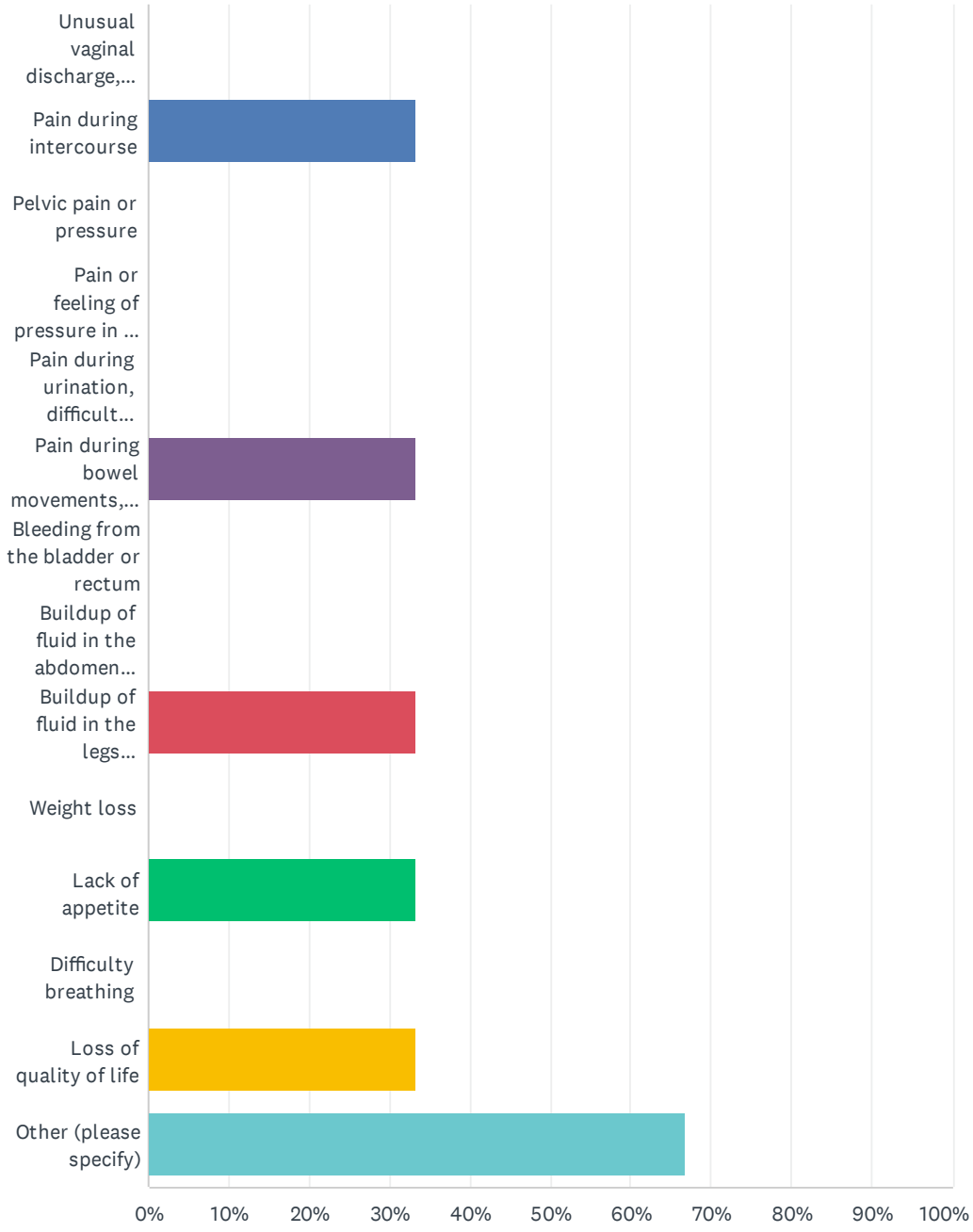


ANSWER CHOICES	RESPONSES	
Just diagnosed (≤ 3 months)	0.00%	0
Stage 1a	0.00%	0
Stage 1b	16.67%	1
Stage 2	16.67%	1
Stage 3a	0.00%	0
Stage 3b	16.67%	1
Stage 3c	0.00%	0
Stage 4a	16.67%	1
Stage 4b	0.00%	0
Other (please specify)	33.33%	2
TOTAL		6

#	OTHER (PLEASE SPECIFY)	DATE
1	mine was breast cancer	10/29/2023 1:28 PM
2	Do not have this type of cancer	10/28/2023 2:53 PM

Q7 What are the symptoms or problems you experience with endometrial cancer that affect your quality of life (such as your day-to-day living)? Please check all that apply.

Answered: 3 Skipped: 3

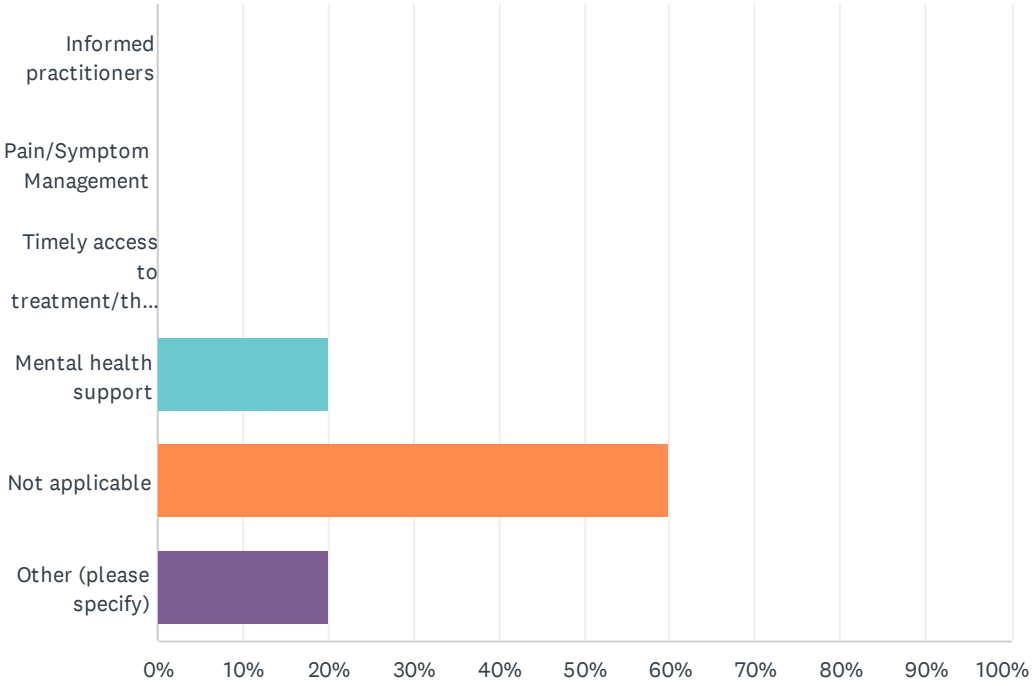


ANSWER CHOICES	RESPONSES	
Unusual vaginal discharge, which can be foul smelling, pus-like, or blood-tinged	0.00%	0
Pain during intercourse	33.33%	1
Pelvic pain or pressure	0.00%	0
Pain or feeling of pressure in the lower abdomen, back, or legs	0.00%	0
Pain during urination, difficult urination, or blood in the urine	0.00%	0
Pain during bowel movements, difficult bowel movements, or blood in the stool	33.33%	1
Bleeding from the bladder or rectum	0.00%	0
Buildup of fluid in the abdomen (Ascites)	0.00%	0
Buildup of fluid in the legs (Lymphedema)	33.33%	1
Weight loss	0.00%	0
Lack of appetite	33.33%	1
Difficulty breathing	0.00%	0
Loss of quality of life	33.33%	1
Other (please specify)	66.67%	2
Total Respondents: 3		

#	OTHER (PLEASE SPECIFY)	DATE
1	n/a	10/29/2023 1:28 PM
2	Tired when I get up, lack of stamina	10/28/2023 11:57 AM

Q8 Are there any needs in your current therapy that are not yet being met?

Answered: 5 Skipped: 1

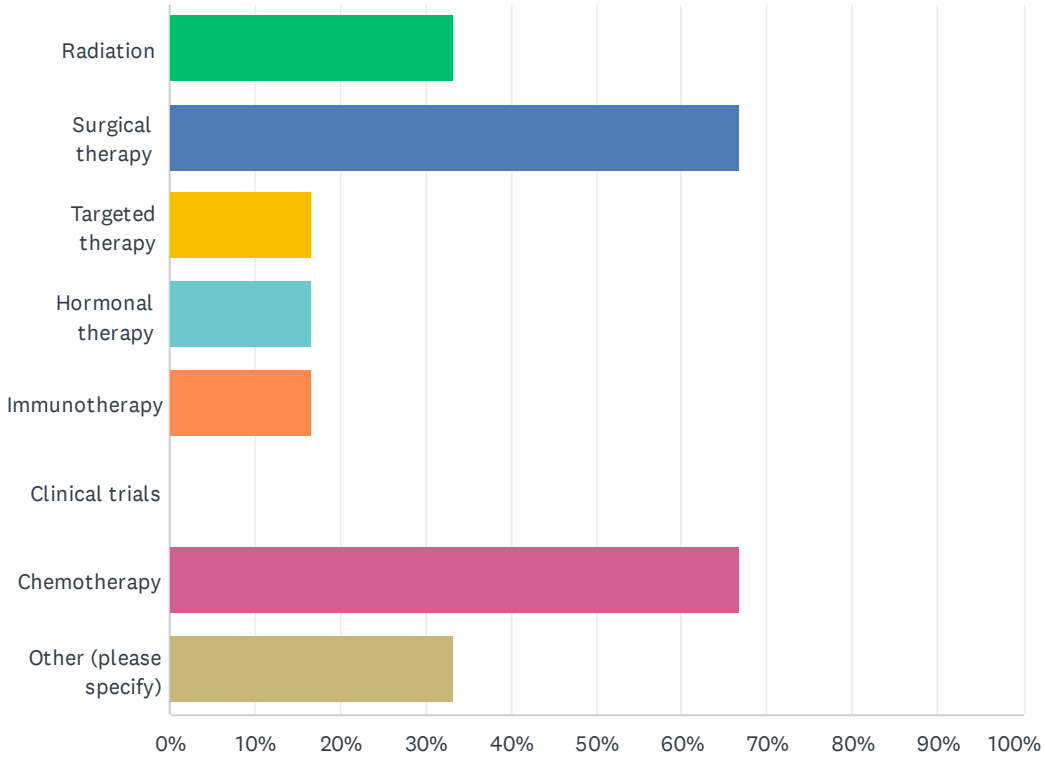


ANSWER CHOICES	RESPONSES	
Informed practitioners	0.00%	0
Pain/Symptom Management	0.00%	0
Timely access to treatment/therapy	0.00%	0
Mental health support	20.00%	1
Not applicable	60.00%	3
Other (please specify)	20.00%	1
Total Respondents: 5		

#	OTHER (PLEASE SPECIFY)	DATE
1	Finished checkups but tgere was never enough time alloted for checkups	10/28/2023 11:57 AM

Q9 What drug therapies or other types of treatments are you currently using, or did you use, to treat your disease? Please check all that apply.

Answered: 6 Skipped: 0



ANSWER CHOICES	RESPONSES	
Radiation	33.33%	2
Surgical therapy	66.67%	4
Targeted therapy	16.67%	1
Hormonal therapy	16.67%	1
Immunotherapy	16.67%	1
Clinical trials	0.00%	0
Chemotherapy	66.67%	4
Other (please specify)	33.33%	2
Total Respondents: 6		

#	OTHER (PLEASE SPECIFY)	DATE
1	I took a pill (don't know the name of it) for 5 years.	10/28/2023 2:53 PM
2	Accupuncture, massage therapy	10/28/2023 11:57 AM

Q10 Is there an aspect of your disease that, to you, is more important to control than others? Please explain.

Answered: 4 Skipped: 2

#	RESPONSES	DATE
1	Recurrence prevention	10/29/2023 3:29 PM
2	no	10/29/2023 1:28 PM
3	I had Brest Cancer that went into the Lymph glans/nodes under my arm	10/28/2023 2:53 PM
4	Kicked out of cancer centre after treament finished. Should have been assigned a nurse for communication. Had to do all my iwn research to get better. Needed better after care.	10/28/2023 11:57 AM

Q11 What adverse effects, if any, were caused by taking Dostarlimab? Please check all that apply.

Answered: 0 Skipped: 6

⚠ No matching responses.

ANSWER CHOICES	RESPONSES	
Anemia	0.00%	0
Fatigue	0.00%	0
Nausea	0.00%	0
Rash	0.00%	0
Diarrhea	0.00%	0
Vomiting	0.00%	0
Other (please specify)	0.00%	0
Total Respondents: 0		

#	OTHER (PLEASE SPECIFY)	DATE
	There are no responses.	

Q12 Were these adverse effects of being treated with Dostarlimab tolerated (i.e. symptoms were managed with other treatment/medications and you did not have to discontinue use of Dostarlimab)? If yes, how did you manage them?

Answered: 0 Skipped: 6

⚠ No matching responses.

ANSWER CHOICES	RESPONSES	
No	0.00%	0
Yes	0.00%	0
TOTAL		0

#	YES	DATE
	There are no responses.	

Q13 How were you able to gain access to Dostarlimab? i.e. clinical trial, private insurance

Answered: 0 Skipped: 6

#	RESPONSES	DATE
	There are no responses.	

Q14 In your own words, please describe the advantages and disadvantages of Dostarlimab and how they made an impact on your life.

Answered: 0 Skipped: 6

#	RESPONSES	DATE
	There are no responses.	

Q15 Would you recommend that Dostarlimab be made available to all patients who qualify for it? 1 being 'Absolutely Not' and 5 being "Yes, immediately'.

Answered: 0 Skipped: 6

⚠ No matching responses.

	1	2	3	4	5	TOTAL	WEIGHTED AVERAGE
(no label)	0.00% 0	0.00% 0	0.00% 0	0.00% 0	0.00% 0	0	0.00

Q16 In comparison to other therapies, how was your treatment experience with Dostarlimab in treating your endometrial cancer?

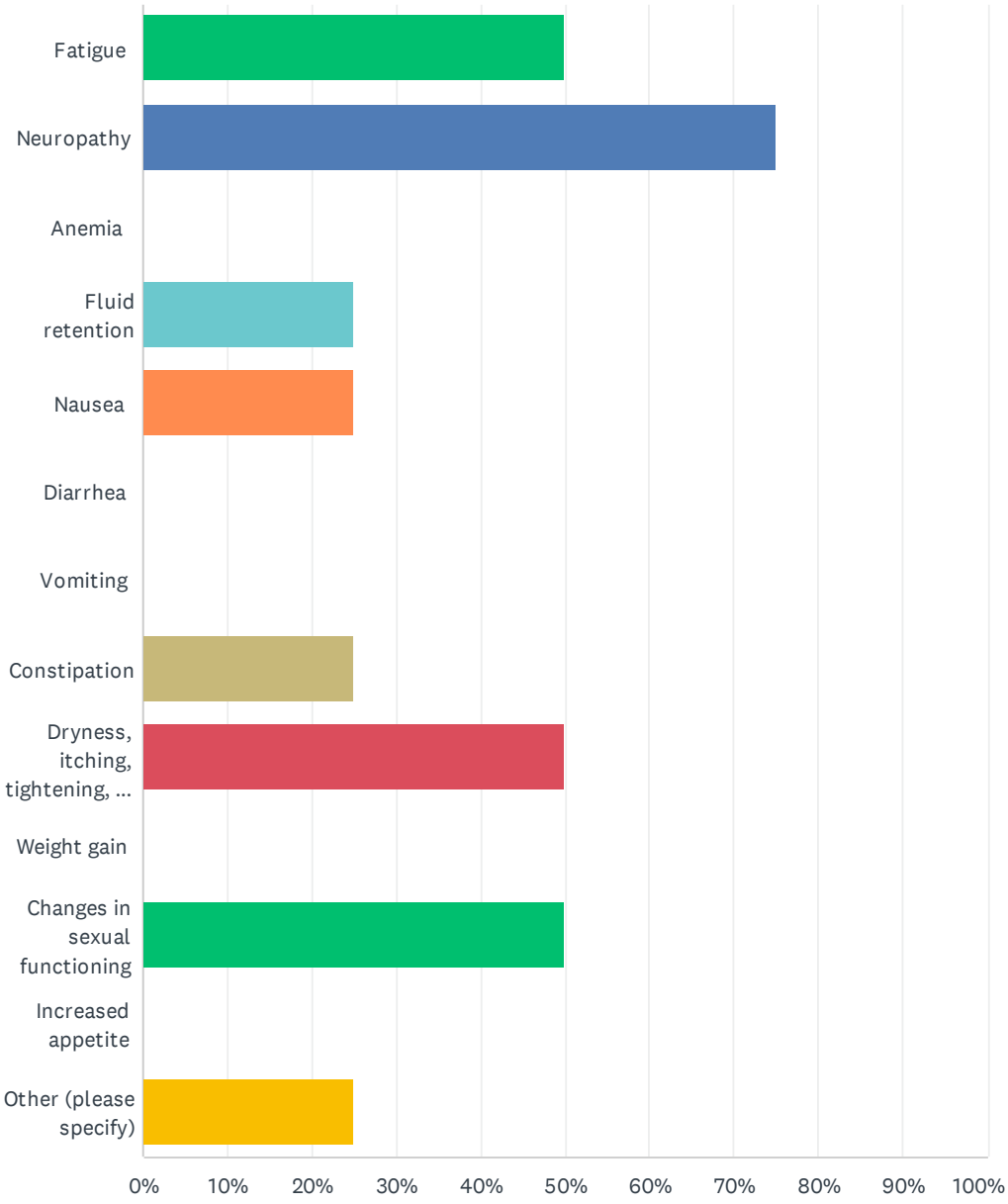
Answered: 0 Skipped: 6

⚠ No matching responses.

	MUCH BETTER	LITTLE OR NO DIFFERENCE	MUCH WORSE	TOTAL	WEIGHTED AVERAGE
Symptom management	0.00% 0	0.00% 0	0.00% 0	0	0.00
Side effects	0.00% 0	0.00% 0	0.00% 0	0	0.00
Ease of use	0.00% 0	0.00% 0	0.00% 0	0	0.00
Disease progression	0.00% 0	0.00% 0	0.00% 0	0	0.00

Q17 What adverse effects, if any, were caused by your current treatments? Please check all that apply.

Answered: 4 Skipped: 2

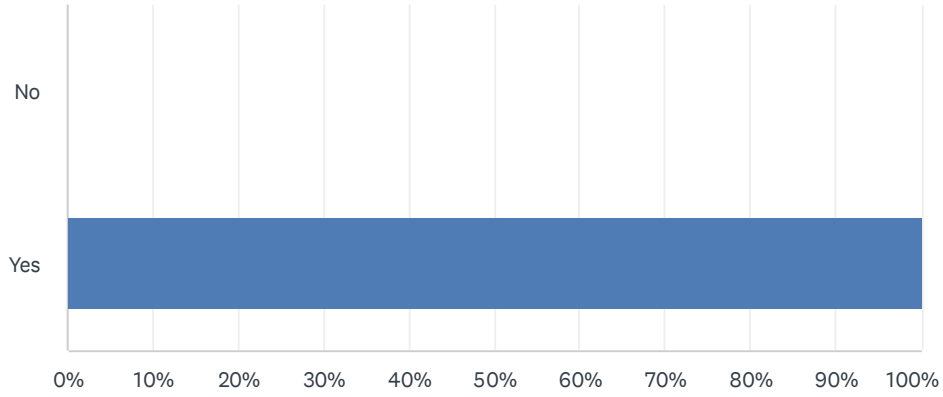


ANSWER CHOICES	RESPONSES	
Fatigue	50.00%	2
Neuropathy	75.00%	3
Anemia	0.00%	0
Fluid retention	25.00%	1
Nausea	25.00%	1
Diarrhea	0.00%	0
Vomiting	0.00%	0
Constipation	25.00%	1
Dryness, itching, tightening, and burning in the vagina	50.00%	2
Weight gain	0.00%	0
Changes in sexual functioning	50.00%	2
Increased appetite	0.00%	0
Other (please specify)	25.00%	1
Total Respondents: 4		

#	OTHER (PLEASE SPECIFY)	DATE
1	Chemo brain	10/28/2023 11:57 AM

Q18 Were the adverse effects of your current treatment tolerated (i.e. symptoms were managed with other treatment/medications and you did not have to discontinue use of Dostarlimab)? If yes, how did you manage them?

Answered: 2 Skipped: 4

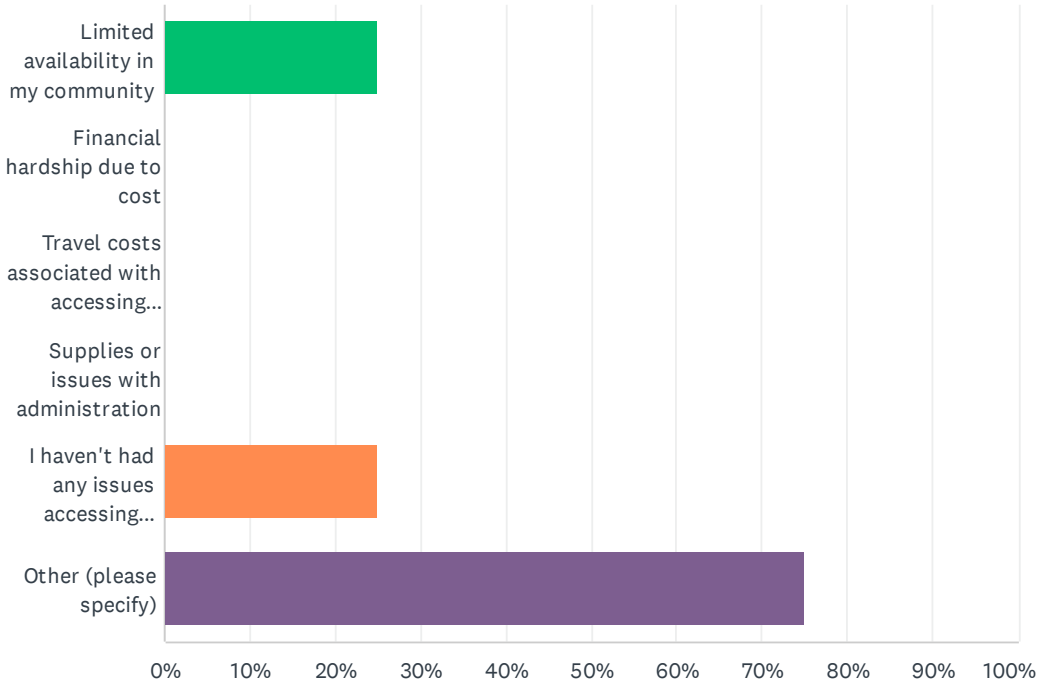


ANSWER CHOICES	RESPONSES	
No	0.00%	0
Yes	100.00%	2
TOTAL		2

#	YES	DATE
1	half dosage; nausea occasionally; proclorperazine	10/29/2023 3:29 PM
2	N/a	10/28/2023 11:57 AM

Q19 Have you had issues accessing any therapies? If so, what issues have you experienced? Please check all that apply.

Answered: 4 Skipped: 2



ANSWER CHOICES	RESPONSES	
Limited availability in my community	25.00%	1
Financial hardship due to cost	0.00%	0
Travel costs associated with accessing therapy/treatment	0.00%	0
Supplies or issues with administration	0.00%	0
I haven't had any issues accessing therapy	25.00%	1
Other (please specify)	75.00%	3
Total Respondents: 4		

#	OTHER (PLEASE SPECIFY)	DATE
1	Any clinical trial using Dostarlimab with niraparib was never mentioned by the clinician	10/29/2023 3:29 PM
2	Had difficulty getting a biopsy at my licsl hospital -cancelled twice	10/28/2023 11:57 AM
3	Driving from home to Clinic in winter weather	10/28/2023 11:55 AM

Q20 If a friend asked you how you are managing at this stage in your treatment, what would you tell them? Please fill out the fields for the treatments you have/are receiving.

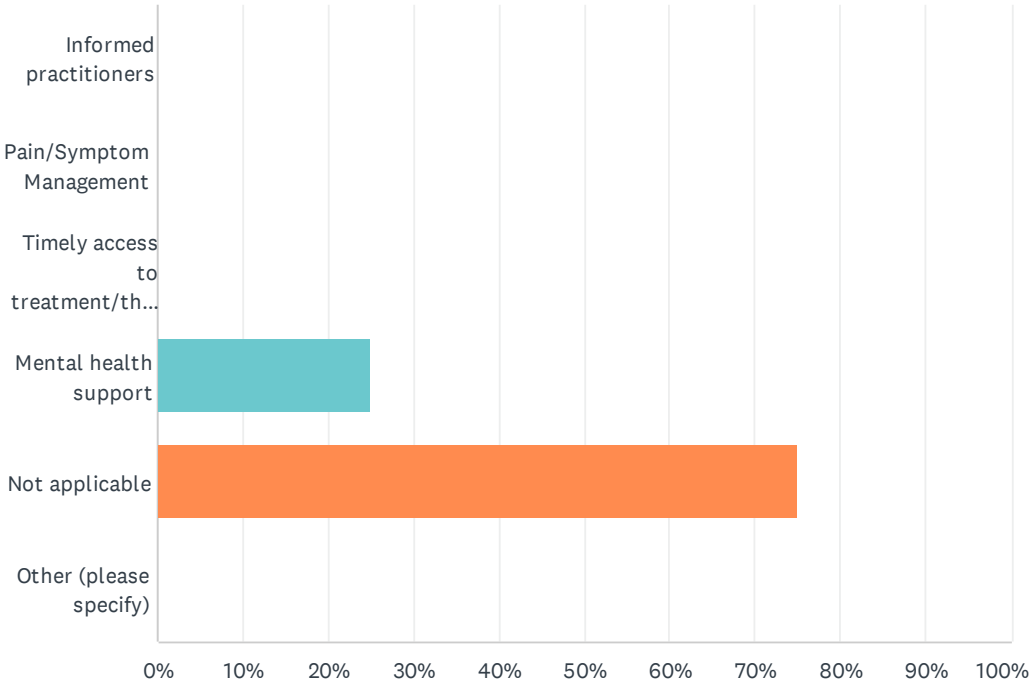
Answered: 3 Skipped: 3

ANSWER CHOICES	RESPONSES	
How are you managing with surgery?	100.00%	3
How are you managing with radiation (internal radiation, brachytherapy, or external beam radiation)?	33.33%	1
How are you managing with hormone therapy (progestins, tamoxifen, LHRH agonists, aromatase inhibitors)?	33.33%	1
How are you managing with chemotherapy (paclitaxel, carboplatin, doxorubicin, cisplatin, docetaxel)?	66.67%	2
How are you managing with immunotherapy (pembrolizumab)?	0.00%	0
How are you managing with targeted therapy (lenvatinib, bevacizumab, mTOR inhibitors)?	0.00%	0

#	HOW ARE YOU MANAGING WITH SURGERY?	DATE
1	Managed well	10/29/2023 3:29 PM
2	ok	10/29/2023 1:28 PM
3	Some bowel oain	10/28/2023 11:57 AM
#	**HOW ARE YOU MANAGING WITH RADIATION (INTERNAL RADIATION, BRACHYTHERAPY, OR EXTERNAL BEAM RADIATION)?**	**DATE**
1	ok	10/29/2023 1:28 PM
#	**HOW ARE YOU MANAGING WITH HORMONE THERAPY (PROGESTINS, TAMOXIFEN, LHRH AGONISTS, AROMATASE INHIBITORS)?**	**DATE**
1	0k	10/29/2023 1:28 PM
#	**HOW ARE YOU MANAGING WITH CHEMOTHERAPY (PACLITAXEL, CARBOPLATIN, DOXORUBICIN, CISPLATIN, DOCETAXEL)?**	**DATE**
1	Was tough; much nausea and contipation	10/29/2023 3:29 PM
2	Affects my thinking, loss of stamina, fatigue	10/28/2023 11:57 AM
#	**HOW ARE YOU MANAGING WITH IMMUNOTHERAPY (PEMBROLIZUMAB)?**	**DATE**
	There are no responses.	
#	**HOW ARE YOU MANAGING WITH TARGETED THERAPY (LENVATINIB, BEVACIZUMAB, MTOR INHIBITORS)?**	**DATE**
	There are no responses.	

Q21 Are there any needs in your current treatment that are not yet being met?

Answered: 4 Skipped: 2

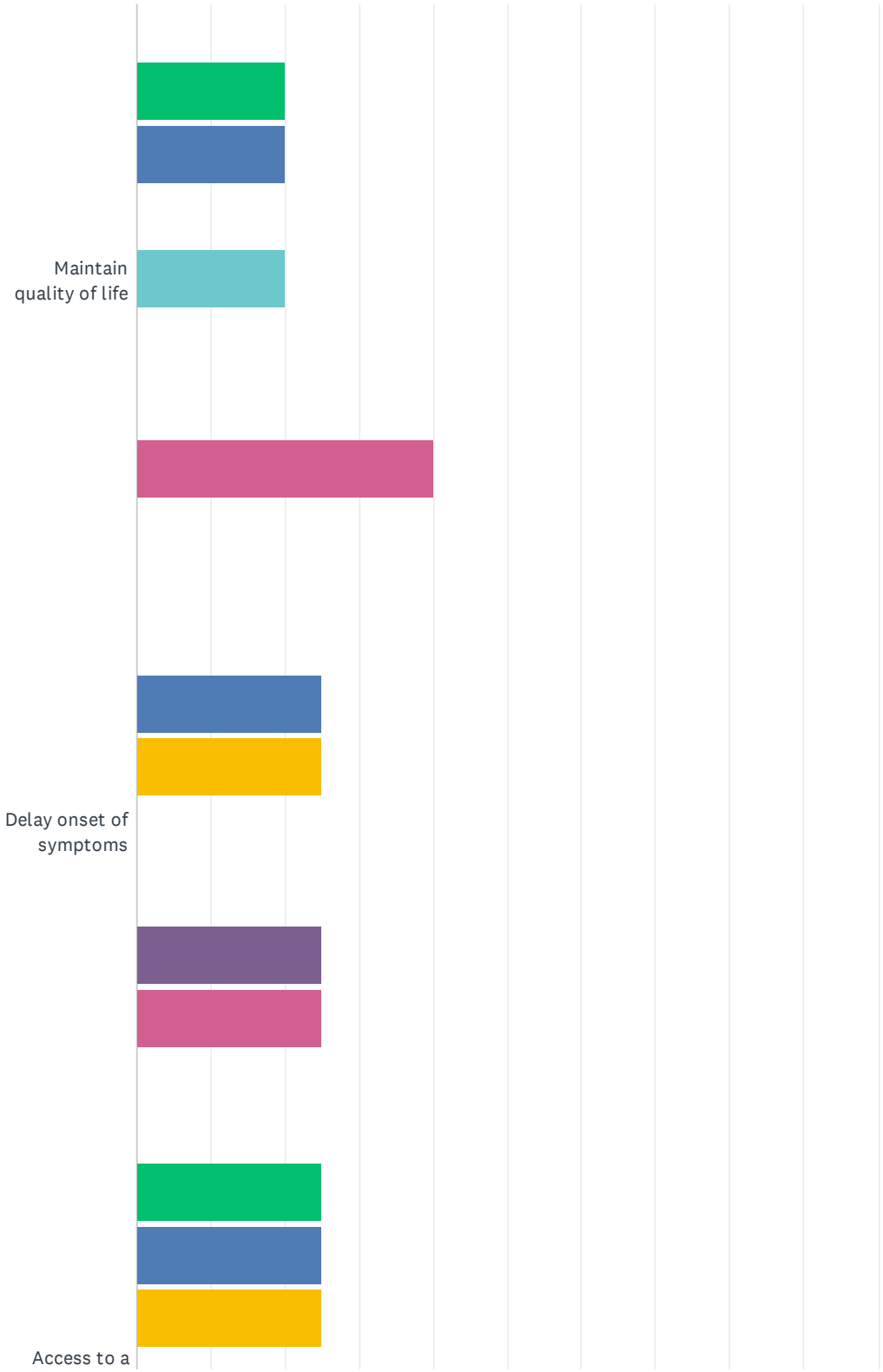


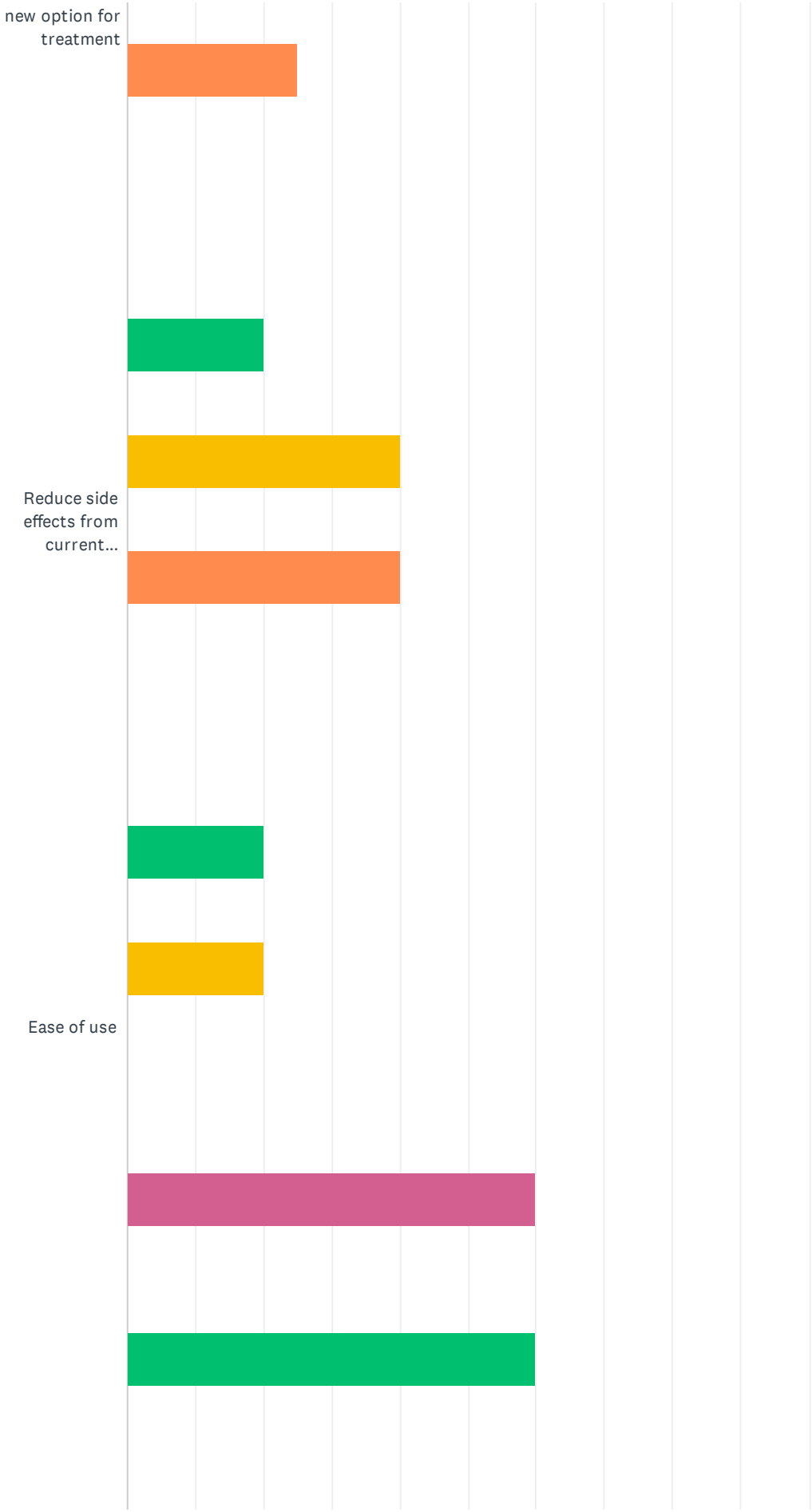
ANSWER CHOICES	RESPONSES	
Informed practitioners	0.00%	0
Pain/Symptom Management	0.00%	0
Timely access to treatment/therapy	0.00%	0
Mental health support	25.00%	1
Not applicable	75.00%	3
Other (please specify)	0.00%	0
Total Respondents: 4		

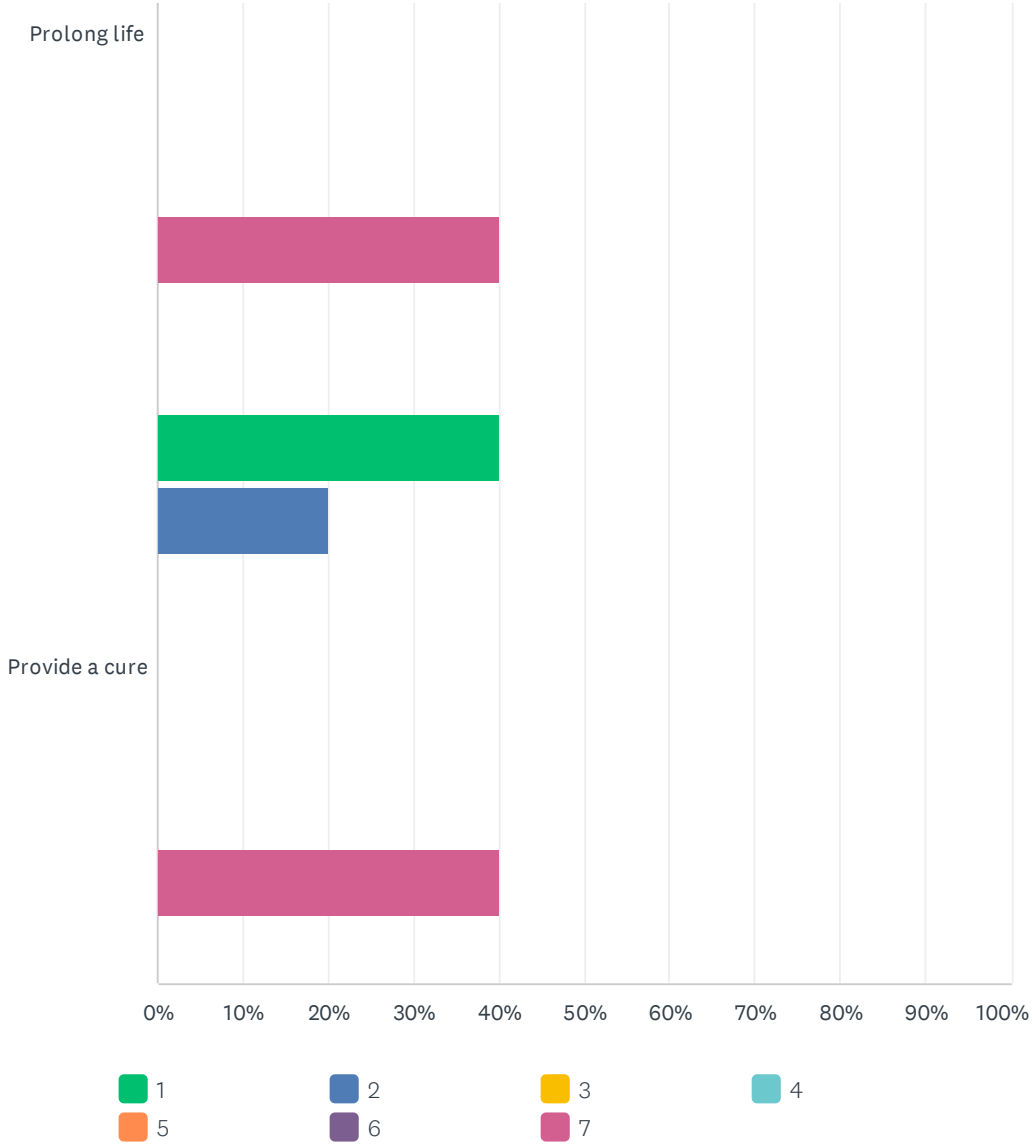
#	OTHER (PLEASE SPECIFY)	DATE
	There are no responses.	

Q22 Which of the following issues would you hope that a new treatment would address to manage your disease? Please rate the options from most important (1) to least important (7).

Answered: 5 Skipped: 1



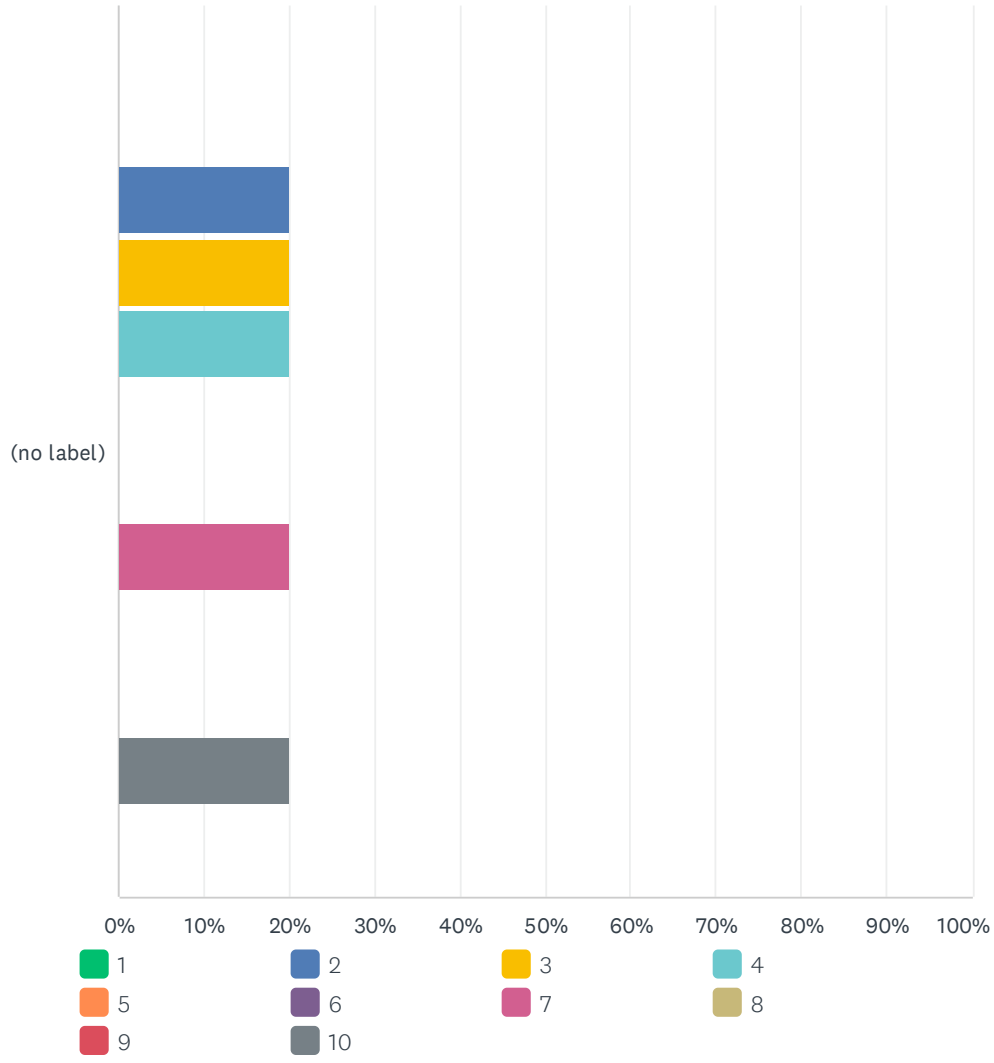

new option for treatment
Reduce side effects from current...
Ease of use



	1	2	3	4	5	6	7	TOTAL	WEIGHTED AVERAGE
Maintain quality of life	20.00% 1	20.00% 1	0.00% 0	20.00% 1	0.00% 0	0.00% 0	40.00% 2	5	4.20
Delay onset of symptoms	0.00% 0	25.00% 1	25.00% 1	0.00% 0	0.00% 0	25.00% 1	25.00% 1	4	4.50
Access to a new option for treatment	25.00% 1	25.00% 1	25.00% 1	0.00% 0	25.00% 1	0.00% 0	0.00% 0	4	2.75
Reduce side effects from current medications or treatments	20.00% 1	0.00% 0	40.00% 2	0.00% 0	40.00% 2	0.00% 0	0.00% 0	5	3.40
Ease of use	20.00% 1	0.00% 0	20.00% 1	0.00% 0	0.00% 0	0.00% 0	60.00% 3	5	5.00
Prolong life	60.00% 3	0.00% 0	0.00% 0	0.00% 0	0.00% 0	0.00% 0	40.00% 2	5	3.40
Provide a cure	40.00% 2	20.00% 1	0.00% 0	0.00% 0	0.00% 0	0.00% 0	40.00% 2	5	3.60

Q23 On a scale of 1-10, with 1 being “no side effects” and 10 being “significant side effects”, if you were to consider taking a new therapy for your cancer, what severity of side effects would you be willing to tolerate in order to extend survival by 2 months, after having been told there is no other available treatment? For example, side effects such as: nausea, fatigue, vomiting, diarrhea.

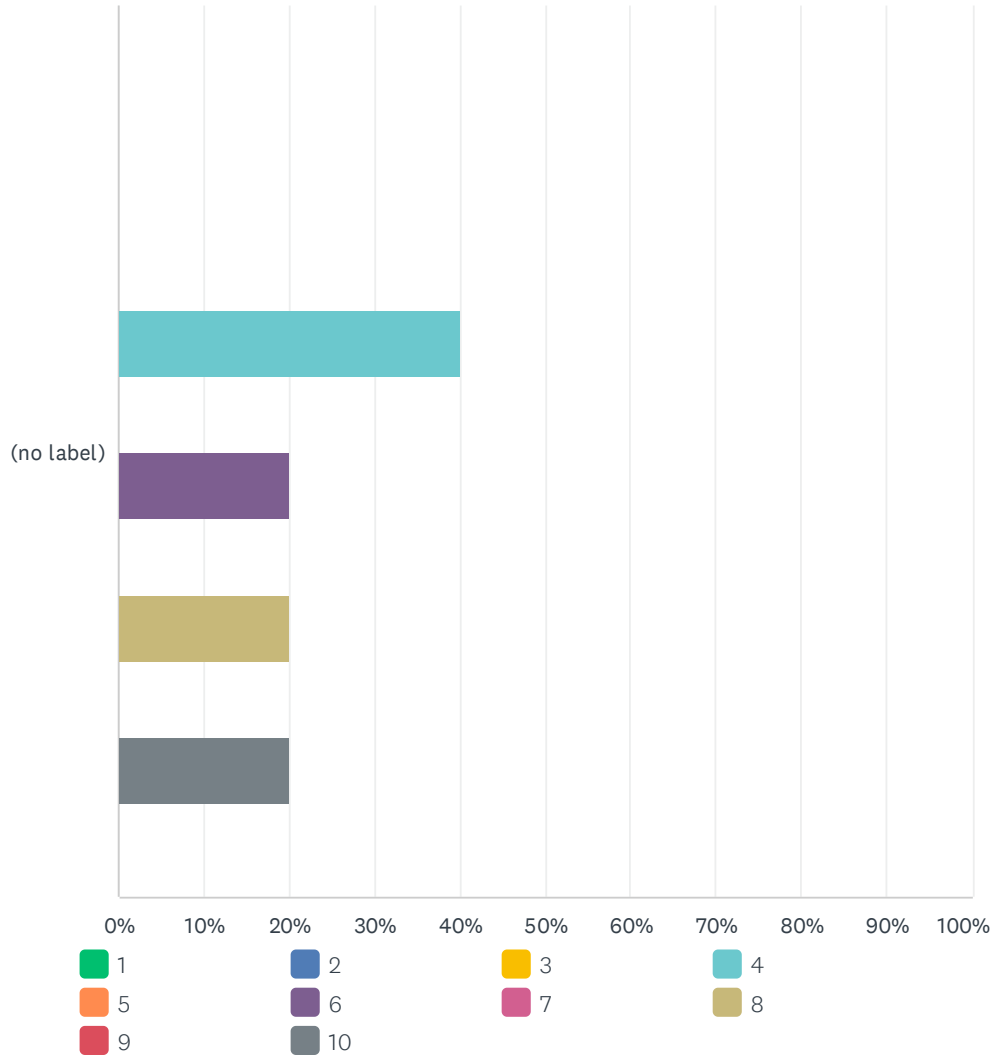
Answered: 5 Skipped: 1



	1	2	3	4	5	6	7	8	9	10	TOTAL	WEIGHTED AVERAGE
(no label)	0.00% 0	20.00% 1	20.00% 1	20.00% 1	0.00% 0	0.00% 0	20.00% 1	0.00% 0	0.00% 0	20.00% 1	5	5.20

Q24 On a scale of 1-10, with 1 being “no side effects” and 10 being “significant side effects”, if you were to consider taking a new therapy for your cancer, what severity of side effects would you be willing to tolerate in order to extend survival by 6 months, after having been told there is no other available treatment? For example, side effects such as: nausea, fatigue, vomiting, diarrhea.

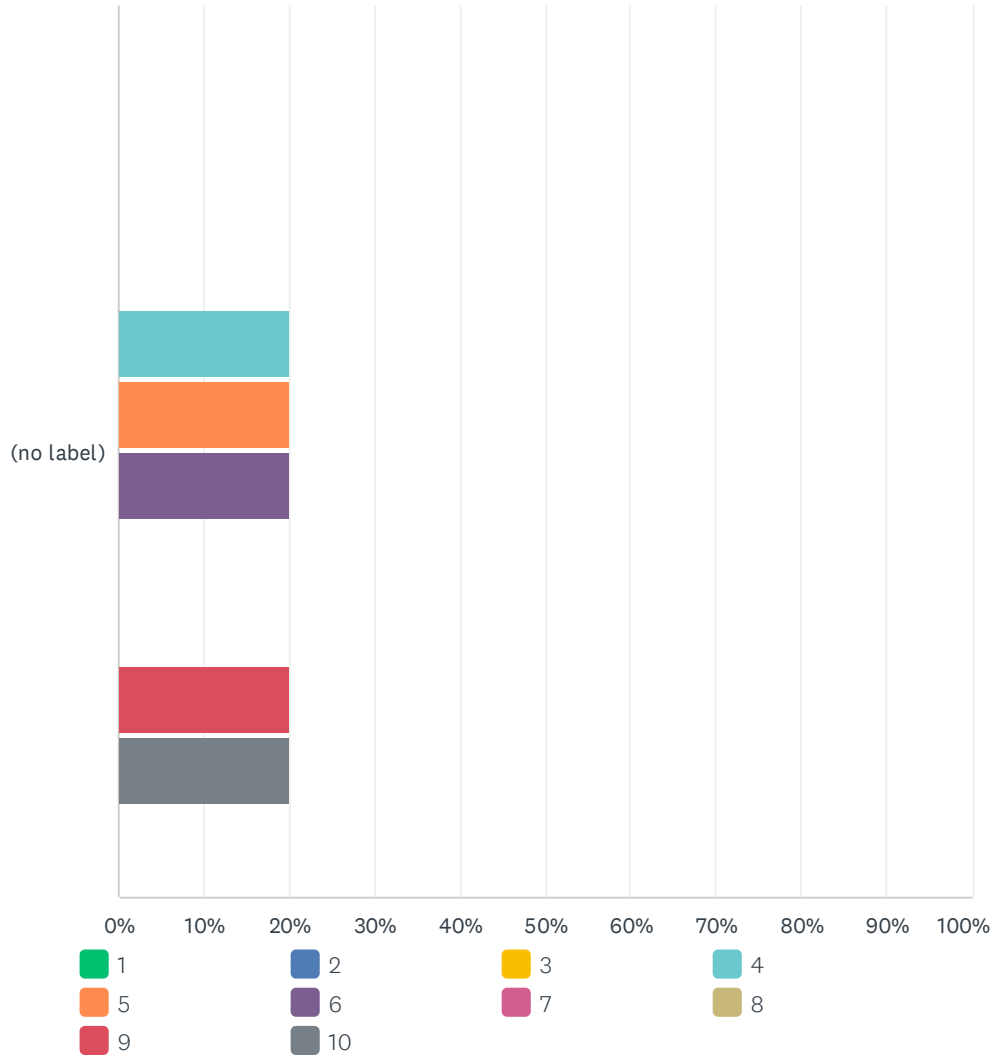
Answered: 5 Skipped: 1



	1	2	3	4	5	6	7	8	9	10	TOTAL	WEIGHTED AVERAGE
(no label)	0.00% 0	0.00% 0	0.00% 0	40.00% 2	0.00% 0	20.00% 1	0.00% 0	20.00% 1	0.00% 0	20.00% 1	5	6.40

Q25 On a scale of 1-10, with 1 being “no side effects” and 10 being “significant side effects”, if you were to consider taking a new therapy for your cancer, what severity of side effects would you be willing to tolerate in order to extend survival by 1 year, after having been told there is no other available treatment? For example, side effects such as: nausea, fatigue, vomiting, diarrhea.

Answered: 5 Skipped: 1



	1	2	3	4	5	6	7	8	9	10	TOTAL	WEIGHTED AVERAGE
(no label)	0.00% 0	0.00% 0	0.00% 0	20.00% 1	20.00% 1	20.00% 1	0.00% 0	0.00% 0	20.00% 1	20.00% 1	5	6.80

Q26 What considerations do you make when it comes to balancing the advantages and disadvantages of a treatment?

Answered: 3 Skipped: 3

#	RESPONSES	DATE
1	Quality of life, energy	10/29/2023 3:29 PM
2	Longevity, How severe the other side effects are.	10/29/2023 1:28 PM
3	Quality of life, extending my life	10/28/2023 11:57 AM

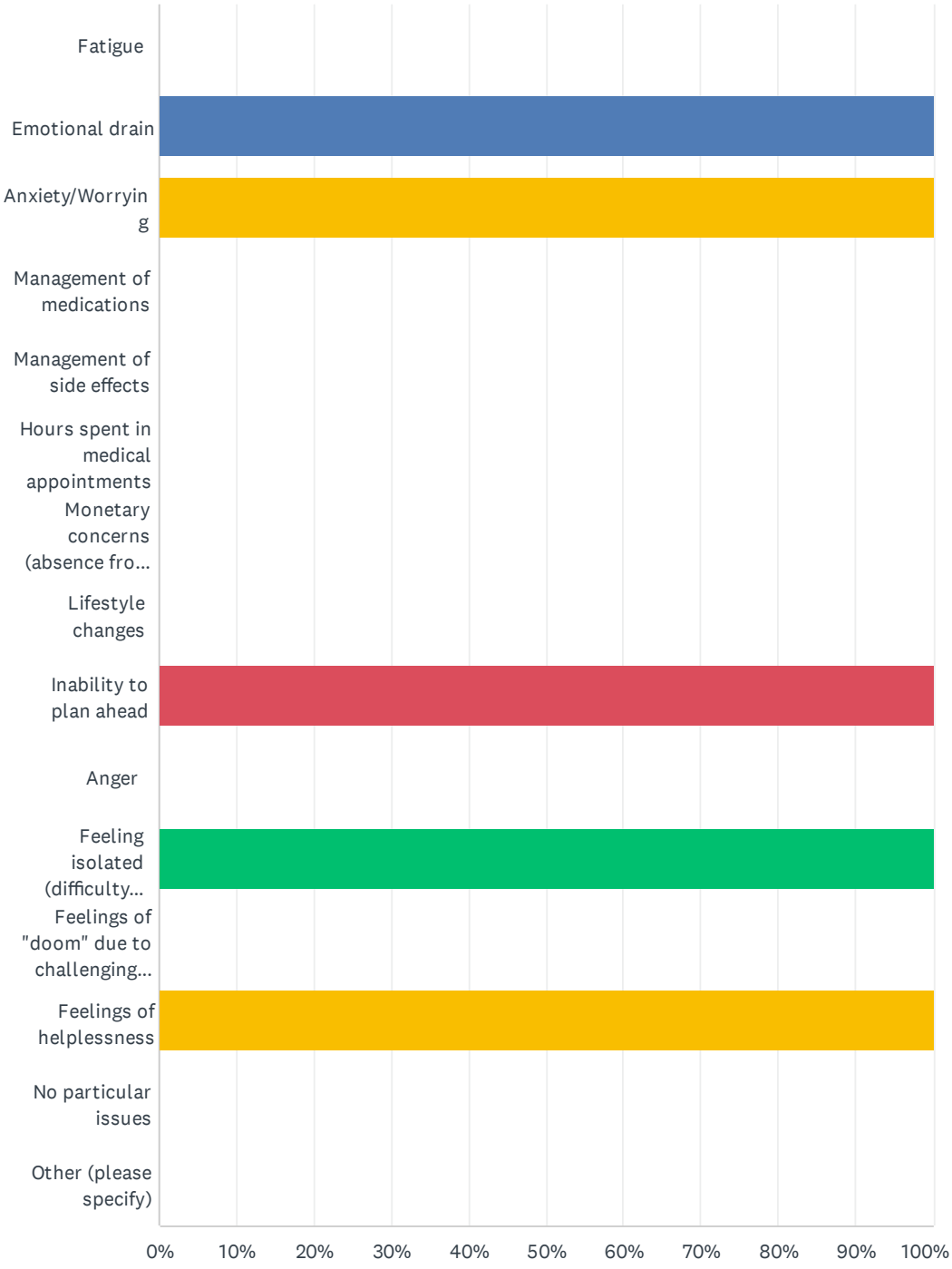
Q27 Is there anything else you would like to share with us about your cancer journey?

Answered: 3 Skipped: 3

#	RESPONSES	DATE
1	I was blessed to have unlimited support through the Cancer foundation of Canada. My radiation went very well. Everyone one was so helpful. I just felt very well cared for everywhere.	10/29/2023 1:28 PM
2	Cancer treatment care was great. Big drop of in care between my gp and gyne doctors. No help for after care.	10/28/2023 11:57 AM
3	I was referred for genetic testing because of family colo-rectal cancer history. However my tumour test was not MSI-High. A wise genetic counsellor encouraged me to have the DNA test regardless which I did. Results were positive for Lynch Syndrome. Subsequently my surviving brother and one of my 2 daughters have also tested positive. A second MSI Tumour test requested by the the genetic counsellor confirmed the original test results. This was not the first time in my now 35 year long cancer journey that I have had a “false negative” on a test. This can be disconcerting knowledge to have lived with as a now 80 year old.	10/28/2023 11:55 AM

Q28 What are the issues you encounter or have encountered as a caregiver for someone with endometrial cancer? Check all that apply.

Answered: 1 Skipped: 5

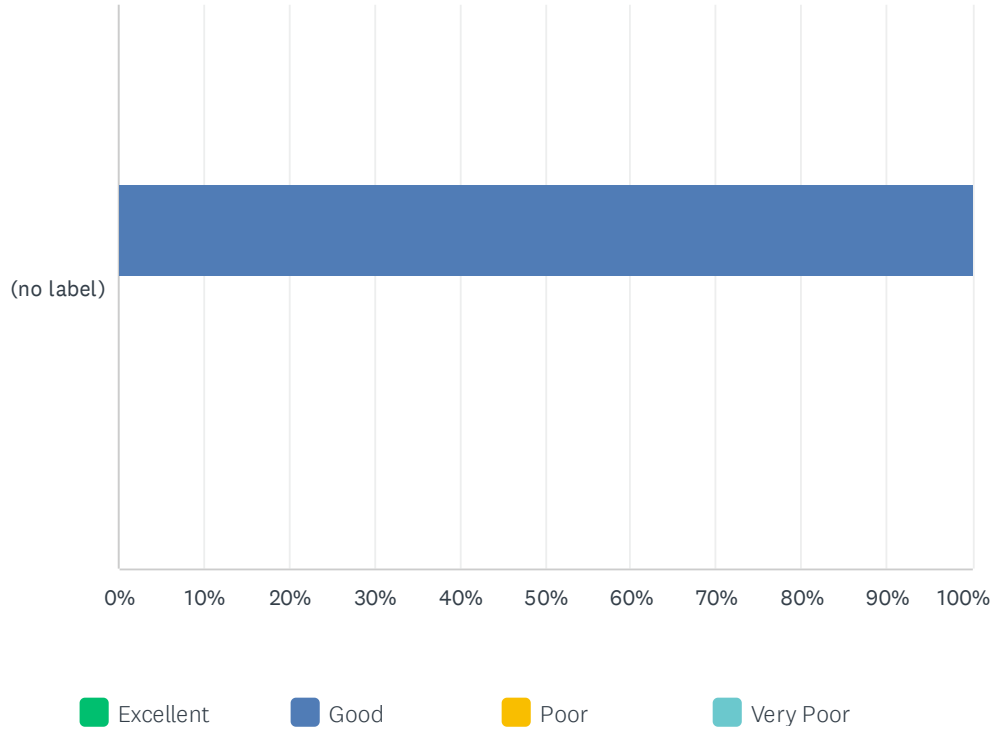


ANSWER CHOICES	RESPONSES	
Fatigue	0.00%	0
Emotional drain	100.00%	1
Anxiety/Worrying	100.00%	1
Management of medications	0.00%	0
Management of side effects	0.00%	0
Hours spent in medical appointments	0.00%	0
Monetary concerns (absence from work, driving expenses, etc.)	0.00%	0
Lifestyle changes	0.00%	0
Inability to plan ahead	100.00%	1
Anger	0.00%	0
Feeling isolated (difficulty connecting with friends, geographical remoteness)	100.00%	1
Feelings of "doom" due to challenging prognosis	0.00%	0
Feelings of helplessness	100.00%	1
No particular issues	0.00%	0
Other (please specify)	0.00%	0
Total Respondents: 1		

#	OTHER (PLEASE SPECIFY)	DATE
	There are no responses.	

Q29 How would you rate the current treatments based on how they address the needs of endometrial cancer patients?

Answered: 1 Skipped: 5



	EXCELLENT	GOOD	POOR	VERY POOR	TOTAL	WEIGHTED AVERAGE
(no label)	0.00% 0	100.00% 1	0.00% 0	0.00% 0	1	2.00

Q30 How has caring for someone with endometrial cancer affected your daily routine or lifestyle?

Answered: 0 Skipped: 6

#	RESPONSES	DATE
	There are no responses.	

Q31 What are the most challenging adverse effects related to your loved one and their current therapy or treatment?

Answered: 1 Skipped: 5

ANSWER CHOICES	RESPONSES	
None	0.00%	0
Anxiety/Worry	0.00%	0
Emotional drain	0.00%	0
Management of medications	0.00%	0
Management of treatment-induced side effects	100.00%	1
Time spent at medical appointments	0.00%	0
Loss of income	0.00%	0
Lifestyle changes	100.00%	1
Inability to plan ahead for future	100.00%	1
Emotional toll on family	0.00%	0
Feelings of helplessness because I cannot help my loved one feel better	100.00%	1
Feelings of doom	0.00%	0
Other (please specify)	0.00%	0
Total Respondents: 1		

#	OTHER (PLEASE SPECIFY)	DATE
	There are no responses.	

Q32 What would you most like to see out of a new treatment for patients with endometrial cancer?

Answered: 0 Skipped: 6

#	RESPONSES	DATE
	There are no responses.	

Q33 Is there anything else that you would like to share with us about your experiences as a caregiver?

Answered: 0 Skipped: 6

#	RESPONSES	DATE
	There are no responses.	

Q34 If you are interested in being contacted as a patient or a caregiver, to provide further information, please leave your contact information below.

Answered: 2 Skipped: 4

ANSWER CHOICES	RESPONSES	
Name	100.00%	2
Company	0.00%	0
Address	0.00%	0
Address 2	0.00%	0
City/Town	0.00%	0
State/Province	0.00%	0
ZIP/Postal Code	0.00%	0
Country	100.00%	2
Email Address	100.00%	2
Phone Number	100.00%	2

#	NAME	DATE
[redacted]		

#	PHONE NUMBER	DATE
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]

CCRAN Colorectal Cancer Resource & Action Network
RISCC Réseau d'informations et soutien pour le cancer colorectal
A PATIENT-FOCUSED ORGANIZATION

APPENDIX B: PEMBROLIZUMAB + CHEMO ENDOMETRIAL CANCER PATIENT & CAREGIVER INTERVIEW DATA						
INTERVIEW QUESTION	**RESPONDENT A [PATIENT]**	**RESPONDENT B [PATIENT]**	**RESPONDENT C [PATIENT]**	**RESPONDENT D [PATIENT]**	**RESPONDENT E [PATIENT]**	**RESPONDENT F [PATIENT]**
PART A: DEMOGRAPHICS/INFORMATION GATHERING						
1. Interview date, time & method	November 19, 2024; 4:00 pm – 5:30 pm; telephone interview	November 26, 2024; 1:00 pm – 2:00 pm; zoom interview	November 26, 2024; 2:30 pm – 3:00 pm; telephone interview	November 26, 2024; 4:00 pm – 4:45 pm; telephone interview	November 27, 2024; 9:30 am – 10:30 am; telephone interview	November 27, 2024; 2:45 pm – 3:45 pm; telephone interview
2. Patient's current age, age at diagnosis, gender identity	34, 33, female	35, 30, female	84, 83, woman	54, 53, female	64, 62, female	69, 67, female
3. City, province / state	Toronto, Ontario	Bristol, South Gloucestershire, England	Los Angeles, California	Mission Viejo, California	Laurel, Maryland	Brooklyn, New York
4. **A. MARITAL STATUS S/M/D/CL** **B. CHILDREN**	Single No children	Married No children	Unmarried Yes – 1	Married Yes, 2	Married Yes - 3	Single No
5. Outreach method: (Canadian clinician, US clinician, etc.)	Canadian Clinician	UK Patient Group	US Patient Group	US Patient Group	US Patient Group	US Patient Group
6. Treatment centre	"Princess Margaret Hospital"	"Beatson West of Scotland Cancer Centre" (moved post-treatment)	"Cedars Sinai Medical Center"	"I moved around a few, - Hoag Hospital was first, then UCLA, then City of Hope"	"John Hopkins (surgery + brachytherapy) Maryland Oncology & Hematology (Community Center connected to John Hopkins)"	"Northwell"
PART B: DISEASE EXPERIENCE & EXPERIENCES WITH CURRENTLY AVAILABLE TREATMENTS						
7. When were you first diagnosed with cancer? And with what type of cancer? At which stage was your disease diagnosed?	"May 2023; endometrial; stage IV"	"I was diagnosed November 2019 with stage III/IV endometrial cancer, which I didn't know at the time. I thought it was stage III, but it was on the cusp and just turned into stage IV."	"Which one? I have 3! July 2022: Diffuse idiopathic pulmonary neuroendocrine cell hyperplasia September 2022: breast cancer December 2023: endometrial cancer	"Early May 2024, during my surgery, after the surgery they knew it was there. It was endometrial carcinoma stage IIIc1"	"A date I'll never forget: December 24, 2022. She called on Christmas Eve. Endometrial cancer, and at that time it was an adenocarcinoma, grade II, they didn't know the stage until after the hysterectomy, but they	"October 2022, stage Ia, grade III endometrial cancer"

			I have no idea of the stage, but I'm doing great! I don't ask the questions that frighten me."		hadn't seen any spread on the CT So, it was stage Ia, grade 3 at the time of diagnosis."	
8. Were you symptomatic which led to investigations? Tell me a bit about your journey?	"I was having serious pain in my left leg. I didn't think of cancer at all. I went to go to the ER because it was causing so much pain that I couldn't sleep at night. I could feel a lump in my l groin and in the ER, they sent me for an ultrasound. They then sent me for a CT of my pelvis that afternoon. The report came in early evening and that evening the ER doc called me to the room and told me the news. That was Friday night and then on Wednesday I was scheduled for a chest and head CT. I was scheduled for a biopsy the next week and 2 weeks later I received the pathology report."	"Yeah, I was very slow to investigate. Symptoms started December 2018, I just had really heavy bleeding that got continually worse and a pot of pain as well. About halfway through the year I was just bleeding constantly and just flooding my sanitary napkins. No real traction with my doc, sometimes women just bleed. I ended up diagnosed in A&E, I was basically hemorrhaging ridiculous amounts of blood, I went in twice and they thought they had stopped it, but I had to go back. I had 8 blood transfusions, and it should never have got that bad. I was in a lot of pain as well and on opioids to manage it."	"Yes. Vaginal bleeding, it went and came, and went and came, and I was so busy with other cancers that I think I ignored it until I couldn't anymore. I think it started around early 2023."	"Yes, I had vaginal discharge at first and then I had vaginal bleeding. I think it was for a couple months, I first saw a gyne and I wasn't bleeding at the time it was just discharge, so in my opinion it progressed kinda quickly. The first time I saw the gyne they misdiagnosed me, and then it turned into bleeding, and I went back, and they did an ultrasound and saw a mass. I did an MRI next, and they still weren't sure, and the CA-125 was high (68) - and all this led to an appt with a gyne oncologist."	"I had odd urinary symptoms. I would pee a lot, or I wouldn't pee and then I had some blood in the urine. My first stop was the urologist. Hie did a cystoscope, and it was completely clear, and he said it must be an infection or something, but he said he had a nagging concern, and he ordered a CT which showed a mass in the endometrium. So, then I had a biopsy with a GYN and then went to a gyn-onc."	"I just had bleeding after sex."
9. How was your cancer detected/ diagnosed?	"Through the series of imaging and the pathology report. Found with US, confirmed with CT based on spread. Confirmed as gyne cancer based on pathology report."	"So, I had two actually. I had a hysteroscopy under general and the laparoscopy to look for endometriosis. They diagnosed hyperplasia but not cancer. In the A&E no one wanted to take the lead and then one doctor took my notes home, looked at all my case, and booked me for my investigations. I	"Biopsy. It was all done at Cedars; I had chosen the doctor. I knew it was something, so I picked a specialist."	"I then had a surgery shortly after and it was after the hysterectomy when they were able to test to the tumour during the surgery and that's when they confirmed the cancer."	"In-office biopsy, I didn't get put under. I was with another doctor and she wanted to do a more extensive biopsy with putting me under, but it would be a 6 week wait and I was really concerned, but the other doctor said I always do in-office first and he did it immediately and had	"I went to my GYN she sent me to a urologist who sent me to an oncologist, I had a battery of tests done. Then I had a hysterectomy. I was referred to a radiation person but did not do radiation. 2 years later I had a recurrence at the same

		think the hyperplasia was hiding the cancer. They found it the second time, about 3 weeks later. I was diagnosed after IVF, I had had quite a lot of HRT. My wife was going to give the eggs, and I was going to carry, so I got a lot of HRT which probably made it worse."			my results back to me within 48 hours. The waiting factor is really bad, it's not good if women have to wait."	place. I strongly did not want radiation. I was referred for brachytherapy and they did it backwards - they read the CT after they did the extensive fitting for brachytherapy, and pelvic therapy. I turned out that I had a couple of lymph nodes that had been affected. They did it backwards, because they looked at the CT after. Like, read the damn scans before you spread my legs and do the fittings. They ended up seeing 2 iliac nodes and 1 near my wind pipe. I did not do the brachytherapy. I also had PET scan and ctDNA testing done as far as diagnostic testing goes."
10. How did you feel when you were delivered the diagnosis of cancer?	"At first I was… {*crying*} I didn't know what to think. I was alone in the emergency room, away from family and friends. I was just in a state of shock. Ummm, when I didn't go to work my boss called when they heard the news, and then I had a colleague who went through breast cancer and I connected with her and she said to focus on getting treatment as soon as possible. So, I tried to get through the imaging as quickly as possible, I had to fight to	"Ummm yeah, really scared. It's absolutely really a terrifying diagnosis. My wife is in the navy and was at sea at the time. My mom flew up and was in the hospital with me. I had many reassurances that it wouldn't be too serious, and it was a shock that it was more serious. Shock and scared."	"Umm I was in shock. When you're in shock you don't know how you feel."	"Well at the time I was shocked, but I was coming out of anesthesia so unfortunately, I was a little bit out of it at the time. I was shocked, I had convinced myself it was a fibroid. Of course, scared..."	"Umm well I was very upset. And when I recurred later it's a completely different story because I went to stage 4. I was very upset, scared, my doctor kept reassuring me that its early, 88% or something of women are cured, but it was early so I had hope. With my recurrence, I suddenly had this bloating and I didn't know what it was. I had gone on an	"I didn't believe it. I was in complete shock, I'm really healthy. I'm a yogi, I'm always working on my body, I'm an old dancer, I just couldn't believe it. I had some sexual trauma growing up, it felt like Catholic whip lash. I never gave thought that if you don't have children or if you have an abortion, it increases your risk. The second time, it didn't feel good, it was

	get the MRI, they didn't have enough techs, and then I had to fight to see the oncologist. It was about a month between the date of diagnosis and getting to my oncologist. So, there was a delay and that was with me calling every day to see if there was a cancellation. My parents, they had to move quickly very to Toronto to help me with everything, I was in a lot of pain and couldn't move very much. It was tough."				antidepressant and was having terrible GI problems from that, so I thought that's what it was. But the bloating got so bad I couldn't eat, I couldn't breathe. Devastated, numb, in shock, I was also angry because during my surgery… you see I wasn't really supposed to recur because there was no invasion into the wall, blah blah, blah, blah… but my surgeon perforated the uterine wall into the abdominal cavity. But when she sat me down afterwards, she didn't tell me that she had perforated the uterus, I didn't find out until 8 weeks later when I was looking through my chart and I hadn't read the surgical notes, but it was written that there had been a small perforation of the uterus… I was mad she didn't tell me, and I would have chosen a different treatment if I knew I had that risk factor. Even the tumour board meeting never mentioned the perforation… so no one told me about this surgical accident. I wasn't mad about the accident, I know they	completely shocking. When they said anything about it being near my lungs, I've smoked pot for years, I felt like I had done it to myself. They set me up with a dietitian and now I have nothing, I don't smoke or drink nothing."

					happen, but I was mad they didn't tell me, because I didn't have the opportunity to make the treatment decision with all the information. And then I recurred 14 months later. I feel patients should be told everything. After my recurrence, I looked up the 5-year survival rate and it was 17% - to say I was devastated doesn't even begin to describe it. I was psychotically upset. It was a terrible emotional trauma."	
11. Please share with me the date of your advanced/ metastatic or recurrent disease diagnosis.	:I don't know what date you would count as the confirmed diagnosis. The CT saw metastatic disease in the lymph nodes, so if that was the date I would say May 23, 2023."	"It had spread to my omentum with my first diagnosis, so my oncologist said stage III-IV, it was November 2019. My bowel stopped working and I had a recurrence in June 2021. My colonoscopy was delayed due to covid, but there was a tumour in my bowel, my scare site and further up. I had surgery which was really unusual and had discussions about debulking surgery. They first thought it was inoperable. It was a pretty dark day, they thought it was uncurable and there was not any clarity, and then my	"Around December 2023."	"The reason it's IIIc1 is the tested the pelvic LN and they removed 4 – 6 of them, initially they thought 4 were positive for cancer, but when city of hope re-evaluated, it was only 2. So, it was in the pelvic lymph nodes and extensive lymphovascular invasion, but not in any other organs."	"I was on spring break in Florida with my son and husband when the bloating just exploded. It was March 2024. I'm very active, I climb mountains! I could not walk to get my flight back to Maryland for Florida. I couldn't breathe, I was just praying I survived the flight back. And I went right from the flight to the hospital and became an in-patient at John Hopkins. When I went to the ER in Florida, they had told me the bloating wasn't GI problems, they told me I had extensive cancer	"Approximately 17 – 18 months after the first time I found out."

		oncologist in Scotland said she'd do anything she can, which really got me, but it's like there's not much they can do."			throughout my abdomen. The first thing they did when they admitted me at JH... I could not eat for 10 days. I literally would pinch of a piece of food the size of a grain of rice. I'm not kidding. The ascites was so much I couldn't breathe. Once I was admitted they drained me, and I immediately felt so much better. I went from literally feeling I was going to die any second, to *ahhh* I could breathe, I could eat. I still had a belly full of cancer, but I could breathe. They drained me and 5 minutes later I went on the Keytruda and chemo. My doctor said not everybody is fortunate enough to get it and respond."	
12. Location of your metastatic disease, if applicable.	"It was lymph nodes in my abdomen, left pelvic region, the larger ones besides the psoas muscle. They called it stage IV because it was in the muscles. I was not a candidate for surgery."	"Omentum and bowel, and some patches that weren't in any organs but floating around in my abdomen, under my rib cage but not in any organs. And there was one in my scar."	"It has not spread; I had a full hysterectomy."	N/A	"Peritoneum and pelvis and lymph nodes."	"2 iliac nodes and a spot by the windpipe."
13. Did you undergo biomarker testing for your cancer? If so, at	"Yes, I did. I had a biopsy and there was limited tissue. I know I'm	"I have information about my tumour now but nothing that was	"I don't know."	"Yes, I did. I was MSI-H and dMMR.	"The minute that they found out I had recurred, I had a CARIS report with	"I did yes. pMMR I think, but I'm not sure.

what point in your cancer journey, and what biomarkers / mutations were identified, if any? Was/is your tumour identified to be pMMR/MSS or dMMR/MSI-H?	dMMR. I didn't do HER2, they didn't have enough tissue. ER and PR were negative. They think my subtype is either endometrioid or clear cell."	communicated to me at the time. I have Lynch Syndrome, Stage 4 G2, MSH2 & MSH6 loss."		I was HER2 positive as well."	my recurrence – I got the very complicated one. I like to know everything, and I have a background in science and medicine – I was an OT before I retired. But no one wanted to talk to me about the genetic report. I belong to SHARE, and I read a lot, everything I know about my biomarkers is from my own reading. From the early-stage pathology and hysterectomy we already knew I was pMMR. My surg oncologist sent her partner to come see me when I was admitted and she bragged about being a part of the testing of the Keytruda for women with pMMR and that it does work for some women with pMMR – she quoted 38% of pMMR women will benefit and she said I should try it because if you do get benefit, the benefit is huge. I'm so glad they didn't exclude me because I am pMMR."	I have estrogen proficient cancer."
14. Is there an aspect of your disease that, to you, is more important to control than others?	"The pain. Because it was moving quickly an invading the muscle it was pressing on the nerve, and I had to take daily pain killers and even then, it was uncomfortable. For me	"I think yeah, I kind of want it to go away and never come back. My symptoms were really severe when I was diagnosed the first time… get rid of it and treat it.	"No, cancer is cancer. You just want it out of your body."	"I wouldn't want it to progress, and I would want to keep the ca-125 low, so it doesn't recur. I'm currently somewhat NED."	"Well, the most important aspect for me is I want my life to be as long as possible because I have a family, and I want to be here with them.	"I don't want to have cancer, period. The aspect of controlling it is to not have it. I was in denial a long time."

	the pain was really important."	The second time was about access to options. I didn't know at the time about how poor the prognosis was and the limited availability of drugs at the time."			I am physically extremely tough, but I am not emotionally tough. It's the emotional… I'm a psychologically healthy person generally. I'm not suffering physically, so for me the thing that I'm struggling with, and I don't feel like the oncologists are really providing enough support with, it's kind of piecemeal, I don't feel like they are providing enough emotional support. It's really scary."	
PART C: EXPERIENCES WITH CURRENTLY AVAILABLE TREATMENTS						
15. What therapies did you receive before pembrolizumab + chemo, if any?	"No. Started with carboplatin + paclitaxel until the funding came through for the pembro."	"Initial Diagnosis: Before I even had surgery, the first treatment I had was progesterol to try to stop me from hemorrhaging, so I had quite a high dose. It was literally just to get me to surgery, and then I had methanolic acid as well. My friend in Scotland who is a GP came and she said she's never heard of someone have that much of the acid and transfusions unless they were in a really bad car accident. They tried to put a coil in as well. Hysterectomy with ovaries and cervix, omentum, and lymph nodes. I had an 8-week recovery and then 4 rounds of paclitaxel + carboplatin, then 25 pelvic radiotherapies and 3 brachytherapy's.	"Hysterectomy and then they wanted me to have chemo and Keytruda. I said I'll make a decision. I did my own investigating, as I always do, I don't follow the herd. I decide to only take Keytruda. Medicare does not cover Keytruda if you're not on chemo. But they told me at the hospital about a plan based on need by Merck, they submitted my plan based on my need and Merck supplies it to the hospital for me. It's every 3 weeks and you can't move the day of the week up before the exact 3-week day, but you can have it after. I wasn't going to take chemo."	"Hysterectomy."	'Hysterectomy and brachytherapy. They did have me on letrozole because my cancer is hormone positive. They had me on it as a single agent and I was on it when I recurred so those did not work."	"Hysterectomy and a resection after the recurrence."

		Recurrence: I had a Hartmann's procedure, and they removed the tumours outside of my bowel and the top of my rectum. I have a colostomy. After about 6 – 8 weeks I started pembro as a monotherapy for 2 years."				
16. Did those treatments control your cancer? **Y or N** **Please explain.**	"Yes. I believe so. I had a CT scan which showed regression, and I was also able to discontinue the pain killers. Finally, after 2 rounds of chemo I was able to add the immunotherapy, the first 2 rounds were purely chemo and then I was able to do a CT and it showed regression. I did a total of 8 chemo infusions, 4 of them included pembro and then pembro every 6 weeks."	"No. I recurred really quickly, within 6 months, it was on the borderline where it might even be called progression. I was having symptoms before that, so I think it probably came back before the 6-month mark."	"Absolutely, you have to believe it. If you're a cancer patient you must always believe that your medication is helping, otherwise why take it?"	N/A	"No, obviously. All of my recurrence has been up in the abdomen area. They've always said on every CT that the vaginal cup is clear. If indeed this was caused by the surgical error, then maybe it did, but who knows. It's a little bit of a mystery."	N/A
17. Please describe your quality of life on those treatments.	"The first round wasn't too bad. I was also pumped with the pre-treatment - steroids + Benadryl. The second one I developed an allergy to paclitaxel I remember sleeping the whole way through chemo and with each one it becomes longer, progressively gets harder, and takes longer to get over the side effects. I developed numbness in my fingers with the 2nd round, it progressively got worse. To help with	"Yeah, um I think um it was, chemotherapy was really tough. I think the biggest things were really debilitating fatigue for the first 4 days. It's like time stops moving, I couldn't sleep because of the steroids. I had a very minor reaction on the hands, and they doubled it, it stopped me from having bone pain I think but no one believed me. I'd have awful fatigue, and I couldn't do anything but lay down, but I also couldn't sleep. I almost	"The hysterectomy leaves you with some incontinence. And you have to remember 2 things: 1. I had my ovaries out in my 60s for something else, but they never gave me the hysterectomy. I haven't had ovaries for a very long time, and I don't know if that has any impact on what I'm going through 20 years later. 2. At this age, it's a different mindset than if you are having children or having sexual	"The surgery was kind of tough. I had bedrest for the first month after and that was a little bit more than I thought it was going to be. Just not being able to get up out of bed normally, I happened to have frozen shoulder at the time as well, and since I'm a musician it's a big deal to me. I've heard that sometimes with surgeries there can be a relationship to frozen shoulder, so I don't know if they were related. I wasn't able to work for	"No restrictions, I ignore side effects because I'm so happy to be alive. Maybe 9 out of 10 I did have a little joint pain with the letrozole."	"It certainly has impacted my want for a sex life. I just didn't feel that great. It was a robotic surgery, so I wasn't sliced apart."

	that, I added ice packs when I was getting the infusion. After the first infusion I had internal bleeding, and I was in hospital over a week. I had to get a blood transfusion, and my hemoglobin fell to under 80. I had to get an endoscopy and colonoscopy. They concluded it was an interaction between the chemo and a pain killer I was taking. It went away on its own, but it took a while for it to go away."	couldn't sit up I was so tired; it was exhausting and painful. Like an awful purgatory. I had some diarrhea as well; it came like clockwork on specific days after. I was really lucky because I never ended up in hospital with neutropenic sepsis, COVID kicked off and I was really scared, I was absolutely terrified of getting any kind of illness before and then when covid hit, no one was allowed near me at all, it was so much social isolation. What else? Oh, I lost my hair, and I didn't mind as much at the time, but I hadn't thought beyond chemo and growing it back was harder than losing it. I couldn't have a wig because of covid the wig place was shut, it made me feel really like an ill person. Covid made it worse, but it was really socially isolating all together. The fatigue is just one of those things where I can't describe just how horrible it was. It was cumulative and by the 3rd or 4th I was crying, and I didn't want to go back. It was horrible. Radiotherapy: diarrhea, I was lucky I didn't get	relations. It's a very different mindset now than if you are sexually active with your partner."	several months, it took at least 3 months to get back to work. There was quite a bit of pain right afterwards. I tried not to take the very strong pain medications since it has so many side effects. that was difficult and it was difficult to sleep, you had to seep on your back with lots of pillows. It was not a pleasant experience. I was worried about the side effects, but it turned out I didn't have any of the complications. I wasn't able to walk normally for a while, but as time went on, I would take very small walks. I did get constipation, and I had to take the drugs to help with that. And then I felt like I fully recovered from that."		

		pelvic radiation disease, but a couple of times when we were going for walks in nature I would just have to run off and go in the woods, but it was such an important thing for me to do mentally. I'm vegan, but I couldn't be vegan on chemo because of the nausea. I was eating chicken even though I didn't want to eat it, I needed protein but couldn't eat my regular diet. I desperately wanted to be vegan but there was nothing I could eat that wasn't high fibre. It was really hard because it was not how I wanted to eat. I felt ethically uncomfortable, but I had to because of the treatment. The brachytherapy caused some narrowing in my vagina, and the shortening of the vagina from surgery as well caused some issues with sexual functioning, which I think is quite important."				
18. How long did it take before you progressed on each of those previous therapies?	N/A	"It was less than 6 months, I think I was already having symptoms before – the tumour was already 5 or 6 cm before they found it."	N/A	N/A	"14 months."	"17 – 18 months."
19. Was there any particular aspect of the	"For me, it was the bitterness. The first time	"No because they had removed everything, so I	"I just want what I'm going through and this	"I had a radical hysterectomy, so I had	"No. I was told I was cured. For those 14	

disease that was difficult to control while on those previous therapies? If so, please explain.	I remember feeling somewhat normal. I knew that losing my hair would be inevitable. I didn't want to, but if that was what it takes to get better, I think it was a small price to pay for my life. Starting with the second one I lost my appetite, and everything tasted bitter. I lost quite a bit of weight, there was so much stuff I was told not to eat – red meat, nightshade, etc. – I overdid things a bit. The tough part was the emotional pain that lasted beyond the chemo. It was emotionally tough to learn I wasn't a candidate for surgery."	felt, confusingly, a lot better in terms of symptoms. It was a bit touch and go when I was in A&E, I was not well but I was no longer losing pints of blood after surgery. It was mainly the side effects of the treatment and generally being very depleted and washed out after a year of no treatment before I was diagnosed. I was obviously anemic as well as an ongoing impact."	telephone conversation to help at least one other person. If it can help at least one other person, I'll be happy. When I was going through this and doing all my research, I went out of my mind looking for organizations that could help. I was talking to people all over the country to learn about Keytruda. I reached out in the Americas, and I was so grateful and a lot still contact me. You NEED help, you NEED to be able to reach out, and your NEED to be able to get someone else's experience so you can make an informed decision about what you want to do. You need others to guide you about their experience, so you know what to do for yourself."	the ovaries removed as well, so I had to go through hot flashes, which I had already been through with peri-menopause, so that wasn't great. I think I was at the beginning of menopause and was finished with my hot flashes before the surgeries."	months life was back to normal, and cancer was not a part of life."	
PART D: EXPERIENCE WITH THERAPY UNDER REVIEW						
20. How did you become aware of pembrolizumab + chemo?	"My doctor recommended right away the trial as a first line therapy. I wanted to start right away but they didn't have time to look into how to get it covered. I'd like to say I discovered it, but as much research as I did, I didn't know about it till my oncologist brought it up. She mentioned there were 2 new research studies published in February	**Note: Patient received pembrolizumab as a monotherapy** "A few people had mentioned it to my surgeon, it came up at the MVT [author's note: multidisciplinary team meeting; similar to a tumour board meeting], he was a CRC surgeon but went to the meeting because I was a gyne patient. He was very blunt – he said its everywhere.	**Note: Patient received pembrolizumab as a monotherapy (it was recommended to be given in combination with chemo first, but the patient declined)** "You're not going to believe this, but in 2019 I was living here in LA, but a friend of mine in New Jersey got diagnosed with lung cancer and she was put on it. I said, 'Oh my god, I never heard of it.' She may have started	"All 3 doctors that I saw they all suggested it. They told me about the studies where its more effective when you take it with chemo. All 3 doctors prescribed it, which made me feel more comfortable with it. Every single one of them said it's a better chance."	As above.	"The doctor told me this is what you're going to have. I'm with SHARE [patient organization] so I've been going to these groups because I knew nothing. Many of the women were far more advanced stages and grades than myself. I knew about it from the group."

	showing immunotherapy added to chemo shows improved outcomes and she thought I should do it. I didn't even know what it was, I asked her to write down the names. I trust her and I looked up the results and knew I had to fight to get the immunotherapy added to the combination."	My oncologist wasn't sure but was hopeful. There was a big period after surgery, the second one in a year and a half and the prospect of having chemo was just horrendous. I was just in bits; I was dreading having it again. But then my oncologist rang, and she was delighted and shared that IO was approved through special licence, because I had less than 2 years to live and I was really young, so I got compassionate access. I could here like that my oncologist was jumping up and down. I didn't get it, I didn't understand at the time, but I do now. IO is game changing."	it too late; she died in less than a year. And then when I was diagnosed my oncologist said I want you to go on chemo and Keytruda and I didn't even want to go on Keytruda because my girlfriend died, but that's when I did my research. But I knew I was not going on chemo. I prayed to God a lot that I would have a good result, prayer is a very powerful thing."			
21. How did you access the therapy under review? E.g., clinical trial, private insurance, self pay, special access?	"It's self-pay but a portion was reimbursed by my private insurance. My oncologist applied to CCO, and my file was rejected, and they wouldn't provide funding. I reached out to Merck myself and learned that they didn't have a compassionate program outside of the US. The PMH reimbursement specialist confirmed this as well. There's no way of getting any funding for this drug and the drug company is not providing compassionate access.	"Through special licence, or compassionate access. In the UK we have the cancer drugs fund, but it wasn't available, so I think it was compassionate access, it was subject to quite a lot of scrutiny. Apparently if I lived in a different health board, I wouldn't get it, which I just terrifying."	"Merck compassionate program, my doctor got me into that, I didn't know about it."	"My insurance pays for it."	"My insurance."	"I have accessed it through my insurance and then I have to go through financial services for each bill. I'm really having a hard time I'm going for grants because I'm struggling to pay the bills. I couldn't find out the cost originally, but now I think it will be $58,000 per dose for 2 years and the co-pay is 20% and I'm trying to figure this out. I'm hugely in debt. I'm sitting here calling for grants, but I'm not in the category to be funded.

	There was no clinical trial open."					Breast cancer is, but endometrial cancer isn't, and it's a growing cancer and it's not getting the funding or attention. There's a lot of gaping holes. I'm an actor and I don't have a lot of money."
22. Access: **A. When did you receive pembrolizumab + chemo (date)?**	"I would have started the pembrolizumab on August 10, 2023, on my 3rd infusion cycle and I am still on the pembrolizumab as a monotherapy."	"I started in June 2021 to June 9, 2023. I missed the last day, but they said it didn't matter very much at that point. I am not currently on any therapy, I am in remission as far as I know, for the last 18 months. I had clear scans after about 6 months."	"January 2024 – current."	"June 14, 2024 – current"	"It was in April 2024 – current, it was given the last time with chemo on July 15 and then it's been Keytruda alone. My husband won a free radio trip to the islands, so we took a one-week break."	"April 2024 pembro in combination with chemo – current I have 1 more session and then it switches to just Keytruda."
B. In what line of therapy?	"I'm not sure, I would think the first."	"I had always assumed second line, but I'm not sure how it was classified. Maybe it was first."	"First."	"First."	"First."	"First."
C. How many cycles did you receive?	"Sometimes, I would get double the dose but get it every 6 weeks. So, in 2023, except for 1, all my doses were 3-week doses, August to December I had 4 single doses and 1 double dose. In 2024 all were double dose, every 6 weeks so I would have had 6 – 7 so far in 2024."	"I can't say for sure because I wasn't counting them. Somewhere around 22."	Every 3 weeks, you'd have to count, I did miss one, but they told me it was okay. I had company from the East Coast, and I didn't want to have the treatment. Every 3 weeks like clockworks."	"I received chemo + Keytruda 6 cycles ended October 2, have since received 2 cycles of just Keytruda."	"I received 6 rounds of Keytruda and chemo, and then every 3 weeks since mid-august just the Keytruda and they said for 2 years."	"I've received 5."
23. Side effects: **A. Have you experienced any side effects while on this therapy? Yes/no**	"Yes."	"Yes."	"Yes."	"Chemo – Yes Pembro – not really sure yet."	"No, I really was lucky. When I was on the chemo at first, I thought, 'oh good lord I'm going to be a wreck', I was watching my 2- and 4-year-old granddaughters, and I really enjoy it. I kept active so I really	"I cold capped through most of it, but I've still lost quite a bit or hair, basically no eyebrows, no eyelashes, virtually no pubes, no leg hair, just no hair anywhere.

					think that made a difference. I do not sit. And I ate a lot of protein. I did really well. I never had any nausea. I was completely bald, but there was no pain in that. It didn't affect my function. I'm not the most vain person. I did love my hair though, but it's growing back."	My skin is super dry I have eczema. I have a tendency to get herpes, so I've been on and off acyclovir. Immediately after I feel just exhausted and then the next couple days I'm wired, so I've got a prescription for lorazepam."
B. What were those side effects? Please describe them.	"Hyperthyroidism, so we paused pembro for infusion 4 – 5. Afterwards it turned to hypothyroidism. Pembrolizumab, I think caused the hyperthyroidism, then it turned to hypothyroidism, and I take Synthroid. It's not fully stabilized, I'm still adjusting my dose. I am asymptomatic from the thyroid though. I developed joint pain in my fingers. It goes away as I move my hands and exercise. That went away after a couple of months on the pembro. Pembro is awesome, my quality of life is just great. Pembro doesn't affect my immune system as much as chemo, I used to have to get the lapelga shots but now I don't worry about it and	"Some thyroid underactive thyroid issues, I'm on thyroxin for life now. It made me feel really dreadful while it was happening. Fatigue's been the worst thing. I've still got chronic fatigue, it's getting better but I've been off treatment for a year, and it still impacts but daily, but its manageable and I'm here, so it's worth it. It was more like a chronic fatigue whereas I think on chemo it was more intense and short-lived. I don't think the fatigue is the same. While on treatment, when at my best, I was exercising, running between 4 – 8 km and doing yoga, but there's peaks and troughs. The first year I had less fatigue and the second year I had more, it was cumulative. I could do a	"In the beginning, you think that there aren't going to be any, for me anyway, but the longer you stay on it, you start to get side effects. Severe, severe diarrhea. Your skin changes. I've been using the same facial cleanser for 50 years and the same moisturizer and I absolutely loved it. But all of the sudden my face started to itch. I had terrible itching on my face and I realized its from the Keytruda, I did my own research and I had to change my facial products. Your body skin gets much dryer than usual. And on top of the breast, under the skin little bumps. Your skin it just changes. But it didn't in the beginning, it started about 3 months ago."	"For the chemo + pembro, the biggest side effect for me was the fatigue, like a lot of fatigue, the hair loss – I did cold capping so didn't lose a ton but definitely more than normal. Sometimes my head would be a little foggy – I think I felt chemo brain a bit. With just the Keytruda, I think my allergies have got a little worse. I take allergy shots. When my allergies are really bad, I get asthma and that got a little worse."		

	my bloodwork is slowly getting back to normal."	lot more than I wanted to do, just have to pace myself. For the last 2 years, my WBC has been below range a bit, and it still is and no one can tell me why. I got pleurisy at one point, I don't know if it was related to treatment, I had a cough, and it damaged the pleura, but it wasn't seen in scans."				
24. On a scale of 1-10, how would you rate your QoL while on pembrolizumab + chemo? **1 being very poor and 10 being very good. Please explain.**	"Pembro would be 9.5 out of 10, while it was with chemo I was really lucky I didn't get sick, I'm really grateful for that, but still I would say 5 or 6 – I wouldn't be able to work for sure. With the pembro, it's just very easy on me. It's half an hour infusion; you're in and out of the hospital very quickly. Other than the thyroid issue, which is a very easy fix, the joint pain wasn't bad, it goes away with walking, other than that the fatigue is really nothing compared to chemo I can still go and travel while I'm on pembro. Especially with the every 6 week regimen it really frees up your schedule."	"It obviously fluctuated, at the best probably an 8 and at the worst probably a 5. If I had to give one, I'd go with a 7. When my thyroid gave out that was the worst, I couldn't get out of bed. But then when I was feeling good and exercising it was good. I worked the whole way through treatment, and I actually got a promotion on treatment, I worked from home, but I was able to do quite a lot of stuff."	"10. I'm fine. Because I don't blame any medication for anything bad, I choose to believe it's all wonderful and good and I'm still alive."	"Combo – maybe a 6 or 7. Keytruda – I would say it's much better, maybe like a 9. With the chemo, there was just a lot of fatigue and some days I couldn't get out of bed, I couldn't do the normal things, I couldn't go for a walk. With the Keytruda I don't feel like it's draining my energy, it's just the allergies. Everything is starting to get better – my hair is growing back, which contributes to my quality of life, and I just feel better, more even so that's why I would give it a higher value. All my blood tests seem to be improving after the chemo as well, my	"I would give 2 measures. Because I had this situation of having cancer, I had weighed 210 lb at 5'5 when I first was diagnosed. I was active but still fell into the obese category. Because of the scare of cancer, I had purposefully lost 60 lbs and I had worked really hard at it. My physical quality of life was really better than before cancer. You feel better when you're not obese. So physically I would say a 12 out of 10. But emotionally and mentally, it puts a bit of a damper on it. I'd say excellent overall. I can still go on vacation, and I can still be intimate with my husband, I can still play with my grandchildren. I can still	"Combo – I'm an optimist so I'd say 8.5. I didn't throw up, anytime I thought I would be constipated, I did preventative care. I mean I've lost quite a bit of hair, and I knew I would, and that sucks. My skin is dry. Out of world tragedies, it's an 8.5 for what it could have been."

				neutrophils are improving now, and I think that's related to the fatigue. I did take Neulasta along with the chemo to keep the neutrophils in check but no, I don't need it anymore."	do anything I want to do."	
25. Did you have any cancer symptoms before starting the therapy? If so, what were they?	"I actually still have it, but it's not the same pain, it's very manageable now. I don't need pain killers, it's discomfort that's always there. I don't know what it is, perhaps it's the muscles that were previously aggravated by the tumour."	"No, not after the surgery."	"No."	"No."	"Ascites, huge bloating."	"No."
26. If you did have cancer symptoms before starting the therapy, did the therapy help resolve those cancer symptoms? If so, which ones?	"Yes, I don't even know if I would be alive if I didn't have the therapies. The tumour was growing so quickly. I went from no pain killers to high doses with a few months and I went from walking on May 23 and by the time I started chemo I was somewhat confined to a wheelchair. Now I can walk fine, I can walk for 2 hours, or more!"	N/A	N/A	N/A	"Oh, my goodness I can't emphasize this enough, 100% and more! They had scheduled me for more paracentesis in case the fluid came back but I never needed one once they drained me initially and put that medicine in me. I felt fine when I was discharged – that quick."	N/A
27. How was response confirmed to pembrolizumab + chemo? Was it clinically (symptoms resolved and you felt better), biochemically (tumour marker went down), or radio-graphically (CT scan results)?	"So, the first few images were the 3 drugs together and the imaging improved, and the tumour marker went down. I would say all 3. I didn't get pembro for rounds 5 and 6 and that was the only time my tumour marker didn't go down. In March or April of this year my tumour marker started going up	"CT Scans – I think I had maybe 2 scans that showed shrinking – it maybe halved in size. My oncologist was careful about how she said it, she didn't' say NED at the time, but said we couldn't see it anymore and that was about 6 months in.	"I get a blood test every 3 weeks before I go into treatment and if they see anything wrong, they don't give you the treatment. I go every 6 months for imaging – so far, so good."	"The imaging there wasn't any evidence of it even before the chemo and afterwards there is still no evidence of any cancer. The Ca-125 tumour marker was very low (8.3) after my last Keytruda infusion, it's progressively going down each cycle.	"It was symptoms – they kept asking me about the fluids and feeling my belly and it was gone. They do the Signatera and CT scans every 3 months. They don't do the CA-125 because it doesn't work for me. My Signatera has been at a 0 since the second or	"Yes, they did a PET after the third round of chemo and nothing lit up."

	when my menstrual cycle resumed and the tumour markers were all over the place, but the CTs were fine, and the tumours have gotten a little bit smaller. For the last little bit, the tumour markers have been a bit out of whack, perhaps because my menstrual cycle came back, but physically and on the CT the tumour is controlled. All the aspects – the drug is doing what we want it to do."	My scans are still clear."		My blood tests as well are all good, showing a good response."	third round of therapy - they say I'm in remission. It was hand in hand with the CTs that were saying it was nearly resolved, and then the last one said there was no sign and the Signatera was still 0."	
28. Have you ever had to stop pembrolizumab + chemo? Why or why not?	"I wish I didn't stop it! I developed hyperthyroidism and my understanding is that the pembro can cause excitement in the immune response and sometimes it can attack other organs. I don't know why I went into hyper first, the endocrinologist didn't want to aggravate it and cause serious side effects, so we held the IO so as to not jeopardize the long-term use of this drug. I think in most people it resolves after a couple weeks, I don't think they foresaw that I would have to pause for 2 cycles, as 1 would usually be enough."	"Yeah, so, I had to stop maybe 2 or 3 times to have a break. That was something me and my oncologist discussed; she was great. At one point I skipped a cycle, because I had diarrhea, which wasn't a side effect I listed and I'll tell you why in a minute - and they were worried about colitis they thought I had that, but it was a food sensitivity. It wasn't a side effect, but they gave me a break. About a year my fatigue was getting worse and worse I had a break. It might have happened another time, I can't remember. It was less about stopping and more about giving a break for my body to recover."	"No, only when I took the break because I had company, and I wanted to be available."	"No. I never had to stop. I think I tolerated it pretty well."	"No – just the one time I delayed to go on vacation, but my doctor said it's not going to have an impact, and my mental health is important. We took a cancer vacation – we didn't even talk about cancer."	"No. I've had some clumped blood tests, but it wasn't something to make them stop it."

29. Has pembrolizumab + chemo been easier to use than any previous therapies? Why or why not?	"For me, if I can have pembro it's not even a question, 100% - 100% this is a really good drug. By the time I had my 8th chemo infusion it was really rough, really really rough. As soon as I got the infusion, I could feel it in my mouth, just really bitter. I would just sleep. I was so tired, I've never been drunk but I think if I had been, the worst possible hangover is what it would feel like. Because I had that reaction, I had additional pre-meds - it was a very long day, and it was a lot of drugs going through my system. And then with the pembro, it's just a quick drip, just 30 minutes. I could have pembro and then go shopping right after if I wanted to. It just feels like a regular IV of liquid."	"I think I was much more able to live a fairly normal life. I had to be very careful not to overdo it, but much better in terms of my QoL. I was able to work 3 – 4 days per week, I got promoted, able to socialize and go out with friends and do things, I was able to go into the office when I needed to. I travelled, I went to Prague, I went on my own to see a friend, being able to travel, spending time with family, doing meaningful life things, whereas with chemo I was really withdrawn and in the hospital every day, I was absolutely shattered and I feel like that would have been the case even if it wasn't the pandemic. I went to Costa Rica right after I finished treatment, had an amazing two weeks. It was life changing for me, I wouldn't be here if I hadn't had IO and I wouldn't be here if I had more chemo, it's QoL but it's survival as well."	"They have to stick your arm and the pain of the needle going into your arm is terrible. I have to tell them all the time to make it slow with the saline and sometimes you get a son of a bitch that gives you the treatment too fast. The pain of needle going into the arm is excruciatingly terrible."	"I can't compare it to anything, but I guess it's somewhat easy. You have to get it through the IV and I have problem veins so it's not completely easy. But convenience wise, you get it done in one day. It was okay. The nurses do all the work."	"Keytruda is a dream. It's a short 30 minutes infusion and for me, no side effects. My husband and I both LOVE it. The chemo I'm glad I got it, it was a long day, but it is what it is, and I would do it again in a heartbeat."	N/A
30. How has your journey impacted your caregiver /family?	"{*crying*} …this is a hard one. I think quite a bit. I think my parents have been really good at supporting me and encouraging me and not letting the emotions	"It was quite exhausting, my wife was my primary caregiver, she spent a lot of time in hospital car parks because it was the pandemic, and she wasn't allowed in. She	"I think they've made me love them more. They've been so wonderful to me, and you just appreciate everything."	"Umm well I actually didn't tell my mother until after the fact because I didn't want to worry her.	"It definitely has affected my husband; this will make me cry. He's been very supportive in every practical way imaginable. But he struggles to know how to support me	"It hasn't impacted them at all because I'm taking care of myself."

	getting to them. But I can imagine how tough it was for them. They don't live in the same city, my parents had to move. By the time my parents reached me I was immobile, and my mom had to find us a place to live. My dad was working overseas, and he resigned to come back to Canada. They sold their place, and they came to Toronto to help me. I'm their only child so I can imagine how tough it could be for them."	did a lot of day to day caring, she worked from home for a while because of my clinical vulnerability and care needs, being miliary it's not easy to work from home. My mom found it really difficult, she had a really, really difficult emotional journey after I was diagnosed. She really shut down. I think a lot of my friends had a lot of struggles, but they didn't want me to know about it, I think they were dealing with their emotions as well, but they kept it from me. A couple of my friends stepped away as well, some stepped forward and some stepped back, and now we can't repair that relationship."		My husband was actually really good about it. I'm sure that it added some stress to him since he was the one that helped me the most. I'm sure it added some stress to him – he had to pick up the slack with the house and chores and stuff – so I would say it probably added more stress to him."	emotionally. I have had to go through stages where I was sitting there crying 24/7 and I didn't understand how he could watch a tv show and laugh and not feel how I was feeling, and I would get mad thinking that he didn't care. I didn't need waiting on, but I was kind of a wreck and was accusatory towards him and took it out on him. I grew to understand, and I joined support groups with women who understood. It's really hard to understand if you don't have cancer. When I got other support, I stopped lashing out at him. I didn't feel I was getting what I wanted from him, and he was trying to do everything he could. It did affect our marriage, and luckily he put up with me and now I apologized and we're doing fine. My kids, they know but I try to keep it from them. My husband, I tell my worst fears, but my kids, I try to hide it as much as possible. Only our youngest is still at home, it's easier to hide from my older ones. My youngest felt more of the effects.	

					Drama and stress and interpersonal stuff all because I did not cope well. Now what's happening is I am a total psychiatric mess right before my scans – crying and snapping at my husband, I'm a wreck and then the next 3 months I'm perfectly fine. I'm just terrified and a wreck around the testing and then when it's done, I forget about it for the next 3 months. It's like a woman suffering from PPD vs PP psychosis. My grandkids help me cope because I won't let myself act emotional around them."	
31. Was it worth accessing pembrolizumab + chemo? Why or why not? Please describe the impact it has had on your life.	"I think it's really important. I think it's one of the few treatments that extends life without negatively impacting quality of life. I think we've all seen the research for that, it has the possibility of having a long-term disease control. So, I think it's extremely important. I think the data speaks for itself. IO is game-changing. Yes, it was worth it, I think I'm really lucky that my insurance at least paid for some of it. I	"Really 100%, wow, I would not be here. I think that's why I'm so keen to be involved with patient advocacy. It saved my life, and I'm living a normal life, and we're going to New Zealand in 3 weeks. I just got another promotion as well, so I'm succeeding as well. I'm here and I'm able to engage in a meaningful life and do all the things that are important to me.	"I'm alive!" *laughs*	"Yes, I do. Because I've had a good response to it, and it just seems to be working for me. With the CT scan and the tumour marker. I mean I don't know what it would have been like if I didn't take it."	"Oh my goodness – huh – I couldn't even begin to describe how much – it saved my life – the only way it wouldn't have been worth it is if I was suicidal and I wanted to die. It saved my life. Period. I can't imagine what my situation would be without it. It's giving me time with my family and all these memories created. It's definitely extended my life and made my life wonderful. I'm so grateful."	"I can't say, I don't know because the diagnostic tests later will tell me if it's been worth it. This whole thing is an operation in faith. You have to have faith in medicine and in science and believe this is the right drug."

	know others that couldn't access it and have since passed away, and to know that their oncologist recommended it, but they couldn't get it, and they passed away it's just unbelievable. I don't know where I would be right now if I didn't have access to Keytruda."	If I hadn't had this drug, I wouldn't be here to tell you about it. It's worked better than I imagined, it's doing its job, it's incredible. It sounds a bit cheesy but, Pembro has allowed me to thrive, with limitations, for the most part for the last 3.5 years with cancer, stage 4, endometrial cancer."				
32. Did accessing pembrolizumab + chemo allow you to fulfill or accomplish anything that you would not have otherwise been able to do had you not accessed the therapy? Please explain.	"I went travelling this year. I went to France. I live a somewhat normal life."	"If I hadn't had it, I would be dead. And yeah, I think the key things are progressed in my career, during and after treatment with promotions, I've been able to travel, which is something very life fulfilling to me, especially that we don't have children, so it's a really important thing to embrace. And exercise, at one point I was running 5 – 8 kms, and I'm doing yoga training at the moment, and I'm hoping to do yoga retreats for people with cancer. When I was first diagnosed, I wouldn't have dreamed to plan that far in advance. And patient advocacy as well, I'm here to help others and share my story and I wouldn't have been otherwise."	"You could only ask me that question if I was dead. I breathe every day."	"I mean I would say I was able to still work a little bit while taking this, so it sort of enabled me to continue my life somewhat normally. I've been able to work more since I've been on just the Keytruda because it didn't cause as much fatigue."	"Yes, I don't think I would be as healthy as I am. I don't think I would be able to complete my daily routine. I don't think I would be able to participate in life. When I was that ill beforehand I was debilitated. I was in a wheelchair, I couldn't walk. The answer's definitely yes. I'm picking my grandchildren up today as a matter of fact. I schedule my infusions while my youngest granddaughter is in preschool and then I get her at 1pm. And I just found out number 3 is on the way!"	"I will say that I considered not having any treatment and did look into holistic treatments, I was open to anything because I couldn't believe I had this. Did it help me? I guess it has, if the PET scan is coming clear and it wasn't clear before. Quite frankly I'll feel really grateful when this chapter is over."

PART E: PATIENT PERSPECTIVES						
33. What improvements would you like to see in a drug therapy that are not currently available in other funded therapies?	"Ideally, I think in Canada we have one of the most stringent medical programs and our oncologists have to go through so much to be where they're at. I think we should trust them. If the oncologist has recommended a treatment, that should be the therapy that's covered. In the small circle that I'm a part of, I meet other people who have cancer and they're trying to access drugs that are proven to work and they just can't access it. If the oncologist has recommended a therapy, I think that therapy should be provided to the patient. Also, I think there is a back log in approving drugs. I actually wrote to my local MP and MPP and they explained that the drug company has to apply for a particular indication and Health Canada has a year to approve it. Just approve it so the drug company can apply! This entire time I was wondering why it wasn't approved. Years - that's a lot of people, waiting. If cost is a concern, maybe the patient can pay for the first 2 or 4 and if it's proven to work then it	"For me its assurance that there will be another line of treatment. I think the most effective use for curative intent treatment. My oncologist is really positive about people with lynch syndrome on pembro, and that ability – being able to treat with durable response – to manage it like a chronic disease."	"A teeny, tiny pill. They've got to eliminate the needle going into the arm. They've got to find a different way to administer the drug."	"It would be great if you could have some kind of therapy that doesn't affect other things – that doesn't cause hair loss and such strong fatigue where you feel like it's something that's bad for the body and wearing everything down. It would be nice if it targeted the cancer and not everything else."	"I would like there not to be fake disqualifying criteria based on factors that may not be the whole picture, for example the pMMR status. If I had lived in certain places, I wouldn't get it and I'd be screwed. For me that's important. And more research for endometrial cancer. It's on the rise and it's not given any attention. A lot of articles I read say there are breast cancer drugs that help endometrial cancer patients in clinical trials, but they're not approved, so getting approval for endometrial cancer drugs from drugs that are used to treat other cancers."	"Patient education is at an all-time low and there's not enough people [staff]. First of all, I think that hospitals should connect with patient organizations and have some roundtable discussions, so you don't get a diagnosis, and you don't know – like I'm a smart chick so I connected with resources right away but not everyone is psychologically able to do that. The hospital should speak about their department, the treatment plan, what it entails, and then led on a path to self-education when they are newly diagnosed, or else SHARE should be introduced to every hospital. I'd like to know more about coming out of this."

	could be funded. That's at least affordable for some people. We know it works; it's going to work. We should trust our oncologists more instead of shutting all the doors, let's think of more creative ways to help more people efficiently."					
34. Do you believe pembrolizumab, has those desired improvements? Why or why not?	"As a recommended first line treatment, yes. Right now, it's a question of finance, the data has been loud and clear."	"Yeah, so it has managed my cancer like a chronic illness, I don't know how long because I'm living it, but I'm actually 5 years from the date of my diagnosis and the fact of making it 5 years with stage 4 endo cancer, which essentially is proof of concept. It's been like living with a chronic illness, and I have optimism, that that will continue, I don't know for how long, but I'm living much more optimistically, with more hope and certainty for the future and ability to make plans and I think that's come out of pembro having such a durable response. I see myself as someone with chronic cancer now."	"I don't know, if they had that they would have offered it to me."	"Possibly, it's a little too early for me to know yet. So far, it's definitely an improvement from the chemo."	"I think it's an effective drug for endometrial cancer and should be used, should be tried, should be given time to work, so I guess I say yes. It's an effective drug, so why not?"	N/A
35. Would you recommend that pembrolizumab + chemo be made available to all patients who qualify for it?	"You know I think it should be made available to all patients, period. From what I can see, in the US its approved for everyone dMMR and pMMR -	"Yeah, I would based on my experience. I definitely think, yeah, it's been life-saving, life-changing for me. It can mean the difference	"It should be made available not to all patients who qualify for it, but everyone who needs it."	"Yeah, absolutely."	"Oh absolutely! Strongly. I feel it would be devastating not to. Very detrimental and cost more money in the long run when they debilitate and can't function and	"I'm just a patient, I can't recommend that because everyone has a different situation. NICH recommends it because its first-line treatment so as long as its first-line

	some pMMR will respond and who are we to say that they don't deserve a shot. I don't think it makes the side effects worse and even if there's a chance, the side effects are manageable."	between living well and not being here."			end up slowly dying in a nursing home, costing money."	therapy that will be what is administered to patients. I can say that I'm alive and my PET scan read clear, so clearly something's working. I would advise any country to have the opportunity to get it if it's found to be helpful, and it has."
36. Do you wish to add anything about why accessing pembrolizumab + chemo is so important to cancer patients and caregivers?	"There's such a long list. The side effects are very, very manageable. Other than the cost, I can't see a downside. Someone would have to come and tell me what the downside could be, other than cost. Before I got Keytruda, I read about side effects that could be severe, but would you give up a chance where you're not going to develop a side effect, when the alternative is that progression is inevitable versus a drug that in the best case can provide cure, or a long-term remission. Sometimes decisions are made focusing on the negatives, but the alternative could be better. I know we have more people impacted by the larger patient population cancers. When they	As above	"There is nothing more wonderful and powerful than anything that keeps a person alive. Whatever drug keeps you alive that person needs to be able to access it, period. Whether they can afford it or not, keeping people alive has no price tag."	"I would just say that the biggest thing that's important is that it can help people to survive. If it lowers and keep their cancer from coming back, especially people with advanced cancer, that's kind of a miracle for them. It enables some people to keep their cancer away. In my case, so far, it's been very positive. I think it would be very beneficial in Canada for everyone to have access."	"I think it is very important because it is an effective treatment and the synergy between the two seems to have a very powerful effect. For me, I wish I could re-do all the extensive, extensive cancer I had when I entered John Hopkins as an in-patient and then after this drug, nearly completely resolved, and then the next one just one small nodule, and the next one no evidence. To me that's a no brainer. It's a powerful combination that effectively works and nobody should be denied that."	"It's important that it is accessible to everyone because it's working. And I'm proof of that. It's clearly making a difference in the shrinking of tumours; we want to be a cancer free society and why shouldn't everyone have access to something that's proven scientifically to reduce tumours. At least have the choice."

	develop a drug, other cancers should have access too. We should give it a shot. If we're worried about cost, I can see areas where we can save costs and make our system more efficient. Not giving people the care they need to survive is not the best answer to the situation. Costs saved can be used for the drugs. I also know of other countries that drugs can be accessed more easily, the drug companies can provide compassionate care, I think this is something we should look for in country."					

CADTH

CADTH Reimbursement Review
Clinician Group Input Template
CADTH Reimbursement Review

Clinician Group Input

CADTH Project Number: PC0383-000
Generic Drug Name (Brand Name): pembrolizumab (Keytruda®)
Indication: Pembrolizumab (Keytruda) in combination with chemotherapy for the treatment of adult patients with primary advanced or recurrent endometrial carcinoma (EC), and then continued as monotherapy.
Name of Clinician Group: Ontario Health (Cancer Care Ontario) Gynecologic Cancer Drug Advisory Committee
Author of Submission: Dr. Sarah Ferguson

1. About Your Clinician Group

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

2. Information Gathering

Information was gathered by email.

3. Current Treatments and Treatment Goals

Current treatments include platinum-based chemo (usually carboplatin-paclitaxel), radiation.

There is currently no publicly funded immunotherapy for first-line dMMR endometrial cancer (EC). However, there is compassionate dostarlimab in combination with chemo available right now for a similar population which is currently under review at CDA. Additionally, durvalumab in combination with chemo is also under review at CDA for a similar population.

Treatment goals include to prolong life, delay disease progression, reduce symptoms, improve health-related QoL, and potentially cure disease.

4. Treatment Gaps (unmet needs)

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

In the pMMR population, there is no other treatment other than carboplatin-paclitaxel and it does not produce a durable response. Therefore there is a need for new therapy to improve oncologic outcomes and prolong life.

Chemotherapy does not provide a durable response in patients with dMMR or pMMR endometrial cancer. There is currently no publicly funded immunotherapy in the first-line setting. Dostarlimab-chemo for the MSI-H/dMMR population was reviewed but is not yet publicly funded. Durvalumab-chemo for EC is currently under review.

5. Place in Therapy

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

Pembrolizumab will be used in the first-line with chemotherapy, followed by maintenance, or in the platinum-sensitive recurrent setting.

Pembrolizumab will be in a similar setting as dostarlimab and durvalumab.

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

GY018 did not include patients with carcinosarcoma (included in RUBY, ~10% in overall population).

GY018 patients must have Stage III or IV measurable disease for primary presentation; Stage IVB +/- measurable

In GY018, pembrolizumab maintenance is every 6 weeks for up to 14 cycles. In RUBY, dostarlimab maintenance is every 6 weeks for up to 3 years); or until disease progression or unacceptable toxicity. In DUO-E, durvalumab maintenance is until disease progression.

Patients least suited are those with a contraindication to immunotherapy or poor ECOG status.

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

Combination of imaging and clinical exam as per physician discretion.

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

Progression of disease, intolerable toxicity

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

Outpatient settings under the care of physician who can give systemic therapy.

6. Additional Information

NA

7. Conflict of Interest Declarations

To maintain the objectivity and credibility of the CADTH drug review programs, all participants in the drug review processes must disclose any real, potential, or perceived conflicts of interest. This conflict of interest declaration is required for participation.

Declarations made do not negate or preclude the use of the clinician group input. CADTH may contact your group with further questions, as needed. Please see the *Procedures for CADTH Drug Reimbursement Reviews* (section 6.3) for further details.

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

   OH-CCO provided secretariat support to the group.

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

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

Declaration for Clinician 1

Name: Dr. Sarah Ferguson
Position: Lead, OH (CCO) Gynecologic Cancer Drug Advisory Committee
Date: 26-11-2024

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

Table 1: Conflict of Interest Declaration for Clinician 1

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

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

Declaration for Clinician 2

Name: <Enter full name>
Position: <Enter currently held position>
Date: <DD-MM-YYYY>

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

Table 2: Conflict of Interest Declaration for Clinician 2

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

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

Declaration for Clinician 3

Name: <Enter full name>
Position: <Enter currently held position>
Date: <DD-MM-YYYY>

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

Table 3: Conflict of Interest Declaration for Clinician 3

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

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

Declaration for Clinician 4

Name: <Enter full name>
Position: <Enter currently held position>
Date: <DD-MM-YYYY>

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

Table 4: Conflict of Interest Declaration for Clinician 4

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

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

Declaration for Clinician 5

Name: <Enter full name>
Position: <Enter currently held position>
Date: <DD-MM-YYYY>

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

Table 5: Conflict of Interest Declaration for Clinician 5

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

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