Canada's Drug Agency
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CDA-AMC REIMBURSEMENT REVIEW

Patient and Clinician Group Input

talazoparib (Talzenna)

(Pfizer Canada ULC)

Indication: In combination with enzalutamide for the treatment of adult patients with homologous recombination repair (HRR) gene-mutated metastatic castration-resistant prostate cancer (mCRPC).

April 7, 2025

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. **If your group has submitted input that is not reflected within this document, please contact Formulary-Support@cda-amc.ca.**

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Patient Input Template

Name of the Drug and Indication	**Talazoparib in combination with enzalutamide for the treatment of adult patients with homologous recombination repair (HRR) gene-mutated metastatic castration-resistant prostate cancer (mCRPC).**
Name of the Patient Group	**Canadian Cancer Society**
Author of the Submission	**Sasha Frost**

1. About Your Patient Group

Website Link: https://cancer.ca/en

Our purpose: To unite and inspire all Canadians to take control of cancer.

Our mission: In trusted partnership with donors and volunteers, we improve the lives of all those affected by cancer through world-class research, transformative advocacy and compassionate support.

We set ourselves apart from other cancer charities by taking a comprehensive approach against cancer. We are also the only national charity that supports all Canadians living with all cancers across the country.

2. Information Gathering

The Canadian Cancer Society conducted a survey to gather perspectives on disease experience from 21 individuals with metastatic castration-resistant prostate cancer (mCRPC) and three caregivers of mCRPC patients. Data collection took place from April to May 18, 2023, with all respondents residing in Canada. The survey was distributed through CCS's patient panel and Cancer Connection forum.

For demographic information, caregivers were asked to respond for the patient. A breakdown of where respondents resided can be found in Figure 1. Annual household income was also collected and located in Figure 2. Ninety-two percent of respondents were white, with 4% indicating they are Jewish. The remaining 4% preferred not to disclose. We also asked how far the nearest treatment center was for the person with cancer to gauge access to treatment, and the results are presented in Figure 3 with the majority living under one hour from a centre.

Figure 1

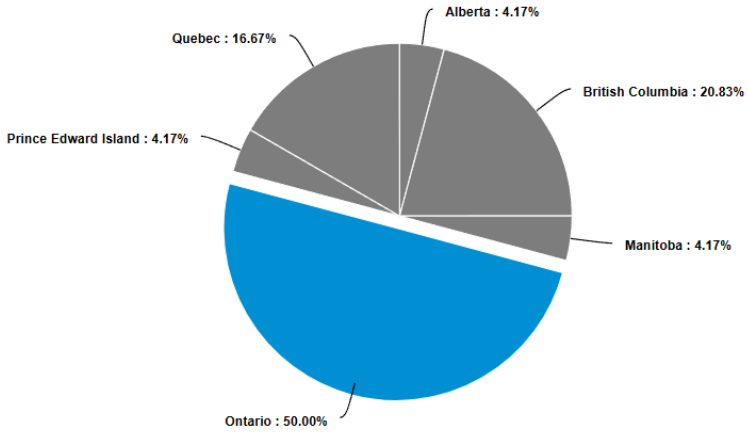


Figure 2

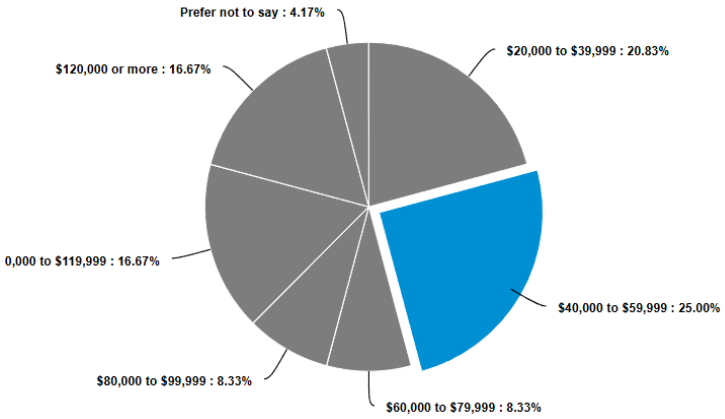
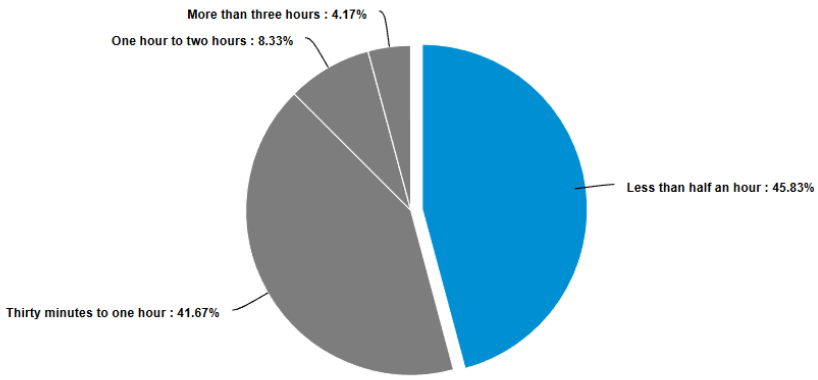


Figure 3



3. Disease Experience

The Canadian Cancer Society asked a series of questions about patients disease experience:

How much of an impact have symptoms associated with metastatic castration resistant prostate cancer had on your day-to-day activities and quality of life?

Figure 4

Question	Count	Score	No impact	Small impact	Moderate impact	Significant impact	I'm not sure
Ability to work	19	2.42					
Ability to travel	21	2.14					
Ability to exercise	21	2.1					
Ability to conduct household chores	21	1.95					
Ability to fulfill family obligations	20	1.9					
Ability to spend time with family and friends	21	1.62					
Ability to concentrate	21	2.14					
Ability to fulfill practical needs (dressing, bathing, preparing meals)	21	1.43					
Ability to maintain positive mental health	21	2.33					
Engage in sexual activity	18	3.56					
	Average	2.14					

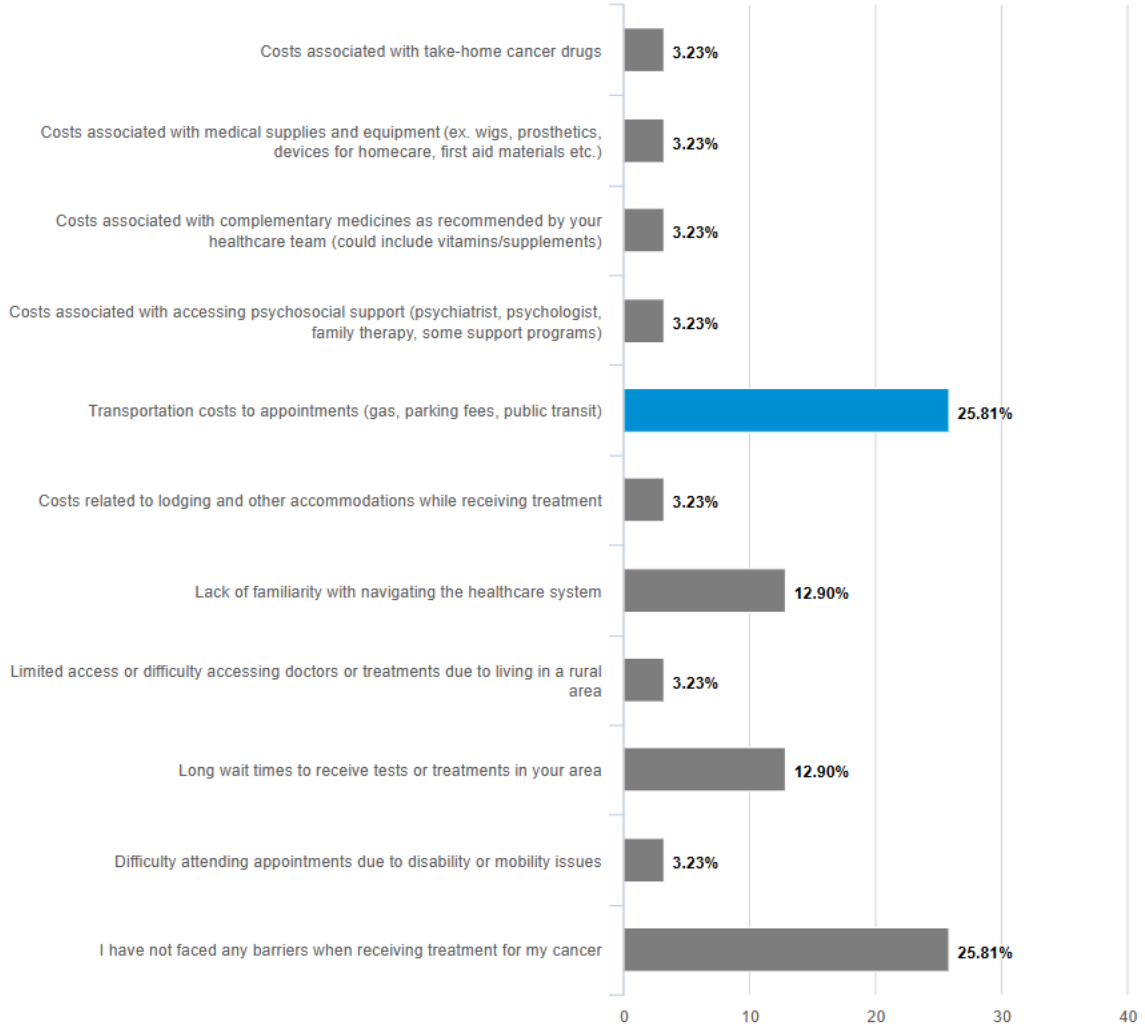
Figure 4 illustrates the average scores patient respondents assigned to each category, with higher scores indicating greater impacts. The key findings from the question on the impact of symptoms associated with metastatic castration-resistant prostate cancer (mCRPC) reveal significant challenges in several areas of daily life. The most notable impact is on the ability to engage in sexual activity, with 61.9% of respondents reporting a significant impact. Other areas, such as maintaining positive mental health and the ability to exercise, show a moderate distribution of impact levels, highlighting the varied experiences of individuals with this condition. These insights underscore the importance of addressing both physical and emotional aspects to improve the quality of life for those affected.

In addition to the data in Figure 4, the three caregivers indicated the patients' symptoms significantly impacted their ability to work. The majority also rated the ability to travel, exercise, conduct chores, fulfil family obligations, maintain positive mental health and engage in sexual activity as significantly impacted. For a detailed heat mat with patient and caregiver responses amalgamated, please see appendix 1.

Which of the following barriers have you faced when receiving treatment for your cancer (select all that apply)?

CCS identified the barriers faced by patients with mCRPC when receiving treatment. The key barriers reported by the respondents are summarized below:

Figure 5



The most commonly reported barriers include transportation costs to appointments (25.81%), long wait times to receive tests or treatments (12.9%) and lack of familiarity with the healthcare system (12.9%). For those with mCRPC, these barriers can be particularly burdensome due to the frequent need for specialized treatments and ongoing care. Additionally, the complexity of navigating the healthcare system may be

exacerbated by the advanced nature of their condition, making it important to address these logistical and systemic obstacles to improve access to effective cancer care.

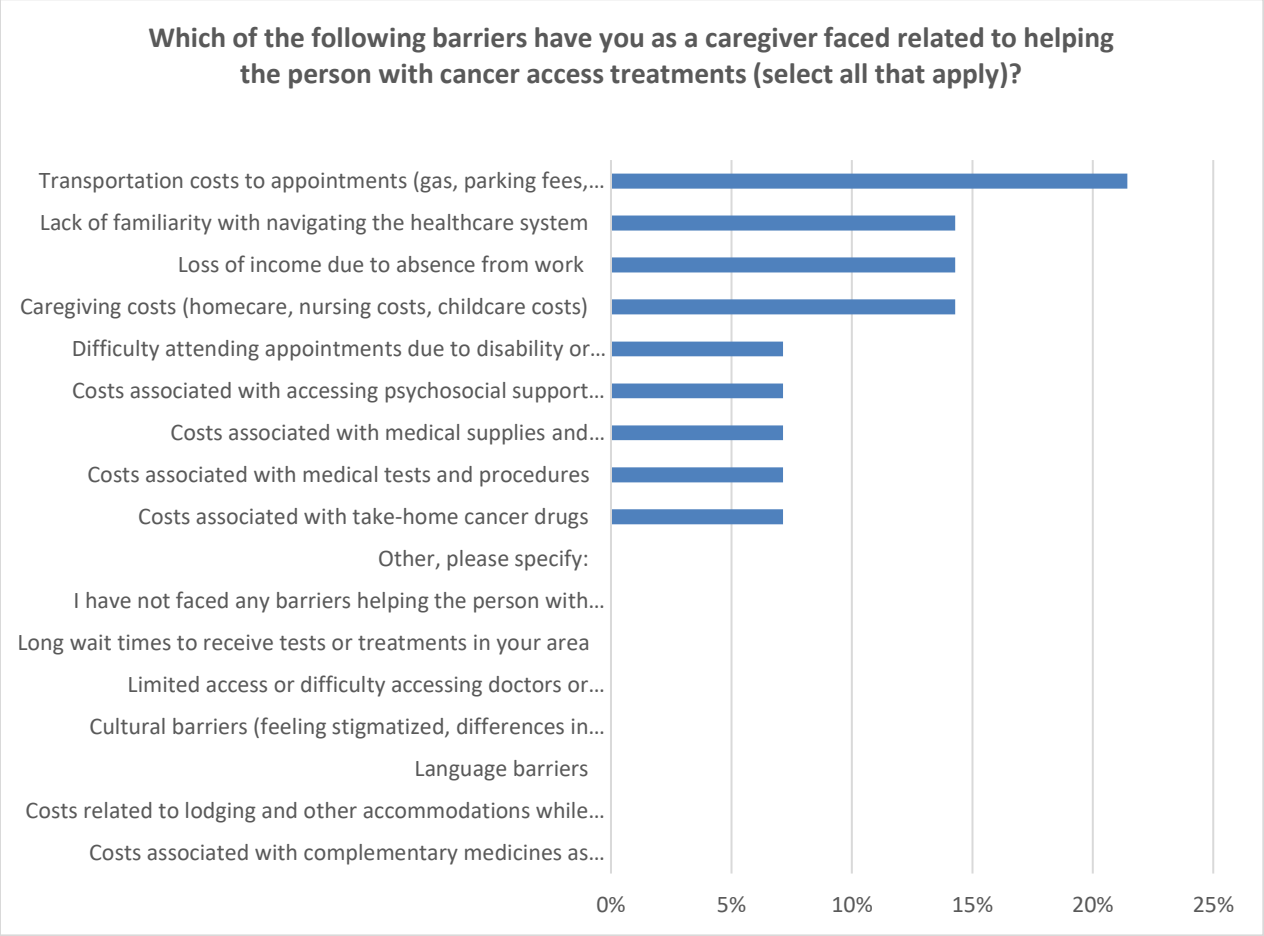
Caregiver Specific Impacts

How has the person with cancer's diagnosis impacted your life as a caregiver?

One caregiver stated "My husbands terminal diagnosis has ruined any real happiness for my young kids. Turned our life upside down and taken over our lives.". Another stated "Focus has been on patient for a year or so in advanced stages. Focus on self has gone wayside.". This underscores the challenges posed by this disease on caregivers and their mental health.

Which of the following barriers have you as a caregiver faced related to helping the person with cancer access treatments (select all that apply)?

Figure 6



Transportation costs, caregiving costs, loss of income due to absence from work and lack of familiarity with the healthcare system were the most common barriers amongst the caregivers surveyed.

Experiences With Currently Available Treatments

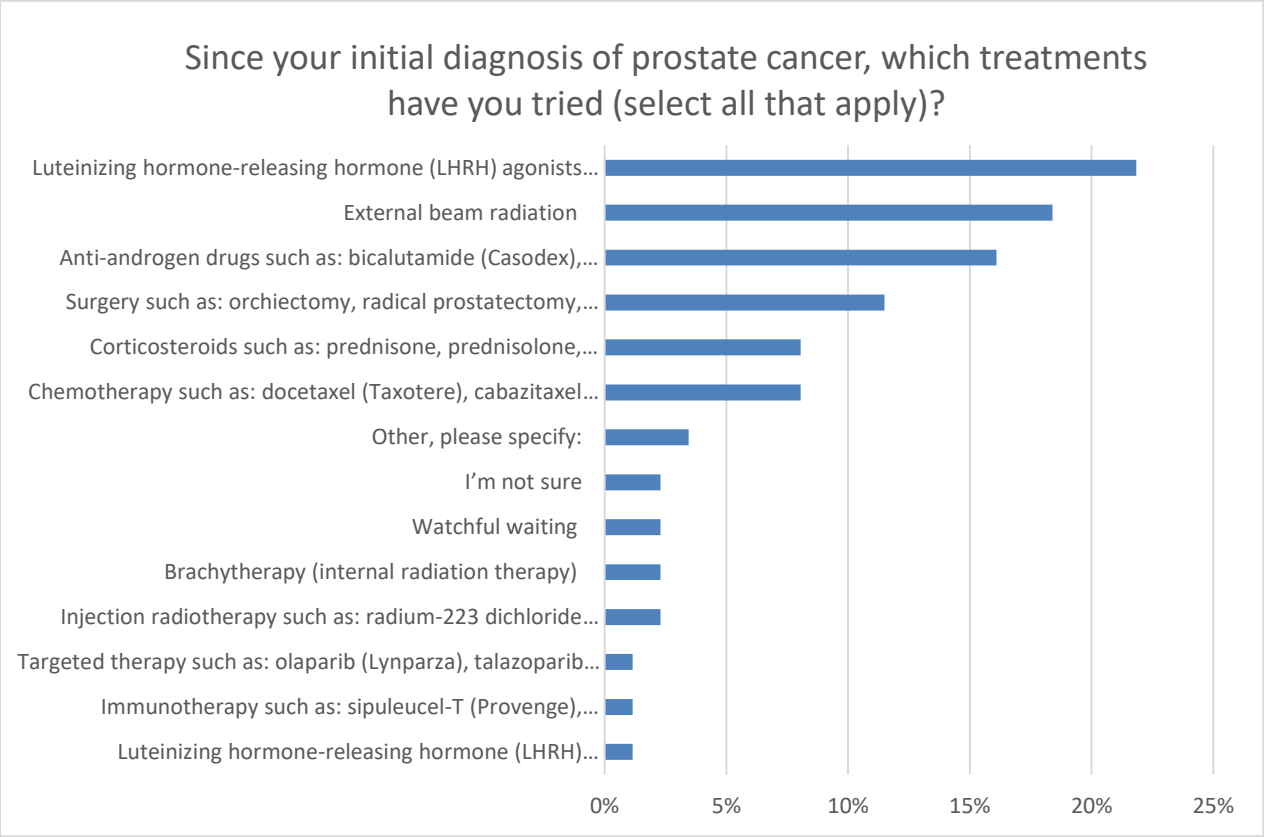
The Canadian Cancer Society asked a series of questions about current treatments.

How many lines of treatment have you undergone since your initial diagnosis of prostate cancer? Please note: one line of treatment could include one complete cycle of a single drug or combination of several drugs, or a planned sequence of therapies. For example, if the first attempt at treatment was radiation and surgery, that would be one line of treatment.

The majority of respondents, (67%) reported receiving three or more lines of treatment at the time of this survey (including caregiver provided responses on behalf of the patient). Among the remaining participants, 8% indicated they had received one line of treatment, while 13% reported having received two lines of treatment. Additionally, 13% of patients were unsure about the number of lines of treatment they had undergone.

Since your initial diagnosis of prostate cancer, which treatments have you tried (select all that apply)?

Figure 6



The most commonly tried treatments include hormone therapies, with 39.44% of respondents using Luteinizing Hormone-Releasing Hormone (LHRH) agonists, antagonists, and anti-androgen drugs. External beam radiation is utilized by 19.72% of respondents, and surgical procedures such as orchiectomy or radical prostatectomy have been undergone by 14.08%. Chemotherapy has been used by 5.63% of respondents, and corticosteroids by 7.04%. Less commonly, 2.82% of respondents have tried injection radiotherapy and brachytherapy, while immunotherapy has been used by 1.41%. Notably, no respondents reported using targeted therapy. No patient opted out of therapy due to concerns about side effects.

How much of an impact have the following cancer treatment side effects had on your daily life? Please note: this is a general list of side effects that could be experienced with various prostate cancer treatments, including less likely ones, and side effects vary from person to person.

Nausea and/or vomiting had the highest percentage of patients reporting no impact (85.7%), but among those affected, it had a significant impact on their daily lives. Changes in libido, sexual function or fertility had a substantial impact, with 72.2% of patients reporting significant impact. Mouth, tongue, and throat problems were reported by 80.9% of patients as having no impact, but for those affected, it was a significant issue.

Additionally, several other side effects were indicated by patients to have a notable side effect.

- Fatigue or low energy: 28.6% of patients reported a significant impact.
- Hot flushes: 19% of patients experienced a significant impact.
- Dizziness or feeling lightheaded: 19% of patients reported a significant impact.
- Peripheral neuropathy (numbness, tingling, and pain in the nerves in the hands and feet): 14.3% of patients reported a significant impact.
- Pain: 14.3% of patients experienced a significant impact.

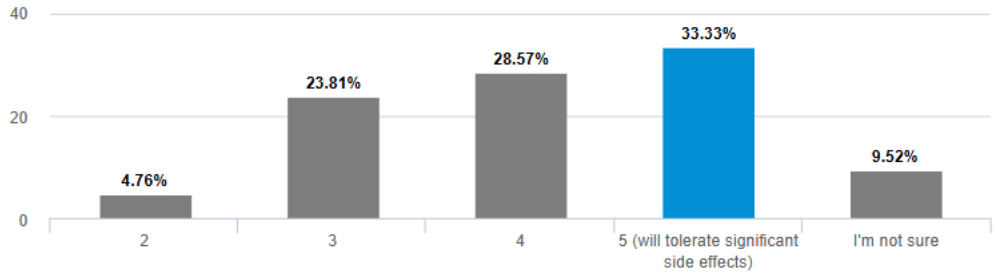
Please see Appendix 2 for a heat map displaying a full list on the severity of side effects for patient respondents.

Caregiver respondents indicated the following side effects were the most impactful for the patient:

- Fatigue or low energy: All caregivers reported a significant impact
- Changes in libido, sexual function or fertility: All caregivers reported a significant impact.
- For Pain, loss of muscle mass/weakness, hot flushes, and fluid retention: One reported a moderate impact and two reported a significant impact.

However, when patients were asked **"On a scale of 1 (will not tolerate side effects at all) to 5 (will tolerate significant side effects), how willing would you be to tolerate new side effects from therapies if they could offer better control of disease progression?"** over 30% of respondents indicated they would be willing to tolerate a significant side effect profile if it meant better disease control, and an additional 28.57% selected option 4, leaning towards accepting a moderate-high level of side effects. This tells us that many in this group are highly motivated to extend survival, despite potential side effects.

Figure 7



In addition to the data above, the three caregiver respondents selected options one (will not tolerate any side effects), four and five (will tolerate significant side effects), with the small majority leaning towards tolerating more side effects in exchange for better control of disease progression.

Given that in the TALAPRO-2 trial, talazoparib and enzalutamide extended overall survival without introducing additional or more severe side effects than standard therapies, this drug combination aligns with patient values on the desire for a longer overall survival without the need to sacrifice quality of life more than the current standard of care.

However, it is important to note that according to the plain language summary of the TALAPRO-2 trial, the combination did have some common side effects, including low levels of red blood cells (66% of patients), neutrophils (36% of patients), and excessive tiredness or exhaustion (34% of patients). Despite these side effects, the overall benefit in terms of extended survival aligns well with patient values on maintaining quality of life while achieving better disease control.

4. Improved Outcomes

When asked "**What improvements would you like to see in new treatments that are not achieved in currently available treatments? For example: effectiveness for relieving certain symptoms or side effects, affordability, ease of use etc.**" respondents expressed a strong desire for more effective treatments that better control the disease and have longer-lasting effects. There is also a significant focus on stopping the progression of cancer into the bones and countering rising PSA levels. Many respondents are seeking treatments that have fewer or less severe side effects. One respondent highlighted the need for "means to mitigate side effects, such as night sweats." In addition, convenient treatment regimens were also valued.

Accessibility and affordability of treatments are also critical issues. One respondent pointed out the non-availability of PSMA PET scanners in Alberta, while another stressed the importance of affordability. Follow-up and support are crucial for patients, with respondents calling for better follow-up over long-term issues caused by radiation and more information about these side effects. One respondent mentioned the need for access to clinicians knowledgeable in prostate cancer for mental health support. Additionally, there is a call for improved follow-up and assessment, as well as access to pain clinics for pain relief.

These insights indicate that the respondents' needs and preferences align well with the benefits offered by talazoparib and enzalutamide, particularly in terms of effectiveness, convenience, accessibility and ease of use.

Talazoparib and enzalutamide, when used together in the TALAPRO-2 trial for metastatic castration-resistant prostate cancer (mCRPC), offer a steroid-sparing treatment option. This means that patients do not need to take corticosteroids as part of their treatment regimen, which can be beneficial in reducing the side effects associated with long-term steroid use, such as weight gain, osteoporosis, and increased risk of infections. In addition, a steroid-sparing regimen can simplify the treatment plan, reducing the number of pills required per day. A comparison of similar treatment regimens for mCRPC with HHR gene mutations can be viewed in Table 1. In addition to this combination being steroid sparing, it also allows for a more flexible administration and can be taken with or without food.

Table 1

	Olaparib + Abiraterone	Niraparib + Abiraterone	Talazoparib + Enzalutamide
Indication	1st line mCRPC for BRCA1/2 mutations	1st line mCRPC for BRCA1/2 mutations	1st line HRRm mCRPC
Dose	1) Olaparib 600 mg (taken as two 150 mg tablets twice daily) 2) Abiraterone 1000 mg once daily (available as 250 or 500 mg strength)	1) 200 mg niraparib and 1000 mg abiraterone (two 100 mg/500 mg) tablets taken as a single daily dose	1) Talazoparib 0.5 mg (taken as two 0.25 mg capsules) once daily 2) Enzalutamide 160 mg (available in 40 mg strength) once daily
With/without food	With or without food	Empty stomach	With or without food
Steroid requirement	Prednisone or prednisolone 5 mg orally twice daily	Prednisone or prednisolone 10 mg daily	N/A

Based on the final overall survival analysis for Cohort 2 presented at ASCO GU (Feb 2025), TALAPRO-2 is the first PARPi and ARPI to show a statistically significant overall survival (OS) benefit vs standard of care ARPI in patients with HRR gene alterations (including BRCA). It demonstrated the longest median OS for HRRm mCRPC (45.8 months vs 37 months in comparator arm). Longer overall survival was a highly desired improved outcome according to patients. In addition, even those without an HHR deficiency showed a trend towards OS improvement.

5. Experience With Drug Under Review

We did not collect data from patients with drug experience, as phase three clinical trials (TALAPRO-2) began in 2018. By this point, it was not possible to locate patients whose disease had not progressed and who were able to participate in an interview.

6. Companion Diagnostic Test

Talazoparib, when used in combination with enzalutamide for the treatment of metastatic castration-resistant prostate cancer (mCRPC), requires a companion diagnostic genetic test. This test is essential for identifying patients with specific genetic mutations in homologous recombination repair (HRR) genes, making this combination therapy suitable for patients with HRR gene-mutated mCRPC.

It is important to note that other drugs targeting HRR gene-mutated mCRPC are typically indicated only for patients with BRCA1 and BRCA2 mutations. In contrast, the talazoparib and enzalutamide combination is unique it's broader indication, encompassing a wider array of HRR gene mutations. This broader indication benefits patients by providing more individuals with access to targeted therapy, potentially improving treatment outcomes and offering a personalized approach to managing their cancer.

According to a study published in the National Center for Biotechnology Information (NCBI), nearly 12% of men with advanced prostate cancer have inherited mutations in genes involved in homologous recombination repair (HRR), such as BRCA2, ATM, and CHEK2. The implementation of genetic testing for homologous recombination repair (HRR) gene mutations across Canadian provinces faces several challenges, particularly regarding coverage by the healthcare system. While most provinces have access to publicly-funded genetic testing programs, the availability and scope of these tests can vary significantly. This inconsistency can impact the timely and equitable access to essential genetic testing required for identifying patients eligible for targeted therapies like the talazoparib and enzalutamide combination. Without uniform access to comprehensive genetic testing, patients in certain regions may face delays or barriers in receiving appropriate treatment, potentially affecting their outcomes. Addressing these disparities is crucial for ensuring that all patients, regardless of their location, can benefit from advanced cancer therapies that rely on precise genetic profiling. A recent publication titled *"Toward Timely and Equitable Advanced Biomarker Testing for Patients with Metastatic Cancer in Canada"* by Servidio-Italiano et al (2025), further highlights these barriers in the Canadian system. This publication suggests that broader access to genetic testing and targeted therapies has the potential to improve the quality of cancer care while reducing costs. It highlights that laboratory testing, including biomarker testing, represents a small proportion of total cancer care costs, and that precision medicine can lead to more effective treatments, thereby potentially reducing overall healthcare expenditures.

The Canadian Urological Association (CUA) recently released comprehensive guidelines on genetic testing for prostate cancer. These guidelines emphasize the importance of genetic testing as a standard of care. According to recommendation eight, "The minimum set of genes for genomic profiling of the tumor in patients with PCa who meet criteria for tumor testing should include BRCA1, BRCA2, and ATM; however, tumor testing panels should be aligned with germline testing panels as much as possible and ideally would also include CHEK2, EPCAM (large deletions), HOXB13, MLH1, MSH2, MSH6, PALB2, PMS2, TP53, and RAD51D. CDK12 may also be included for prognostic purposes. Additional genes may be included for research purposes, prognostic purposes, or inclusion of patients in clinical trials." Limitations and disparities in accesses to genetic testing should be addressed to ensure patients can access talazoparib and enzalutamide for mCRPC with an HHR gene mutation.

Anything Else?

Currently, there are significant gaps in the treatment of metastatic castration-resistant prostate cancer (mCRPC) with homologous recombination repair (HRR) gene mutations. Existing therapies often fail to provide adequate disease control and come with significant side effects that negatively impact patients' quality of life.

Unmet needs in mCRPC treatment talazoparib and enzalutamide may help address:

1. **Limited Efficacy:** Many current treatments have limited efficacy for mCRPC with HHR gene mutations outside of BRCA 1 and 2 in slowing disease progression, leading to a continuous decline in patients' health and well-being.
2. **Significant Side Effects:** Treatments often cause several side effects, including ones from the use of added steroids impacting patients' daily lives and mental health.
3. **Lack of Personalized Treatment:** Current therapies do not adequately address the genetic diversity of mCRPC, leaving many patients without effective, targeted treatment options.

How talazoparib and enzalutamide address these needs:

- **Improved Efficacy for Patients with HHR:** The combination of talazoparib and enzalutamide has shown to significantly extend overall survival in patients with HRR gene-mutated mCRPC, offering an effective treatment option. The TALAPRO-2 trial demonstrated a statistically significant overall survival benefit, making it the first PARPi and ARPI combination to achieve this milestone.
- **No Side Effects from Steroids:** This combination therapy avoids the need for corticosteroids, reducing the risk of exacerbating side effects identified as significant to several patients in the survey such as fatigue, hot flushes, reduced muscle mass and fluid retention.
- **Broader Indication:** Unlike other treatments that are limited to BRCA 1 and 2 mutations, talazoparib and enzalutamide target a wider range of HRR gene mutations, providing more patients with access to a targeted treatment approach.

Survey responses suggest that talazoparib and enzalutamide for patients with HRR gene mutations would address several unmet needs experienced by this population. This combination aligns with patient values by increasing overall survival without adding to the number of side effects. Additionally, the treatment's availability for home administration avoids added travel costs associated with in-hospital treatments.

Appendix: Patient Group Conflict of Interest Declaration

To maintain the objectivity and credibility of the 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. CDA-AMC may contact your group with further questions, as needed.

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

No

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

No

3. List any companies or organizations that have provided your group with financial payment over the past two years AND who may have direct or indirect interest in the drug under review.

Company	Check Appropriate Dollar Range			
	$0 to 5,000	$5,001 to 10,000	$10,001 to 50,000	In Excess of $50,000
Pfizer				X
Astellas	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: Sasha Frost
Position: Public Engagement Project Manager
Patient Group: Canadian Cancer Society
Date: March 25, 2025

Appendix 1 – Disease Impact

Statement	No impact	Small impact	Moderate impact	Significant impact	I'm not sure	Not applicable	Overall
	6	4	4	8	0	2	24
Ability to work	25%	17%	17%	33%	0%	8%	
	11	2	4	6	1	0	24
Ability to travel	46%	8%	17%	25%	4%	0%	
	8	5	7	4	0	0	24
Ability to exercise	33%	21%	29%	17%	0%	0%	
	10	5	5	3	1	0	24
Ability to conduct household chores	42%	21%	21%	13%	4%	0%	
	11	6	0	5	1	1	24
Ability to fulfill family obligations	46%	25%	0%	21%	4%	4%	
	14	4	3	3	0	0	24
Ability to spend time with family and friends	58%	17%	13%	13%	0%	0%	
	12	1	5	5	1	0	24
Ability to concentrate	50%	4%	21%	21%	4%	0%	
	17	2	3	2	0	0	24
Ability to fulfill practical needs (dressing, bathing, preparing meals)	71%	8%	13%	8%	0%	0%	
	9	3	4	7	1	0	24
Ability to maintain positive mental health	38%	13%	17%	29%	4%	0%	
	2	1	1	15	2	3	24
Engage in sexual activity	8%	4%	4%	63%	8%	13%	

Appendix 2 – Side Effects

Statement	No impact	Small impact	Moderate impact	Significant impact	I'm not sure	Not applicabl
Loss of bone density or osteoporosis	5 23.81%	10 47.62%	2 9.52%	0 0%	4 19.05%	0 0%
Breast swelling and/or discharge	10 47.62%	5 23.81%	2 9.52%	0 0%	0 0%	4 19.05%
Loss of muscle mass or muscle weakness	3 14.29%	7 33.33%	7 33.33%	3 14.29%	1 4.76%	0 0%
Abnormal electrolytes (Low blood potassium levels)	12 57.14%	2 9.52%	0 0%	2 9.52%	4 19.05%	1 4.76%
Hot flushes	1 4.76%	6 28.57%	9 42.86%	4 19.05%	1 4.76%	0 0%
Fluid retention (e.g. swollen legs)	10 47.62%	5 23.81%	4 19.05%	0 0%	1 4.76%	1 4.76%
Changes in blood sugar levels or diabetes	13 61.9%	1 4.76%	3 14.29%	1 4.76%	1 4.76%	2 9.52%
Fatigue or low energy	4 19.05%	5 23.81%	4 19.05%	6 28.57%	2 9.52%	0 0%
Hair loss	12 57.14%	6 28.57%	2 9.52%	1 4.76%	0 0%	0 0%
Anemia (easy bruising and bleeding)	11 52.38%	4 19.05%	3 14.29%	1 4.76%	2 9.52%	0 0%
Issues with memory or concentration	9 42.86%	6 28.57%	2 9.52%	3 14.29%	1 4.76%	0 0%
Increase in cholesterol levels	9 42.86%	6 28.57%	3 14.29%	1 4.76%	1 4.76%	1 4.76%
Frequent infections (low white blood cell counts)	14 66.67%	3 14.29%	1 4.76%	0 0%	2 9.52%	1 4.76%
Nausea and/or vomiting	18 85.71%	1 4.76%	1 4.76%	1 4.76%	0 0%	0 0%
Appetite changes	13 61.9%	4 19.05%	2 9.52%	2 9.52%	0 0%	0 0%
Bowel problems (constipation or diarrhea)	8 38.1%	5 23.81%	5 23.81%	3 14.29%	0 0%	0 0%
Peripheral neuropathy (numbness, tingling and pain in the nerves in the hands and feet)	7 33.33%	5 23.81%	4 19.05%	3 14.29%	2 9.52%	0 0%
Kidney problems	16 76.19%	2 9.52%	0 0%	1 4.76%	2 9.52%	0 0%
Weight changes	7 33.33%	4 19.05%	6 28.57%	3 14.29%	1 4.76%	0 0%
Changes in libido, sexual function or fertility	3 14.29%	2 9.52%	0 0%	13 61.9%	0 0%	3 14.29%
Pain	7 33.33%	7 33.33%	3 14.29%	3 14.29%	1 4.76%	0 0%
Mouth, tongue, and throat problems such as sores and pain with swallowing	17 80.95%	3 14.29%	0 0%	0 0%	1 4.76%	0 0%
Blood pressure changes	11 52.38%	6 28.57%	1 4.76%	1 4.76%	2 9.52%	0 0%
Irregular heartbeats (palpitations) or chest pain	13 61.9%	5 23.81%	1 4.76%	1 4.76%	1 4.76%	0 0%
Slow breathing or difficulty breathing	10 47.62%	4 19.05%	4 19.05%	2 9.52%	1 4.76%	0 0%
Difficulties with urination (Incontinence, frequent or urgent need for urination, painful urination)	6 28.57%	8 38.1%	3 14.29%	3 14.29%	1 4.76%	0 0%
Headaches or pounding in the neck or ears	13 61.9%	4 19.05%	2 9.52%	1 4.76%	1 4.76%	0 0%
Blurred vision	13 61.9%	3 14.29%	3 14.29%	1 4.76%	1 4.76%	0 0%
Liver problems or abnormal liver function tests	15 71.43%	1 4.76%	1 4.76%	0 0%	4 19.05%	0 0%
Dizziness or feeling lightheaded	7 33.33%	6 28.57%	3 14.29%	4 19.05%	1 4.76%	0 0%
Dry mouth	9 42.86%	3 14.29%	6 28.57%	2 9.52%	1 4.76%	0 0%

CADTH

Patient Input Template for CADTH Reimbursement Reviews

Name of Drug: TALZENA (Talazoparib)
Indication: Talazoparib (Talzenna) in combination with enzalutamide (Xtandy) for the treatment of adults with metastatic castration-resistant prostate cancer (mCRPC) with HRR gene alterations.
Name of Patient Group: PROCURE – CANCER PROSTATE
Author of Submission: Marie-Christine Beauchemin

1. About Your Patient Group

PROCURE Website

Founded in 2003, PROCURE is a charitable organization in the fight against prostate cancer. It educates, supports, and informs people affected by this disease. It promotes and contributes to the financing of world-class research.

In Canada, we are recognized by both the CUA and the AUQ as the leading authority on prostate cancer.

Our services include: Our full range of free support and information services aims to help people affected by prostate cancer and their loved ones. We offer quick access to healthcare professionals specialized in uro-oncology, available 7 days a week via a toll-free support line, as well as comprehensive information tools and a variety of resources to help individuals affected by prostate cancer—including caregivers, employers, the public, and healthcare professionals—better understand the disease and treatment options.

We raise awareness: We organize a variety of events throughout the year to raise awareness about prostate cancer. The funds we raise during these activities allow us to pursue our mission to help people affected by this disease and to fund world-class research projects.

We advance research: We are fully committed to prostate cancer research, and we play an essential role in its advancement by providing biospecimens and data of high scientific value from our PROCURE Biobank. We are doing everything we can to better understand this disease, diagnose it earlier and treat it in a targeted and precise manner.

2. Information Gathering

External information with references below in this document.

Results of the Phase 3 TALAPRO-2 clinical trial

- FDA approval of the Talzenna/Xtandi combination in June 2023
- European Commission approval of the Talzenna/Xtandi combination in January 2024*
- Positive reimbursement recommendation by HAS in March 2024*

*Treatment indication less restrictive than in North America

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Internal information for PROCURE

Analysis of patient calls to our specialized uro-oncology healthcare professionals via our toll-free line.

- Cohort of over 3,500 patients with localized, locally advanced, metastatic, recurrent, hormone-sensitive, or castration-resistant prostate cancer, with or without metastases.
- In addition to distress and treatment decisions, rising PSA levels after treatment, recurrence, hormone therapy and its side effects, as well as metastases are among the main concerns of patients who contact us. For these types of calls, more than 60 minutes are generally required, along with periodic follow-ups.
- In 2024, 17% of our interventions were related to advanced prostate cancer, and another third of patients initially treated for prostate cancer reached out to us due to a recurrence of their disease.

PROCURE's surveys

In May 2022, in collaboration with the Leger firm, PROCURE conducted an online Canadian survey on the quality of life of our patients treated for prostate cancer, in which 263 patients participated. According to this survey, the main challenges posed by treatment for 50% of respondents included managing side effects, living with uncertainty, and maintaining a positive attitude.

In March 2018, PROCURE conducted an online Quebec survey on the needs of our patients treated for a recurrence or advanced prostate cancer. In response to the question, "What do you hope for from future treatments for prostate cancer?"

- Slows down the progression of cancer: 95%
- Extends life expectancy: 94%
- Improves the quality of life: 98%
- Helps manage or diminish side effects: 93%
- Decreases PSA levels: 91%

3. Disease Experience

Prostate cancer presents in various forms, ranging from low-risk to highly aggressive stages. As a complex disease, it affects both patients and their loved ones. Prostate cancer is initially considered a disease with a favorable prognosis. However, once it reaches the metastatic stage, its prognosis worsens, with an overall 5-year survival rate of only 30%.

Metastatic castration-resistant prostate cancer (mCRPC) is a form of the disease that has spread beyond the prostate gland and continues to progress despite treatment aimed at lowering testosterone levels. The most common metastatic sites are the bones, followed by the lungs and liver. Approximately 10% to 20% of prostate cancer patients will progress to mCRPC within 5 to 7 years of diagnosis. [https://doi.org/10.1111/j.1742-1241.2011.02799.x]

HRR* gene mutations are present in approximately 25% of mCRPC patients and are associated with a more aggressive form of the disease, poorer outcomes, and shorter survival. (See references in this press release: [https://www.pfizer.com/news/press-release/press-release-detail/pfizers-talzennar-combination-xtandir-receives-us-fda])

**ATM, ATR, BRCA1, BRCA2, CDK12, CHEK2, FANCA, MLH1, MRE11A, NBN, PALB2, or RAD51C*

The impact of prostate cancer treatments in general

Physical impact: Side effects are a significant burden, including incontinence, erectile dysfunction, bowel issues, hormone therapy effects (hot flashes, loss of libido, weight gain, cardiovascular risks, osteoporosis, etc.), and pain related to metastases.

Psychological impact: Anxiety, depression, and loss of self-confidence are common, worsened by diagnosis, recurrence, or cancer progression. Physical and mental fatigue limits activities and complicates relationships, especially for men living alone.

Recurrence: The fear of cancer returning causes stress and uncertainty, affecting sleep, appetite, and concentration. Our nurses emphasize the importance of emotional support in addition to medical care.

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Quality of life: Access to healthcare professionals (sexologists, psychologists, physiotherapists, kinesiologists) is often limited due to cost, lack of available services, or long wait times, leaving many patients without adequate support.

Partners and Family: The emotional and genetic Impact

Partners often become caregivers, sometimes unintentionally. This role is demanding and comes with stress, anxiety, and depression. They also frequently have to grieve the loss of a fulfilling sexual relationship. Similarly, intimate relationships are affected—loss of libido, fatigue, and changes in masculine characteristics often lead men to avoid intimacy with their partners, resulting in significant consequences.

Advanced cancer creates anxiety within couples, as they face uncertainty about how much time they have left together while also managing treatment side effects. On a family level, children are at lifelong risk. If the cancer is aggressive and fatal, they may have to experience the loss of their father at a young age.

If a father carries a genetic mutation and has prostate cancer, both sons and daughters are at an increased risk of developing certain cancers, such as prostate, breast, and ovarian cancer, if they inherit the altered gene.

This is why genetic evaluation and regular medical follow-up are essential to detect and treat any signs of the disease early. Appropriate preventive measures can also be considered based on each child's individual risk.

In addition, children may experience anxiety due to the family history and concerns about their own risk of developing cancer.

4. Experiences With Currently Available Treatments

Patient perception - Patients often struggle to understand when their specialist tells them, "If I had to choose a cancer, prostate cancer would be at the top of my list." This statement downplays the complexity of the disease, especially when it has spread beyond the prostate capsule. The situation becomes even more challenging when it reaches the metastatic stage, making treatment more difficult. While current treatments are often effective, they eventually face resistance over time, limiting their long-term benefits.

Impact of treatments - Standard treatments for metastatic cancer, such as hormone therapy and chemotherapy, are systemic and non-targeted, exposing the entire body to often severe side effects. Therapeutic options targeting genetic mutations in prostate cancer remain limited to the BRCA gene and are only available when this mutation is confirmed through tumor biopsy or genetic testing. This restriction reduces treatment alternatives for many patients, highlighting the need for new therapeutic approaches.

Major concerns - Standard hormone therapy causes significant side effects that are difficult to manage, especially when taken long-term. The worsening of these effects when changing or adding treatments raises concerns about their effectiveness. Additionally, metastases are a major source of anxiety, as patients face both emotional and practical concerns, including treatment efficacy, cancer progression, long-term health impact, and overall life expectancy.

5. Improved Outcomes

Given that patients do not all respond the same way to treatments, including new drugs or combination treatments, we believe it is important for patients and specialists to have access to all new agents and new indications that have demonstrated their effectiveness with minimal side effects, while maintaining stable PSA levels and a good quality of life.

Metastases are a very worrisome aspect for men.
Based on our surveys, the patients' expectations with regards to new treatments are as follow:

- Stabilize/control their cancer
- Delay the onset or eliminate metastases
- Decrease or keep their PSA levels stable over a long period (a source of anxiety)
- Prolong their life and quality of life
- Be heard and taken seriously

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6. Experience With Drug Under Review

We did not have access to the patients who participated in the TALAPRO-2 clinical trial for this assessment. However, we have reviewed publicly available positions to formulate our own standpoint.

Our conclusion

The treatment of metastatic prostate cancer remains a challenge, particularly for patients with HRR gene alterations. However, the combination of Talzenna and Xtandi represents a new targeted therapeutic option that could significantly reduce the risk of disease progression while improving patient survival and quality of life.

There are **two distinct indications for this therapy**, depending on its use in **North America** versus **Europe**. The European indication, which is broader, allows the use of this combination in mCRPC patients, with or without a genetic mutation, when chemotherapy is not clinically indicated. In contrast, in the United States and Canada, the approach remains more conservative, restricting the use of this treatment to patients with HRR gene alterations. However, the results of the Phase 3 TALAPRO-2 clinical trial have demonstrated the effectiveness of this therapy beyond patients with HRR mutations, highlighting **its potential** for a broader range of patients.

In the long run, this combination could be approved in Canada as a first-line treatment with an expanded indication, allowing mCRPC patients, with or without a genetic mutation, to access an effective therapeutic option.

That being said, we believe it is essential that patients who meet the indication criteria **can access this therapy without delay** and that specialists have the necessary information to make informed decisions about the most appropriate treatments for each case.

ARGUMENTATION

Benefits of Talzenna in combination for prostate cancer
The results of the TALAPRO-2 study demonstrated that the combination of Talzenna and Xtandi is the first and only combination of a PARP inhibitor with a second-generation hormone therapy (ARPI) to significantly improve survival in patients with metastatic castration-resistant prostate cancer (mCRPC).

This combination is approved:

- In **the United States**, for patients with **HRR gene alterations**. (https://www.pfizer.com/news/press-release/press-release-detail/pfizers-Talzennar-combination-Xtandyr-receives-us-fda)
- By the **European Commission**, for patients with **mCRPC**, with or without a genetic mutation, when chemotherapy is not clinically indicated. (https://www.pfizer.com/news/press-release/press-release-detail/european-commission-approves-pfizers-Talzennar-combination)

Talzenna has also shown effectiveness in prolonging the duration during which patients live without disease progression.

Regarding reimbursement, the Talzenna/Xtandi combination for the treatment of adult patients with mCRPC, for whom chemotherapy is not clinically indicated, **received a favorable reimbursement opinion** from the Haute Autorité de Santé (HAS) in March 2024. (https://www.has-sante.fr/jcms/p_3512093/fr/talzenna-talazoparib-cancer-de-la-prostate#toc_1_1_2)

About TALAPRO-2
The TALAPRO-2 phase 3 clinical trial is a multicenter, randomized, double-blind, placebo-controlled study that enrolled 1,035 unique patients with metastatic castration-resistant prostate cancer (mCRPC). These patients had not received new systemic treatments to prolong survival after confirmation of mCRPC. The trial was conducted at multiple centers in the United States, Canada, Europe, South America, and the Asia-Pacific region.

The study included two patient cohorts:

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- All-comers cohort: n=805, including 169 patients with mutations in HRR genes and 636 without mutations.
- HRR gene mutation cohort: n=399, including 169 patients from Cohort 1 and 230 patients recruited in Cohort 2.

Patients with castrate testosterone levels were randomized to receive either Talzenna 0.5 mg/day + Xtandi 160 mg/day or a placebo + Xtandi 160 mg/day. (https://www.pfizer.com/news/press-release/press-release-detail/pfizers-Talzennar-combination-Xtandyr-prolongs-overall)

Results from cohorts
In support of the approval of the Talzenna + Xtandi combination by Health Canada for patients with HRR gene mutations:

In the study of patients with mCRPC and HRR gene mutations (n=399), the primary objective was to evaluate progression-free survival (PFS). The risk of **cancer progression was reduced by 55%** in patients receiving Talzenna + Xtandi compared to those receiving placebo + Xtandi. (https://TalzennaXtandy.pfizerpro.com/)

Cancer progression occurred in 66 of 200 men (33%) receiving Talzenna + Xtandi, compared to 104 of 199 men (52.3%) receiving placebo + Xtandi. Progression was defined as cancer worsening, measured by imaging exams, or patient death, regardless of cause. (https://www.TalzennaXtandy.com/how-treatment-may-help)

In the all-comers cohort study, which included 805 adults with castration-resistant prostate cancer with metastases and who had not received chemotherapy, disease progression, visible on imaging exams, occurred after approximately 21.9 months in patients who received the placebo.

However, for patients receiving Talzenna, this time point could not be calculated, as after approximately 28 months of follow-up, an insufficient number of patients had experienced disease progression.
(https://www.ema.europa.eu/en/medicines/human/EPAR/Talzenna#assessment-history)
Patients also observed a reduced likelihood of needing chemotherapy, which is another indicator of slowed disease progression.

Side effects
The side effects of Talzenna were generally acceptable and could be managed, when necessary, with dose adjustments or standard supportive medical treatment.

Most adverse effects were similar to those observed when the active substances were used individually, and the other side effects were generally well-controlled.

October 2024 - A breakthrough with this combination
According to a press release from Pfizer, at the time of the final analysis, the clinically significant improvement in radiographic progression-free survival (rPFS) was maintained in both cohorts, as indicated in the previously reported and published primary analysis in The Lancet.

Furthermore, the safety profile of Talzenna + Xtandi was generally consistent with the known safety profiles of each drug. (https://www.pfizer.com/news/press-release/press-release-detail/pfizers-Talzennar-combination-Xtandyr-prolongs-overall)

These results are encouraging for a first-line treatment, as the presence of genetic alteration is not necessary to achieve a favorable therapeutic effect.

7. Companion Diagnostic Test

<Enter Response Here>

8. Anything Else?

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Our five clinical benefits takeaway from this new combination therapy:

- Better control over mCRPC with HRR gene alterations
- A new first-line treatment option for mCRPC
- A significant reduction in the risk of progression of this cancer
- A significant reduction in the risk of death associated with this cancer
- Prolonged life and improved quality of life, providing hope

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
Astellas (Xtandy)				X
Pfizer (Talzena)			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: Marie-Christine Beauchemin
Position: Information and Support Consultant
Patient Group: PROCURE – CANCER PROSTATE
Date: February 28, 2025

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CADTH

CADTH Reimbursement Review
Clinician Group Input Template

Clinician Group Input

CADTH Project Number: PC0417-000
Generic Drug Name (Brand Name): Talazoparib (Talzenna) - Pfizer
Indication:
Manufacturer Requested Reimbursement Criteria[1]:
In combination with enzalutamide for the treatment of adult patients with homologous recombination repair (HRR) gene-mutated metastatic castration-resistant prostate cancer (mCRPC).

Name of Clinician Group: Ontario Health (Cancer Care Ontario) Genitourinary Cancer Drug Advisory Committee ("OH (CCO) GU DAC")
Author of Submission: Dr. Girish Kulkarni and Dr. Urban Emmenegger

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 via email.

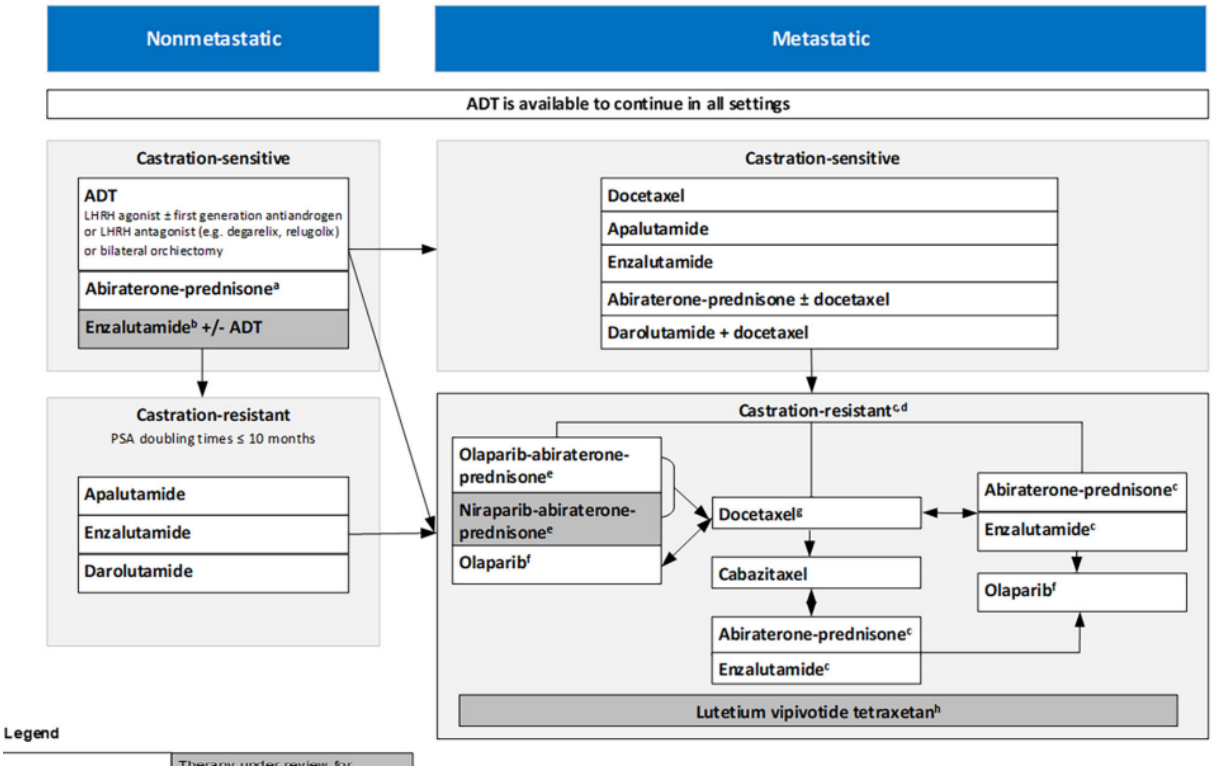
3. Current Treatments and Treatment Goals

In the mCRPC setting, therapy is aimed at prolonging life. There currently remains no cure for these patients. Treatments should also aim to maximize QOL.

The current treatment landscape options include: abiraterone OR enzalutamide OR Docetaxel OR Radium-223 (in docetaxel ineligible patients) all given concurrently with ADT.

Cabazitaxel is another option after docetaxel intensification in the mCRPC setting.

Similarly, olaparib monotherapy might be a treatment option after intensification with an androgen receptor signaling inhibitor (ARPI) for mCRPC in men with BRCA2, BRCA1 or ATM aberrations. Olaparib-abiraterone is also available (while niraparib-abiraterone is under funding consideration) for those who have not intensified with ARPI in the metastatic castration sensitive (mCSPC) setting or non-metastatic castration-resistant (nmCRPC) setting.



[a] Abiraterone-prednisone should be reimbursed in patients with very high-risk nmPC, per the initiation criteria, which are as follows: node positive or node negative with 2 of the following: clinical tumour stage T3 or T4, Gleason sum score 8 to 10, PSA greater than or equal to 40 ng/mL. Abiraterone-prednisone should not be reimbursed in combination with enzalutamide. A relapse of 6 months or longer from the completion of abiraterone is an appropriate interval for re-treatment.

[b] Enzalutamide should be reimbursed in patients with nmCSPC with biochemical recurrence at high risk of metastasis after radical prostatectomy or radiation.

[c] In some provinces, ARAT or ARPI with a different mechanism of action may be available following progression on a previous ARAT or ARPI.

[d] Radium 223 is a funded option in many jurisdictions across Canada for metastatic castration-resistant prostate cancer for appropriate patients.

[e] For those with somatic or germline *BRCA* mutations who have not received a prior ARPI (in the mCSPC or nmCRPC setting), prior systemic therapy for mCRPC (except for < 4 months of abiraterone acetate with prednisone for mCRPC), or a prior PARP inhibitor.

[f] For somatic or germline *BRCA* or *ATM* mutations, if not received previously and if there is disease progression following an ARAT.

[g] Subsequent docetaxel is available if progression is longer than 3 months after prior docetaxel; otherwise, cabazitaxel should be offered.

[h] Treatment should be initiated in those who are PSMA positive (per the criteria in the VISION trial) and who were previously treated with an ARPI and at least 1 prior taxane-containing regimen.

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.

As there are no cures currently available in the 1L mCRPC setting, therapies that can prolong life are needed. Talazoparib with enzalutamide adds to a current SOC therapy (enzalutamide) with improved OS in HRR mutated and non-mutated mCRPC patients and thus addresses the goal of prolonged life. Moreover, combining talazoparib with enzalutamide provides a clinically meaningful OS benefit in patients with HRR defects, which includes BRCA1, BRCA2, and ATM, but also additionally: ATR, CDK12, CHEK2, FANCA, NBN, MLH1, MRE11A, PALB2, RAD51C.

5. Place in Therapy

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

As per the trial, in treatment naïve mCRPC patients, talazoparib and enzalutamide would become a standard of care.

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?

The combination of talazoparib and enzalutamide should be reserved for patients in the mCRPC setting. As per the TALAPRO-2 trial, treatment with chemotherapy or ARPI in the mCSPC setting should not preclude talazoparib and enzalutamide in the 1L mCRPC setting. However, patients treated with ARPI in the nmCRPC setting were excluded from the TALAPRO 2 trial.

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?

PSA will be used as a burden of disease marker and to monitor response to therapy. Serial radiographic imaging will also be used for response assessment and to determine progression as per standard of care. Other markers of disease burden can also be used such as LDH and ALP in select individuals.

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

Significant side effects and progression of disease on imaging.

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]?

Currently medical oncologists primarily have been prescribing PARP inhibitors. The number of mCRPC patients is significant, so additional specialists/prescribers would be required including radiation oncologists and urologists specialized in prostate cancer care.

6. Additional Information

Access to this (and other) combinations in this setting will also require ongoing efforts to ensure equitable, timely access to genomic testing of relevant alterations for all eligible Canadian men with prostate cancer.

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.

   Yes, OH (CCO) PDRP 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. Girish Kulkarni
Position: Lead, OH (CCO) GU DAC
Date: 4-April-2025

☒ **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: Dr. Urban Emmenegger
Position: Member, OH (CCO) GU DAC
Date: 31-March-2025

☒ 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
Pfizer	x			
Astellas		x		
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

	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.