Drug Access Listing: Advanced Prostate Cancer

Oral agents and Outpatient Injections

Click on province or patient assistance programs.

The information in this document is intended for healthcare professionals experienced in the treatment of prostate cancer.

The drug funding descriptions found within are based on information acquired from pharmaceutical manufacturers and internet resources. Please report any gaps, outdated information, or inaccuracies to the CUA so that appropriate revisions can be made with future updates.

ADT, androgen deprivation therapy; ALT, alanine transaminase; ARAT, androgen receptor – axis targeted therapy; ARI, androgen receptor inhibitor (second-generation); AST, aspartate transaminase; CAROC, Canadian Association of Radiologists and Osteoporosis Canada; CRPC, castration-resistance prostate cancer; ECOG PS, Eastern Cooperative Oncology Group Performance Status; FRAX, World Health Organization's Fracture Risk Assessment; HRR, homologous recombination repair; LVEF, left ventricular ejection fraction; mCRPC, metastatic castration-resistance prostate cancer; nmCRPC, non-metastatic castration-resistance prostate cancer; mCSPC, metastatic castration-sensitive prostate cancer; PSA, prostate-specific antigen; PSADT, prostate-specific antigen doubling time; SRE, skeletal related event; ULN, upper limit of normal.

Funding:
Cancer patients may receive treatment at cancer centres, their community hospitals, or taken at home.
Alberta provides cancer drugs specified in the Outpatient Cancer Drug Benefit Program, at no charge, to eligible residents for the treatment of cancer.

Formularies:
Alberta Health Drug Benefit List - https://idbl.ab.bluecross.ca/idbl/load.do
Alberta Health Services Outpatient Cancer Drug Benefit Program - https://www.albertahealthservices.ca/assets/programs/ps-1025651-drug-benefit-list.pdf

DRUG (Brand Name) Manufacturer	Indication	Strength, Route	DIN	Provincial Funding Eligibility Criteria	References
Abiraterone (Zytiga) Janssen Generic	**mCRPC**	Oral	Not specified	Group 2* **Eligibility**: • Abiraterone for the treatment of mCRPC ○ May be used following progression on or intolerance to apalutamide/enzalutamide/ darolutamide used in nmCRPC setting ○ May be used following apalutamide/enzalutamide used in mCSPC setting for patients who discontinued due to intolerance or toxicity. Not to be used in patients whose mCSPC has previously progressed on apalutamide/enzalutamide, unless they are unable tolerate, or are not candidates for other therapeutic options. Patients must not have progressed previously on abiraterone. ○ May be used after progression on docetaxel if not received before	AHS Outpatient Cancer Drug Benefit Program [3-22]
	mCSPC	Oral	Not specified	Group 2* **Eligibility**: • Abiraterone (plus prednisone) in combination with ADT for treatment of patients with mCSPC defined as: ○ No prior ADT in the metastatic setting, OR ○ Within 6 months of beginning ADT for metastatic disease, OR ○ > 1 year since prior ADT for early-stage disease with good performance status • Patients may receive only one of these agents (apalutamide, enzalutamide, or abiraterone) in this setting and switching only if intolerant (without progression)	AHS Outpatient Cancer Drug Benefit Program [3-22]
Alendronate Generic	**Osteoporosis**	70 mg PO	Multiple	Regular Benefit: No form required	Alberta Health Drug Benefit List [3-22]
Apalutamide (Erleada) Janssen	**nmCRPC**	Oral	Not specified	Group 2* **Eligibility:** • Apalutamide in combination with ADT for the treatment of patients with nmCRPC who are at high risk of developing metastases. High risk defined as: ○ PSADT ≤ 10 months, during continuous ADT/post orchiectomy • Patients may receive only one of these agents (darolutamide, apalutamide or enzalutamide) in this setting and switching only if intolerant (without progression)	AHS Outpatient Cancer Drug Benefit Program [3-22]

Apalutamide (Erleada) Janssen	**mCSPC**	Oral	Not specified	Group 2*
				
				Eligibility:
				• Apalutamide in combination with ADT for the treatment of patients with mCSPC defined as:
				  ○ No prior ADT in the metastatic setting, OR
				  ○ Within 6 months of beginning ADT for metastatic disease, OR
				  ○ > 1 year since prior ADT for early-stage disease with good performance status
				• Patients may receive only one of these agents (apalutamide, enzalutamide, or abiraterone) in this setting and switching only if intolerance, not progression
				• May follow prior docetaxel for mCSPC, if treatment has been within the last 3 months and there has been no disease progression (time limited needed)
					AHS Outpatient Cancer Drug Benefit Program [3-22]

Darolutamide (Nubeqa) Bayer	**nmCRPC**	Oral	Not specified	Group 2* **Eligibility:** • Darolutamide in combination with ADT for the treatment of patients with nmCRPC who are at high risk of developing metastases. High risk defined as: ○ PSADT ≤ 10 months during continuous ADT/post orchiectomy • Patients may receive only one of these agents (darolutamide, apalutamide or enzalutamide) in this setting and switching only if intolerant (without progression)	AHS Outpatient Cancer Drug Benefit Program [3-22]

Denosumab (Prolia) Amgen	**Osteoporosis**	60 mg / Syr Injection	02343541	Special authorization
				
				Eligibility:
				• Treatment of osteoporosis in patients who have:
				  ○ A high 10-year risk (> 20%) of experiencing a major osteoporotic fracture OR a moderate 10-year fracture risk (10-20%) and have experienced a prior fragility fracture
				• AND at least one of the following:
				  ○ Oral bisphosphonates are contraindicated due to drug-induced hypersensitivity (ie, immunologically mediated), OR
				  ○ Oral bisphosphonates are contraindicated due to an abnormality of the esophagus which delays esophageal emptying, OR
				  ○ Bisphosphonates are contraindicated due to severe renal impairment (i.e. creatinine clearance < 35 mL/min), OR
				  ○ Demonstrated persistent severe gastrointestinal intolerance to a course of therapy with either alendronate or risedronate, OR
				  ○ Had an unsatisfactory response (defined as a fragility fracture despite adhering to oral alendronate or risedronate treatment fully for 1 year and evidence of a decline in BMD below pre-treatment baseline level).
					Alberta Health Drug Benefit List [3-22]

Denosumab (Xgeva) Amgen	**mCRPC with Bone mets**	120 mg / Vial Injection	02368153	Not a benefit	Alberta Health Drug Benefit List [3-22]

Enzalutamide (Xtandi) Astellas	**mCRPC**	Oral	Not specified	Group 2* **Eligibility:** • Enzalutamide for the treatment of mCRPC • May not be used following apalutamide, enzalutamide, or darolutamide use in nmCRPC setting unless discontinuation due to intolerance (without progression) • May not be used following apalutamide or enzalutamide use in mCSPC setting unless discontinuation due to intolerance (without progression) • May be used after progression on docetaxel if not received before	AHS Outpatient Cancer Drug Benefit Program [3-22]
	nmCRPC	Oral	Not specified	Group 2* **Eligibility:** • Enzalutamide in combination with ADT for the treatment of nmCRPC who are at high risk of developing metastases. High risk defined as: ○ PSADT ≤ 10 months during continuous ADT/post orchiectomy • Patients may receive only one of these agents (darolutamide, apalutamide or enzalutamide) in this setting and switching only if intolerant (without progression)	AHS Outpatient Cancer Drug Benefit Program [3-22]

	mCSPC	Oral	Not specified	Group 2*
				
				Eligibility:
				• Enzalutamide in combination with ADT for the treatment of patients with mCSPC defined as:
				  ○ No prior ADT in the metastatic setting, OR
				  ○ Within 6 months of beginning ADT, OR
				  ○ > 1 year since prior ADT for early-stage disease with good performance status
				• Patients may receive only one of these agents (apalutamide, enzalutamide, or abiraterone) in this setting and switching only if intolerant (without progression)
				• May follow prior docetaxel for mCSPC provided treatment has been within the last 3 months and there has been no disease progression (time limited need)
					AHS Outpatient Cancer Drug Benefit Program [3-22]

Olaparib (Lynparza) AstraZeneca	**mCRPC**	Oral	Not specified	Group 2* **Eligibility:** • Olaparib monotherapy for mCRPC and deleterious or suspected deleterious germline and/or somatic mutations in the HRR genes BRCA1/2 or ATM who have progressed following prior treatment with ARAT • May be offered to patients who are unable to tolerate an ARAT • Patients who have received prior taxane-based chemotherapy are eligible	AHS Outpatient Cancer Drug Benefit Program [3-22]

*Cancer Drugs in group 2 of the Schedule may be dispensed by a Cancer Pharmacy only if the initial prescription is written by a Cancer Centre Medical Staff member, but a subsequent prescription for the same patient may be written by a person authorized by Alberta Health Services to prescribe Cancer Drugs and who is a physician, a regulated member under the Health Professions Act authorized to prescribe drugs, or a person authorized to prescribe drugs pursuant to another enactment.

Funding:
Medications for active cancer treatment are funded by BC Cancer for all BC Medical Services Plan patients (including First Nations Health Authority clients). These medications are supplied at no charge to registered BC cancer patients at BC Cancer Centres and Clinics.
Patients may also have private drug plans that cover some or all of medication costs.

Formularies:
BC Pharmacare Formulary - https://pharmacareformularysearch.gov.bc.ca/
BC Cancer Benefit Drug List - http://www.bccancer.bc.ca/systemic-therapy-site/Documents/Policy%20and%20Forms/Benefit%20Drug%20List.pdf

DRUG (Brand Name) Manufacturer	Indication	Strength, Route	DIN	Provincial Funding Eligibility Criteria	References

Abiraterone (Zytiga) Janssen Generic	**mCRPC**	Tablet	Not specified	A BC Cancer Compassionate Access Program request must be approved prior to treatment.[1] Restricted funding*[2]
				Eligibility (Abiraterone + Prednisone)[1]:
				• Patients with mCRPC who are chemotherapy-naïve OR have received prior chemotherapy containing docetaxel
				  ○ ECOG PS 0-2
				  ○ Life expectancy > 3 months
				• Patients can receive abiraterone (UGUPENZ) OR enzalutamide (UGUPABI, but not sequential use of these agents
				Exclusions[1]:
				• Active or symptomatic viral hepatitis or chronic liver disease
				• History of adrenal dysfunction
				• Clinically significant heart disease (LVEF < 50% at baseline)
				• Previously received abiraterone, enzalutamide or apalutamide for mCSPC
				• Previously received apalutamide, enzalutamide or darolutamide in nmCRPC
				Caution[1]:
				• Bilirubin > 1.5 x ULN, ALT > 2.5 x ULN
				• Uncontrolled hypertension
					1. BC Cancer Protocol UGUPABI [2-22]
					2. BC Cancer Benefit Drug List [3-22]

	mCSPC	Tablet	Not specified	A BC Cancer Compassionate Access Program request must be approved prior to treatment.[1] Restricted funding*[2] **Eligibility** (Abiraterone + Prednisone)[1]: • Patients with mCSPC who are either chemotherapy-naïve OR received prior chemotherapy containing docetaxel ○ No prior ADT or ADT for < 6 months for mCSPC • Should have ECOG PS 0-2 • Should have serum potassium > 3.5 mmol/L Note: • Patients treated with abiraterone for mCSPC and develop mCRPC are eligible to receive enzalutamide (but not abiraterone) **Caution[1]:** • Uncontrolled hypertension (systolic blood pressure > 160 mmHg or diastolic > 95 mmHg)	1. BC Cancer Protocol UGUMCSPABI [2-22] 2. BC Cancer Benefit Drug List [3-22]

Alendronate Generic	**Osteoporosis**	10 mg, 70 mg, 70mg/ 5600 IU VitD3 Tablet	Multiple[1]	Limited coverage drug requiring Special Authority Request Form[2] **Eligibility[1]**: • Clinical or radiographically documented fracture due to osteoporosis, OR • Glucocorticoid-induced osteoporosis in patients who are receiving or expected to receive the equivalent dose of ≥ 7.5 mg of prednisone per day and for ≥ 90 consecutive days	1. BC Pharmacare Formulary [3-22] 2. Limited Coverage Drug Program [3-22]

Apalutamide
(Erleada)
Janssen
	nmCRPC	Tablet	Not specified	A BC Cancer Compassionate Access Program request must be approved prior to treatment.[1] Restricted funding*[2]
				
				Eligibility[1]:
				• Patients with nmCRPC who meet the following criteria:
				  ○ Chemotherapy naïve
				  ○ ECOG PS 0-2
				  ○ PSADT ≤ 10 months
				  ○ No radiologic evidence of metastates (negative bone scan, negative CT of pelvis, abdomen, chest)
				• Patients with nmCRPC are eligible to receive one of apalutamide (UGUPAPA), darolutamide (UGUNMPDAR), or enzalutamide (UGUNMPENZ, UGUPENZ), but not their sequential use
				• Patients who have progressed on apalutamide in nmCRPC (UGUPAPA):
				  ○ Are eligible to receive docetaxel (GUPDOC) and/or cabazitaxel in mCRPC
				  ○ Are NOT eligible to receive enzalutamide (UGUPENZ) or abiraterone (UGUPABI) in mCRPC
				Exclusions[1]:
				• Patients with mCRPC
				• Prior enzalutamide or darolutamide in nmCRPC
				• Uncontrolled hypertension (systolic BP > 160 mmHg or diastolic > 95 mmHg)
					1. BC Cancer Protocol UGUPAPA [8-21]
					2. BC Cancer Benefit Drug List [3-22]

	mCSPC	Tablet	Not specified	A BC Cancer Compassionate Access Program request must be approved prior to treatment.[1] Restricted funding*[2]
				
				Eligibility[1]:
				• Patients with mCSPC who meet the following criteria:
				  ○ Chemotherapy naïve OR received prior chemotherapy containing docetaxel
				  ○ No prior ADT or ADT for < 6 months for mCSPC
				  ○ Should have ECOG PS 0-2
				  ○ Should have serum potassium > 3.5 mmol/L
				
				Exclusions[1]:
				• Patients treated with apalutamide for mCSPC and develop mCRPC are NOT eligible to receive abiraterone or enzalutamide
					1. BC Cancer Protocol UGUMCSPAPA [12-21]
					2. BC Cancer Benefit Drug List [3-22]

Darolutamide (Nubeqa) Bayer	**nmCRPC**	Tablet	Not specified	A BC Cancer Compassionate Access Program request must be approved prior to treatment.[1] Restricted funding*[2] **Eligibility[1]:** • Patients with nmCRPC who meeting the following criteria: ○ No radiological evidence of metastases (negative bone scan, negative CT of pelvis abdomen, chest) within the last 6 months (exception: pelvic lymph nodes < 2 cm in short axis below the aortic bifurcation) ○ No prior chemotherapy for nmCRPC ○ PSADT ≤ 10 months ○ Should have ECOG PS 0-2 • Patients with nmCRPC are eligible to receive apalutamide (UGUPAPA), darolutamide (UGUNMPDAR) or enzalutamide (UGUNMPENZ/UGUNPENZ), but not sequentially. • Patients who have progressed to mCRPC on darolutamide (UGUNMPDAR) are eligible to received docetaxel, cabazitaxel and radium • Patients who have progressed to mCRPC on darolutamide (UGUNMPDAR) are not eligible to receive enzalutamide or abiraterone **Exclusions[1]:** • Patients with mCRPC (exception: pelvic lymph nodes < 2 cm in short axis below the aortic bifurcation) • Prior treatment for nmCRPC with apalutamide (UGUPAPA) or enzalutamide (UGUNMPENZ) • Prior chemotherapy for nmCRPC	1. BC Cancer Protocol UGUNMPDAR [8-21] 2. BC Cancer Benefit Drug List [3-22]
Denosumab (Prolia) Amgen	**Osteoporosis**	60 mg/ mL Syr	02343541[1]	Limited coverage drug requiring Special Authority Request Form[2] **Eligibility[2]:** • Men with osteoporosis AND ○ Clinical or radiographically-documented fracture due to osteoporosis ○ Contraindication to oral bisphosphonates for one of the following reasons: ○ immune-mediated hypersensitivity reaction to oral bisphosphonates OR ○ abnormalities of the esophagus which delay esophageal emptying such as stricture or achalasia	1. BC Pharmacare Formulary [3-22] 2. Limited Coverage Drug Program [3-22]
Denosumab (Xgeva) Amgen	**mCRPC with Bone mets**	120 mg / 1.7 mL Vial	02368153[1]	Covered by BC Pharmacare Plan P (Palliative Drug Benefit). Application form must be submitted prior to treatment initiation[2] BC Palliative Care Benefit Application **Eligibility[2]:** • Patients with mCRPC with bone metastases • Evidence of castration resistance (progressive disease despite testosterone < 1.7 nmol/L) • As a supportive care medication, denosumab is not covered by BC Cancer Agency but may be reimbursed by private insurance plans	1. BC Pharmacare Formulary 2. BC Cancer Protocol SCDMAB [5-14]

Enzalutamide (Xtandi) Astellas	**mCRPC**	Tablet	Not specified	A BC Cancer Compassionate Access Program request must be approved prior to treatment.[1] Restricted funding*[2]
				Eligibility[1]:
				• Patients with mCRPC who meet the following criteria:
				  ○ Chemotherapy-naïve OR received prior chemotherapy containing docetaxel
				  ○ Should have ECOG PS 0-2
				  ○ Should have life expectancy > 3 months
				• Patients treated with abiraterone for mCSPC (UGUMCSPABI) are eligible to receive enzalutamide (UGUPENZ) for mCRPC
				• Patients can receive either enzalutamide (UGUPENZ) or abiraterone (UGUPABI) in mCRPC but not sequential use of these agents
				Exclusions[1]:
				• Previously received enzalutamide, apalutamide or darolutamide for nmCRPC
				• Previously received enzalutamide or apalutamide for mCSPC
				Caution[1]:
				• Uncontrolled hypertension
					1. BC Cancer Protocol UGUPENZ [12-21]
					2. BC Cancer Benefit Drug List [3-22]

	nmCRPC	Tablet	Not specified	A BC Cancer Compassionate Access Program request must be approved prior to treatment.[1] Restricted funding*[2]
				Eligibility[1]:
				• Patients with nmCRPC who meet the following criteria:
				  ○ Chemotherapy-naïve
				  ○ No radiologic evidence of metastases (negative bone scan, negative CT of pelvis, abdomen, chest)
				  ○ ECOG PS 0-2
				  ○ PSADT ≤ 10 months
				• Patients with nmCRPC are eligible to receive one of apalutamide (UGUPAPA), darolutamide (UGUNMPDAR), or enzalutamide (UGUNMPENZ, UGUPENZ), but not their sequential use
				• Patients who have progressed on enzalutamide in nmCRPC (UGUNMPENZ)
				  ○ Are eligible to receive docetaxel (GUPDOC) and/or cabazitaxel in metastatic CRPC
				  ○ Are NOT eligible to receive enzalutamide (UGUPENZ) or abiraterone (UGUPABI) in metastatic CRPC
				Exclusions[1]:
				• mCRPC
				• Prior treatment with apalutamide or darolutamide in nmCRPC
				• Uncontrolled hypertension (systolic BP > 160 mmHg or diastolic BP > 95 mmHg)
					1. BC Cancer Protocol UGUNMPENZ [8-21]
					2. BC Cancer Benefit Drug List [3-22]

	mCSPC	Tablet	Not specified	A BC Cancer Compassionate Access Program request must be approved prior to treatment.[1] Restricted funding*[2]
				Eligibility[1]:
				• Patients with mCSPC who meet the following criteria:
				  ○ Chemotherapy-naïve OR received prior chemotherapy containing docetaxel
				  ○ No prior ADT or ADT for < 6 months for mCSPC
				  ○ Should have ECOG PS 0-2
				  ○ Should have serum potassium > 3.5 mmol/L *… continued*
					1. BC Cancer Protocol UGUMCSPENZ [12-21]
					2. BC Cancer Benefit Drug List [3-22]

				Exclusions[1]: • Patients treated with enzalutamide for mCSPC and develop mCRPC are not eligible to receive abiraterone (UGUPABI)
Olaparib (Lynparza) AstraZeneca	**mCRPC**	-	-	No listing for prostate cancer as of Mar. 2022

*Restricted funding is reimbursed for approved indications only. Completion of the BC Cancer Compassionate Access Program Application (formerly Undesignated Indication Form) is necessary to provide the appropriate clinical information for each patient.

Funding:
CancerCare Manitoba covers in- and outpatient cost of injectable and oral treatments no matter where they are taken. Certain drugs or other items are approved for coverage under the Exception Drug Status (EDS) Program when they meet specific criteria and upon review and recommendation of the Manitoba Drug Standards and Therapeutics Committee (MDSTC).

Formularies:
Manitoba Drug Benefits: https://www.gov.mb.ca/health/mdbif/index.html Formulary Lookup: https://web22.gov.mb.ca/eFormulary/
Bulletin Archive: https://www.gov.mb.ca/health/mdbif/bulletins.html
Manitoba Home Cancer Drug Program https://www.gov.mb.ca/health/pharmacare/profdocs/oral_oncology_drugs_list.pdf

DRUG (Brand Name) Manufacturer	Indication	Strength, Route	DIN	Provincial Funding Eligibility Criteria	References
Abiraterone (Zytiga) Janssen Generic	**mCRPC**	250 mg Tab, 500 mg Tab	Multiple[1]	Exceptional Drug Status (EDS) Benefits – Part 3 Benefits: will be considered for Pharmacare reimbursement upon an individual prescriber/patient request basis[2] **Eligibility[2]:** • For patients with histologically confirmed mCRPC with disease progression after prior ADT or with disease progression after prior chemotherapy with docetaxel	1. Manitoba Drug Interchangeability Formulary [2-22] 2. MB Drug Benefits Bulletin 111 [11-21]
	mCSPC	250 mg Tab, 500 mg Tab	Multiple[1]	Exceptional Drug Status (EDS) Benefits – Part 3 Benefits: will be considered for Pharmacare reimbursement upon an individual prescriber/patient request basis[1] **Eligibility[1]:** • Abiraterone and prednisone in combination with ADT for mCSPC ○ Good performance status ○ Must be castration-sensitive (ie, no prior ADT for mCSPC or within 6 months of beginning ADT) ○ Treatment is continued until disease progression or unacceptable toxicity	1. MB Drug Benefits Bulletin 114 [11-21]
Alendronate	-	10 mg Tab, 70 mg Tab	Multiple[1,2]	Part 1 Benefit – no therapeutic criteria attached to the benefit[1]	1. MB Drug Benefits Formulary [3-22]
Apalutamide (Erleada) Janssen	**nmCRPC**	60 mg Tab	02478374	Exceptional Drug Status (EDS) Benefits – Part 3 Benefits: will be considered for Pharmacare reimbursement upon an individual prescriber/patient request basis[1] **Eligibility[1]:** • Apalutamide in combination with ADT ○ For the treatment of patients with CRPC who have no detectable distant metastases by either CT, MRI or technetium-99m bone scan and who are at high risk of developing metastases. ○ High risk is defined as a PSADT of ≤ 10 months during continuous ADT ○ Should have good performance status and no risk factors for seizures. ○ Treatment should continue until unacceptable toxicity or radiographic disease progression	1. MB Drugs Benefit Bulletin 106 [3-20]

continued

Apalutamide (Erleada) Janssen	**mCSPC**	60 mg Tab	02478374	Exceptional Drug Status (EDS) Benefits – Part 3 Benefits: will be considered for Pharmacare reimbursement upon an individual prescriber/patient request basis[1]
				
				Eligibility[1]:
				• Apalutamide in combination with ADT for mCSPC
				  ○ Must be castration sensitive (ie, no prior ADT or within 6 months of beginning ADT)
				  ○ Good performance status
				  ○ Treatment should be continued until unacceptable toxicity or disease progression
					1. MB Drug Benefits Bulletin 114 [11-21]

Darolutamide (Nubeqa) Bayer	**nmCRPC**	300 mg Tab	02496348	Exceptional Drug Status (EDS) Benefits – Part 3 Benefits: will be considered for Pharmacare reimbursement upon an individual prescriber/patient request basis[1]
				
				Eligibility[1]:
				• Darolutamide in combination with ADT for the treatment of patients with nmCRPC who are at high risk of developing metastases
				  ○ High risk is defined as PSADT ≤ 10 months during continuous ADT
				  ○ Castration-resistant according to the Prostate Cancer Working Group 2 (PCWG2) criteria which was used in the ARAMIS trial
				  ○ Absence of metastases was determined by a negative CT scan and negative bone scan
				  ○ Should have good performance status
				  ○ Treatment should continue until unacceptable toxicity or radiographic disease progression
					1. MB Drug Benefits Bulletin 112 [8-21]

Denosumab (Prolia) Amgen	**Osteoporosis**	60 mg/mL Inj	02343541	Exceptional Drug Status (EDS) Benefits – Part 3 Benefits: will be considered for Pharmacare reimbursement upon an individual prescriber/patient request basis[1]
				
				Eligibility:
				• To increase bone mass in men with osteoporosis who are at a high risk for fracture or who have failed or are intolerant to other available osteoporosis therapy, where the following clinical criteria are met:
				  ○ High fracture risk defined as either:
				  ▪ moderate 10-year fracture risk (10% to 20%) as defined by either the CAROC tool or (FRAX) tool with a prior fragility fracture; OR
				  ▪ high 10-year fracture risk (≥ 20%) as defined by either the CAROC or FRAX
				  AND
				  ○ Contraindication to oral bisphosphonates
				
				Notes:
				• Bisphosphonate failure will be defined as a fragility fracture and/or evidence of a decline in bone mineral density below pre-treatment baseline levels, despite adherence for one year
				• Contraindication to oral bisphosphonates will be considered. Contraindications include renal impairment, hypersensitivity, and abnormalities of the esophagus (e.g., esophageal stricture or achalasia).
					1. MB EDS [2-22]

Denosumab (Xgeva) Amgen	**mCRPC with Bone mets**	120 mg Inj	02368153	Exceptional Drug Status (EDS) Benefits – Part 3 Benefits: will be considered for Pharmacare reimbursement upon an individual prescriber/patient request basis[1]
				
				• For the prevention of skeletal-related events (SREs) in patients with CRPC
				  ○ One or more documented bony metastases
				  ○ ECOG performance status 0-2
					1. MB EDS [2-22]

Enzalutamide (Xtandi) Astellas	**mCRPC**	40 mg Cap	02407329	Exceptional Drug Status (EDS) Benefits – Part 3 Benefits: will be considered for Pharmacare reimbursement upon an individual prescriber/patient request basis[1] **Eligibility:** • For the treatment of histologically confirmed mCRPC with disease progression after prior chemotherapy with docetaxel1 • For the treatment of histologically confirmed mCRPC with disease progression after prior ADT and no prior chemotherapy2	1. MB Drug Benefits Bulletin 77 [4-14] 2. MB Drug Benefits Bulletin 85 [1-16]

	nmCRPC	40 mg Cap	02407329	Exceptional Drug Status (EDS) Benefits – Part 3 Benefits: will be considered for Pharmacare reimbursement upon an individual prescriber/patient request basis[1]
				
				Eligibility[1]:
				• Enzalutamide in combination with ADT for patients with nmCRPC who are at high risk of developing metastases
				  ○ High risk is defined as PSADT ≤ 10 months during continuous ADT
				  ○ Should have good performance status
				  ○ No risk factors for seizures
				• Treatment should continue until unacceptable toxicity or radiographic disease progression
					1. MB Drug Benefit Bulletin 108 [7-20]

	mCSPC	40 mg Cap	02407329	Exceptional Drug Status (EDS) Benefits – Part 3 Benefits: will be considered for Pharmacare reimbursement upon an individual prescriber/patient request basis[1]
				
				Eligibility:
				• Enzalutamide in combination with ADT for the treatment of mCSPC
				  ○ Patients must be castration-sensitive (ie, no prior ADT in the metastatic setting or within 6 months of beginning ADT)
				  ○ Should have good performance status
				  ○ No risk for seizures
				• Treatment should continue until unacceptable toxicity or radiographic disease progression
					• MB Drug Benefits Bulletin 114 [11-21]

Olaparib (Lynparza) AstraZeneca	**mCRPC**			• Listed on MB List of Oral Oncology Drugs Dispensed at CCMB[1] • No announcement of prostate cancer indications in Manitoba Drug Benefit Bulletins as of Mar. 2022[2]	1. MB Oral Onc Drugs [11-21] 2. MB Bulletin Archive

Funding:
Take-home cancer drugs are covered by the New Brunswick Drug Plans for eligible beneficiaries.
Patients not covered by the New Brunswick Drug Plans may have private insurance coverage.

Formulary:
New Brunswick Drug Plans Formulary https://www2.gnb.ca/content/dam/gnb/Departments/h-s/pdf/en/NBDrugPlan/NewBrunswickDrugPlansFormulary.pdf

DRUG (Brand Name) Manufacturer	Indication	Strength, Route	DIN	Provincial Funding Eligibility Criteria	References
Abiraterone (Zytiga) Janssen Generic	**mCRPC**	250 mg Tab 500 mg Tab	Multiple	Special Authorization Criteria **Eligibility:** • Patients with mCRPC Renewal Criteria: • Written confirmation that the patient has responded to treatment and there is no evidence of disease progression Clinical Notes: • Patients must have a good performance status • Treatment should be discontinued upon disease progression or unacceptable toxicity Claim Notes: • Initial approval period: 1 year • Renewal approval period: 1 year	1. NB Drug Plans Formulary [3-22]
	mCSPC	250 mg Tab 500 mg Tab	Multiple	Special Authorization Criteria **Eligibility:** • Abiraterone in combination with ADT for the treatment of patients with mCSPC ○ No prior ADT or are < 6 months of beginning ADT in the metastatic setting Renewal Criteria: • Written confirmation that the patient has responded to treatment and there is no evidence of disease progression Clinical Notes: • Patients must have a good performance status • Treatment should be discontinued upon disease progression or unacceptable toxicity Claim Notes: • Initial approval period: 1 year • Renewal approval period: 1 year	1. NB Drug Plans Formulary [3-22]

Alendronate	**Osteoporosis**	10 mg Tab 70 mg Tab	Multiple	Regular benefit	1. NB Drug Plans Formulary [3-22]

Apalutamide (Erleada) Janssen	**nmCRPC**	60 mg Tab	02478374	Special Authorization Criteria
				
				Eligibility:
				• Apalutamide in combination with ADT for the treatment of patients with nmCRPC who meet all the following criteria:
				  ○ No detectable distant metastases by either CT, MRI or technetium-99m bone scan
				  ○ PSADT ≤ 10 months during continuous ADT (ie, high risk of developing metastases)
				
				Renewal Criteria:
				• Written confirmation that the patient has responded to treatment and there is no evidence of radiographic disease progression
				
				Clinical Notes:
				• Castration-resistance must be demonstrated during continuous ADT and is defined as a ≥ 3 rises in PSA, measured ≥ 1 week apart, with the last PSA > 2 mcg/L
				• Castrate levels of testosterone must be maintained throughout treatment
				• Patients must have a good performance status and no risk factors for seizures
				• Treatment should be discontinued upon radiographic disease progression or unacceptable toxicity
				
				Claim Notes:
				• Requests for apalutamide will not be considered for patients who experience disease progression on enzalutamide or darolutamide
				• Initial approval period: 1 year
				• Renewal approval period: 1 year
					1. NB Drug Plans Formulary [3-22]

	mCSPC	60 mg Tab	02478374	Special Authorization Criteria **Eligibility:** • Apalutamide in combination with ADT for the treatment of patients with mCSPC ○ No prior ADT or are < 6 months of beginning ADT in the metastatic setting Renewal Criteria: • Written confirmation that the patient has responded to treatment and there is no evidence of disease progression Clinical Notes: • Patients must have a good performance status and no risk factors for seizures • Treatment should be discontinued upon disease progression or unacceptable toxicity Claim Notes: • Requests for apalutamide will not be considered for patients who experience disease progression on enzalutamide • Initial approval period: 1 year • Renewal approval period: 1 year	1. NB Drug Plans Formulary [3-22]

Darolutamide (Nubeqa) Bayer	**nmCRPC**	300 mg Tab	02496348	Special Authorization Criteria **Eligibility:** • In combination with ADT for the treatment of patients with nmCRPC ○ PSADT ≤ 10 months during continuous ADT (ie, high risk of developing metastases) Renewal Criteria: • Written confirmation that the patient has responded to treatment and there is no evidence of radiographic disease progression Clinical Notes: • Castration-resistance must be demonstrated during continuous ADT and is defined as a ≥ 3 rises in PSA, measured ≥ 1 week apart, with the last PSA > 2 mcg/L • Castrate levels of testosterone must be maintained throughout treatment • Patients must have a good performance status • Treatment should be discontinued upon radiographic disease progression or unacceptable toxicity Claim Notes: • Requests for darolutamide will not be considered for patients who experience disease progression on apalutamide or enzalutamide • Initial approval period: 1 year • Renewal approval period: 1 year	1.	NB Drug Plans Formulary [3-22]

Denosumab (Prolia) Amgen	**Osteoporosis**	60 mg/mL	02343541	Special Authorization Criteria
				
				Eligibility:
				• For the treatment of osteoporosis in patients who meet the following criteria:
				  ○ Have a contraindication to oral bisphosphonates
				  ○ High risk for fracture, or refractory or intolerant to other available osteoporosis therapies
				
				Clinical Notes:
				• Refractory is defined as a fragility fracture or evidence of a decline in bone mineral density below pre-treatment baseline levels, despite adherence for one year to other available osteoporosis therapies
				• High fracture risk is defined as:
				  ○ Moderate 10-year fracture risk (10% to 20%) as defined by the CAROC tool or the FRAX tool with a prior fragility fracture, OR
				  ○ High 10-year fracture risk (≥ 20%) as defined by the CAROC or FRAX tool
					1.	NB Drug Plans Formulary [3-22]

Denosumab (Xgeva) Amgen	**mCRPC with Bone mets**	120 mg/1.7 mL vial	02368153	Special Authorization Criteria
				
				Eligibility:
				• For the prevention of skeletal-related events (SREs) in patients with CRPC
				  ○ ≥ 1 documented bone metastases
				  ○ ECOG PS of 0-2*
				  * patients who are asymptomatic and those who are symptomatic and in bed less than 50% of the time
					1.	NB Drug Plans Formulary [3-22]

Enzalutamide (Xtandi) Astellas	**mCRPC**	40 mg Cap	02407329	Special Authorization Criteria **Eligibility:** • Patients with mCRPC Renewal Criteria: • Written confirmation that the patient has responded to treatment and there is no evidence of disease progression Clinical Notes: • Patients must have a good performance status and no risk factors for seizures • Treatment should be discontinued upon disease progression or unacceptable toxicity. Claim Notes: • Requests for enzalutamide will not be considered for patients who experience disease progression on apalutamide or darolutamide • Initial approval period: 1 year • Renewal approval period: 1 year	1. NB Drug Plans Formulary [3-22]
	nmCRPC	40 mg Cap	02407329	Special Authorization Criteria **Eligibility:** • Enzalutamide in combination with ADT for the treatment of patients with nmCRPC ○ PSADT ≤ 10 months during continuous ADT (ie, high risk of developing metastases) Renewal Criteria: • Written confirmation that the patient has responded to treatment and there is no evidence of radiographic disease progression Clinical Notes: • Castration-resistance must be demonstrated during continuous ADT and is defined as a ≥ 3 rises in PSA, measured ≥1 week apart, with the last PSA > 2 mcg/L • Castrate levels of testosterone must be maintained throughout treatment • Patients must have a good performance status and no risk factors for seizures • Treatment should be discontinued upon radiographic disease progression or unacceptable toxicity Claim Notes: • Requests for enzalutamide will not be considered for patients who experience disease progression on apalutamide or darolutamide • Initial approval period: 1 year • Renewal approval period: 1 year	1. NB Drug Plans Formulary [3-22]
	mCSPC	40 mg Cap	02407329	Special Authorization Criteria **Eligibility:** • Enzalutamide in combination with ADT for the treatment of patients with mCSPC ○ No prior ADT or are < 6 months of beginning ADT in the metastatic setting	1. NB Drug Plans Formulary [3-22]

continued

	mCSPC *continued*			Renewal Criteria: • Written confirmation that the patient has responded to treatment and there is no evidence of disease progression Clinical Notes: • Patients must have a good performance status and no risk factors for seizures • Treatment should be discontinued upon disease progression or unacceptable toxicity Claim Notes: • Requests for enzalutamide will not be considered for patients who experience disease progression on apalutamide • Initial approval period: 1 year • Renewal approval period: 1 year	
Olaparib (Lynparza) AstraZeneca	**mCRPC**	-	-	No listing for prostate cancer as of Mar. 2022	1. NB Drug Plans Formulary [3-22]

NEWFOUNDLAND & LABRADOR

Funding:
For oral cancer drugs and take-home injectables, the patient must cover the drug under public or private insurance and pay deductibles.
Drugs not covered on the basic NLPDP formulary, for eligible beneficiaries, can be assessed for coverage by special authorization.

Formularies:
Newfoundland and Labrador Interchangeable Drug Products Database https://www.health.gov.nl.ca/health/prescription/newformulary.asp
Special Authorization Drug Products https://www.gov.nl.ca/hcs/prescription/covered-specialauthdrugs/
Special Authorization Drug Product Criteria https://www.health.gov.nl.ca/health/prescription/special_auth_drug_products.pdf
Benefit List Update Bulletins – Search https://nlpdp.bell.ca/

DRUG (Brand Name) Manufacturer	Indication	Strength, Route	DIN	Provincial Funding Eligibility Criteria	References
Abiraterone (Zytiga) Janssen Generic	**mCRPC**	250 mg Tab 500 mg Tab	Multiple[1,2]	Special Authorization Drug[1,2]: Form **Eligibility[2]:** • Abiraterone in combination with prednisone for the treatment of patients with mCRPC Renewal Criteria[3]: • Written confirmation that the patient has responded to treatment and there is no evidence of disease progression. Clinical Notes[3]: • Patients must have a good performance status • Treatment should be discontinued upon disease progression or unacceptable toxicity Claim Notes[3]: • Initial approval period: 1 year • Renewal approval period: 1 year	1. NLPDP Drug Product Database [3-22] 2. Benefit List Update Bulletin 33 [2-22]
	mCSPC	250 mg Tab 500 mg Tab	-Not specified	Special Authorization[1]: Form **Eligibility:** • In combination with ADT for the treatment of patients with mCSPC Renewal Criteria: • Written confirmation that the patient has responded to treatment and there is no evidence of disease progression Clinical Notes: • Patients must be castration sensitive (ie, no prior ADT in the metastatic setting or within six months of beginning ADT). • Patients must have a good performance status. • Treatment should be discontinued upon radiographic disease progression or unacceptable toxicity Claim Notes: • Requests for abiraterone will not be considered for patients who experience disease progression on apalutamide or enzalutamide • Initial approval period: 1 year • Renewal approval period: 1 year	1. Benefit List Update Bulletin 33 [2-22]

Alendronate	**Osteoporosis**	10 mg Tab 70 mg Tab	Multiple[1,2]	Open benefit if beneficiary is ≥ 65 years of age or older.[1,2] Special Authorization Drug can be considered < 65 years of age[2]: Form **Eligibility[2]:** • For the treatment of osteoporosis associated with documented fracture • For the treatment of osteoporosis without documented fracture when a patient has a high 10-year fracture risk (based on age, sex and T-score, see Appendix 1 of Special Authorization Products List for fracture risk table) • As prophylaxis of corticosteroid induced osteoporosis in patient who will be or have been on systemic corticosteroid therapy for > 3 months	1. NLPDP Drug Product Database [3-22] 2. NL Special Auth Products [1-16]

Apalutamide (Erleada) Janssen	**nmCRPC**	60 mg Tab	2478374	Special Authorization[1]: Form
				
				Eligibility[2]:
				• In combination with ADT for the treatment of patients with CRPC who meet all of the following criteria:
				  ○ No detectable distant metastases by either CT, MRI or technetium-99m bone scan
				  ○ PSADT ≤ 10 months during continuous ADT (ie, high risk of developing metastases)
				
				Renewal Criteria[2]:
				• Written confirmation that the patient has responded to treatment and there is no evidence of radiographic disease progression
				
				Clinical Notes[2]:
				• Castration-resistance must be demonstrated during continuous ADT and is defined as a minimum of three rises in PSA, measured at least one week apart, with the last PSA greater than 2 mcg/L
				• Castrate levels of testosterone must be maintained throughout treatment with apalutamide
				• Patients must have an ECOG PS of ≤ 2 and no risk factors for seizures
				• Treatment should be discontinued upon radiographic disease progression or unacceptable toxicity
				
				Claim Notes[2]:
				• Requests for apalutamide will not be considered for patients who experience disease progression on enzalutamide
				• Initial approval period: 1 year
				• Renewal approval period : 1 year
					1. NLPDP Drug Product Database [3-22]
					2. NL Special Auth - Apalutamide [3-21]

	mCSPC	-	-	No listing for mCSPC as of Mar. 2022	

Darolutamide
(Nubeqa)
Bayer
	nmCRPC	300 mg Tab	02496348	Special Authorization[1]: Form
				
				Eligibility[2]:
				• In combination with ADT for the treatment of patients with nmCRPC who meet all of the following criteria:
				  ○ No detectable distant metastases by either CT, MRI or technetium-99m bone scan
				  ○ PSADT ≤ 10 months during continuous ADT (ie, high risk of developing metastases)
				
				Renewal Criteria[2]:
				• Written confirmation that the patient has responded to treatment and there is no evidence of radiographic disease progression.
				
				Clinical Notes[2]:
				• Castration-resistance must be demonstrated during continuous ADT and is defined as 3 PSA rises at least one week apart, with the last PSA > 2 ng/mL.
				• Castrate levels of testosterone must be maintained
				• Patients with N1 disease, pelvic lymph nodes < 2cm in short axis located below the aortic bifurcation are eligible for darolutamide
				• Patients should have good performance status
				• Treatment should be discontinued upon radiographic disease progression or unacceptable toxicity
				
				Claim Notes[2]:
				• Darolutamide will not be funded for patients who experience disease progression on apalutamide or enzalutamide
				• Patients receiving darolutamide for the treatment of nmCRPC will be eligible for funding of abiraterone at the time of disease progression to mCRPC. Enzalutamide is not funded for patients who experience disease progression to mCRPC while on darolutamide.
				• Either abiraterone or enzalutamide may be used to treat mCRPC in patients who discontinued darolutamide in the non-metastatic setting due to intolerance without disease progression.
				• Initial approval period: 1 year
				• Renewal approval period: 1 year
					1. NLPDP Drug Product Database [3-22]
					2. NL Special Auth – Darolutamide

Denosumab
(Prolia)
Amgen
	Osteoporosis	60 mg/mL Syr	02343541	Special Authorization[1]: Form
				
				Eligibility[1]:
				• For the treatment of osteoporosis in male patients who meet the following criteria:
				  ○ Have a contraindication to oral bisphosphonates
				  ○ High risk for fracture, or refractory or intolerant to other available osteoporosis therapies
				
				Clinical Criteria:
				• High fracture risk defined as either: a moderate 10-year fracture risk (10% to 20%) with a prior fragility fracture; or a high 10-year fracture risk (≥ 20%) as defined by either the CAROC tool or FRAX tool
				• Refractory is defined as an unsatisfactory response to bisphosphonates is typically defined as a fragility fracture and/or evidence of a decline in BMD below pre-treatment baseline levels, despite adherence for one year
					1. NLPDP Drug Product Database [3-22]
					2. NL Special Auth Products [3-18]

Denosumab (Xgeva) Amgen	**mCRPC with Bone mets**	120 mg/ 1.7 mL Vial	02368153	Special Authorization[1]: Form
				
				Eligibility[2]:
				• For the prevention of skeletal related events (SREs) in patients with CRPC with:
				  ○ One or more documented bony metastases
				  ○ ECOG PS of 0-2
				
				Notes[2]:
				• Approval Period: Indefinite
				• Recommended Dose: 1.7 ml every four weeks
					1. NLPDP Drug Product Database [3-22]
					2. NL Special Auth Products [4-14]

Enzalutamide (Xtandi) Astellas	**mCRPC**	40 mg Cap	02407329	Special Authorization[1]: Form **Eligibility[2]:** • Patients with mCRPC Renewal Criteria[2]: • Written confirmation that the patient has responded to treatment and there is no evidence of disease progression Clinical Notes[2]: • Patients must have a good performance status and no risk factors for seizures • Treatment should be discontinued upon disease progression or unacceptable toxicity Claim Notes[2]: • Requests for enzalutamide will not be considered for patients who experience disease progression on apalutamide • Initial approval period: 1 year • Renewal approval period: 1 year	1. NLPDP Drug Product Database [3-22] 2. NL Special Auth - Enzalutamide [10-21]
	nmCRPC	40 mg Cap	02407329	Special Authorization[1]: Form **Eligibility[2]:** • In combination with ADT for the treatment of patients with nmCRPC ○ PSADT of ≤ 10 months during continuous ADT (ie, high risk of developing metastases) Renewal Criteria[2]: • Written confirmation that the patient has responded to treatment and there is no evidence of disease progression Clinical Notes[2]: • Castration-resistance must be demonstrated during continuous ADT and is defined as a minimum of three rises in PSA, measured at least one week apart, with the last PSA greater than 2 mcg/L • Castrate levels of testosterone must be maintained throughout treatment with enzalutamide • Patients must have a good performance status and no risk factors for seizures	1. NLPDP Drug Product Database [3-22] 2. NL Special Auth - Enzalutamide [10-21]

				• Treatment should be discontinued upon radiographic disease progression or unacceptable toxicity *…continuted* Claim Notes[2]: • Requests for enzalutamide will not be considered for patients who experience disease progression on apalutamide • Initial approval period: 1 year • Renewal approval period: 1 year	
Enzalutamide (Xtandi) Astellas	**mCSPC**	40 mg Cap	02407329	Special Authorization[1]: Form **Eligibility[2]:** • In combination with ADT for the treatment of patients with mCSPC Renewal Criteria[2]: • Written confirmation that the patient has responded to treatment and there is no evidence of disease progression Clinical Notes[2]: • Patients must be castration sensitive (ie, no prior ADT in the metastatic setting or within six months of beginning ADT) • Patients must have a good performance status and no risk factors for seizures • Treatment should be discontinued upon radiographic disease progression or unacceptable toxicity Claim Notes[2]: • Requests for enzalutamide will not be considered for patients who experience disease progression on apalutamide • Initial approval period: 1 year • Renewal approval period: 1 year.	1. NLPDP Drug Product Database [3-22] 2. NL Special Auth - Enzalutamide [10-21]
Olaparib (Lynparza) AstraZeneca	**mCRPC**			No listing for prostate cancer as of Mar. 2022.	

Funding:
For oral cancer drugs and take-home injectables, the patient must cover the drug under public or private insurance and pay deductibles.

Formularies:
Nova Scotia Pharmacare https://novascotia.ca/dhw/pharmacare/formulary.asp
Nova Scotia Formulary https://novascotia.ca/dhw/pharmacare/documents/formulary.pdf
Exception Status Drugs https://novascotia.ca/dhw/pharmacare/documents/Criteria-for-Exception-Status-Coverage.pdf

DRUG (Brand Name) Manufacturer	Indication	Strength, Route	DIN	Provincial Funding Eligibility Criteria	References
Abiraterone (Zytiga) Janssen Generic	**mCRPC**	250 mg Tab 500 mg Tab	Multiple	Exception status applies[1,2]: Form **Eligibility[1,2]:** • Patients with mCRPC Clinical notes[1,2]: • Patients should have good performance status • Treatment should be discontinued upon disease progression or unacceptable toxicity	1. NS Formulary [3-22] 2. Criteria for Exception Status Coverage [3-22]
	mCSPC	250 mg Tab 500 mg Tab	Multiple	Exception status applies[1,2]: Exception status Drug request form **Eligibility[1,2]:** • In combination with prednisone and ADT for the treatment of patients with mCSPC ○ Patients must have had either no prior ADT, or are within six months of beginning ADT in the metastatic setting Clinical notes[1,2]: • Patients should have good performance status • Treatment should be discontinued upon disease progression or unacceptable toxicity Claim Notes[1,2]: • Patients receiving abiraterone for the treatment of mCSPC will be eligible for funding of enzalutamide at the time of disease progression to mCRPC.	1. NS Formulary [9-213-22] 2. Criteria for Exception Status Coverage [3-22]
Alendronate	**Osteoporosis**	5 mg Tab 10 mg Tab 70 mg Tab	Multiple	**Eligibility:** • Senior's pharmacare • Community services pharmacare (under 65-long term care pharmacare, family pharmacare) • Drug assistance for Cancer Patients	1. NS Formulary [3-22]
Apalutamide (Erleada) Janssen	**nmCRPC**	60 mg Tab	02478374	Exception status applies[1,2]: Form **Eligibility[1,2]:** • In combination with ADT for the treatment patients with CRPC who have no detectable distant metastasis (M0) by either CT, MRI or technetium-99m bone scan and who are at high risk of developing metastases (defined as PSADT ≤ 10 months during continuous ADT) • Patients should have a good performance status and no risk factors for seizures • Treatment should continue until unacceptable toxicity or radiographic disease progression	1. NS Formulary [3-22] 2. Criteria for Exception Status Coverage [3-22]

…continued

Apalutamide (Erleada) Janssen				Clinical Notes[1,2]: • Castration-resistance must be demonstrated during continuous ADT and is defined as 3 PSA rises ≥ 1 week apart, with the last PSA > 2 ng/mL • Castrate levels of testosterone must be maintained • Patients with N1 disease, pelvic lymph nodes < 2cm in short axis located below the common iliac vessels are eligible for apalutamide • Apalutamide will not be funded for patients who experience disease progression on enzalutamide • Patients receiving apalutamide for the treatment of nmCRPC will be eligible for funding of abiraterone at the time of disease progression to mCRPC • Enzalutamide is not funded for patients who experience disease progression to mCRPC while on apalutamide • Abiraterone or enzalutamide may be used to treat mCRPC patients who discontinued apalutamide in the non-metastatic setting due to intolerance without disease progression	
	mCSPC	60 mg Tab	02478374	Exception status applies[1,2]: Form **Eligibility[1,2]:** • In combination with ADT for the treatment patients with mCSPC ○ Patients must have had either no prior ADT, or are within six months of beginning ADT in the metastatic setting. Clinical Notes[1,2]: • Patients should have a good performance status and no risk factors for seizures • Treatment should continue until unacceptable toxicity or disease progression Claim Notes[1,2]: • Patients receiving apalutamide for the treatment of metastatic CSPC will be eligible for funding of abiraterone at the time of disease progression to metastatic CRPC • Enzalutamide is not funded for patients who experience disease progression to metastatic CRPC while on apalutamide	1. NS Formulary [3-22] 2. Criteria for Exception Status Coverage [3-22]

Darolutamide
(Nubeqa)
Bayer
	nmCPRC	300 mg Tab	02496348	Exception status applies[1,2]: Form
				
				Eligibility[1,2]:
				• In combination with ADT for the treatment of patients with nmCRPC
				  ○ Patients who are at high risk of developing metastases (defined as PSADT ≤ 10 months during continuous ADT)
				  ○ Patients should have a good performance status.
				• Treatment should continue until unacceptable toxicity or radiographic disease progression.
				
				Clinical Notes[1,2]:
				• Castration-resistance must be demonstrated during continuous ADT and is defined as 3 PSA rises ≥ 1 week apart, with the last PSA > 2 ng/mL
				• No detectable distant metastasis (M0) by either CT, MRI or technetium-99m bone scan
				• Castrate levels of testosterone must be maintained
				• Patients with N1 disease, pelvic lymph nodes < 2cm in short axis located below the aortic bifurcation are eligible for darolutamide
				• Darolutamide will not be funded for patients who experience disease progression on apalutamide or enzalutamide
				• Patients receiving darolutamide for the treatment of nmCRPC will be eligible for funding of abiraterone at the time of disease progression to mCRPC, enzalutamide is not funded for patients who experience disease progression to mCRPC while on darolutamide
				• Abiraterone or enzalutamide may be used to treat mCRPC patients who discontinued darolutamide in the non-metastatic setting due to intolerance without disease progression
					1. NS Formulary [3-22]
					2. Criteria for Exception Status Coverage [3-22]

Denosumab
(Prolia)
Amgen
	Osteoporosis	60 mg/mL Inj	02343541	Exception status applies[1,2]: Form
				
				Eligibility[1,2]:
				• For the treatment of osteoporosis in men who meet the following criteria:
				  ○ Have a contraindication to oral bisphosphonates
				  ○ High risk for fracture, or refractory or intolerant to other available osteoporosis therapies.
				
				Clinical Notes[1,2]:
				• Refractory is defined as a fragility fracture or evidence of a decline in bone mineral density below pre-treatment baseline levels, despite adherence for one year to other available osteoporosis therapies.
				• High fracture risk is defined as:
				  ○ Moderate 10-year fracture risk (10% to 20%) as defined by the Canadian Association of Radiologists and Osteoporosis Canada (CAROC) tool or the World Health Organization's Fracture Risk Assessment (FRAX) tool with a prior fragility fracture; or
				  ○ High 10-year fracture risk (≥ 20%) as defined by the CAROC or FRAX tool
					1. NS Formulary [3-22]
					2. Criteria for Exception Status Coverage [3-22]

Denosumab
(Xgeva)
Amgen
	SRE prevention in mCRPC	120 mg / 1.7 mL Sol	02368153	Exception status applies[1,2]: Form
				
				Eligibility[1,2]:
				• As a single agent for the prevention of skeletal related events (SREs) for mCRPC patients with:
				  ○ ≥ 1 documented bone metastases
				  ○ ECOG PS 0-2
					1. NS Formulary [3-22]
					2. Criteria for Exception Status Coverage [3-22]

Enzalutamide (Xtandi) Astellas	**mCRPC**	40 mg Cap	02407329	Exception status applies[1,2]: Form **Eligibility[1,2]:** • Patients with mCRPC Clinical Notes[1,2]: • Patients should have a good performance status and no risk factors for seizures • Treatment should be discontinued upon disease progression or unacceptable toxicity Claim Notes[1,2]: • Requests for enzalutamide will not be considered for patients who experience disease progression on apalutamide	1. NS Formulary [3-22] 2. Criteria for Exception Status Coverage [3-22]
	nmCRPC	40 mg Cap	02407329	Exception status applies[1,2]: Form **Eligibility[1,2]:** • In combination with ADT for the treatment of patients with nmCRPC who are at high risk of developing metastases (defined as a PSADT of ≤ 10 months during continuous ADT) • Patients should have a good performance status and no risk factors for seizures • Treatment should continue until unacceptable toxicity or radiographic disease progression Clinical Notes[1,2]: • Castration-resistance must be demonstrated during continuous ADT and is defined as 3 PSA rises ≥ 1week apart, with the last PSA > 2 ng/mL • Castrate levels of testosterone must be maintained • Patients with N1 disease, pelvic lymph nodes < 2cm in short axis located below the common iliac vessels are eligible for enzalutamide Claim Notes[1,2]: • Enzalutamide will not be funded for patients who experience disease progression on apalutamide • Patients receiving enzalutamide for the treatment of nmCRPC will be eligible for funding of abiraterone at the time of disease progression to mCRPC	1. NS Formulary [3-22] 2. Criteria for Exception Status Coverage [3-22]

	mCSPC	40 mg Cap	02407329	Exception status applies[1,2]: Form
				
				Eligibility[1,2]:
				• In combination with ADT for the treatment of patients with mCSPC
				  ○ Patients must have had either no prior ADT or are within six months of beginning ADT in the metastatic setting
				  ○
				  ○ Clinical Notes[1,2]:
				• Patients should have a good performance status and no risk factors for seizures
				• Treatment should continue until unacceptable toxicity or disease progression
				
				Claim Notes[1,2]:
				• Patients receiving enzalutamide for the treatment of mCSPC will be eligible for funding of abiraterone at the time of disease progression to mCRPC
					1. NS Formulary [3-22]
					2. Criteria for Exception Status Coverage [3-22]

Olaparib (Lynparza) AstraZeneca	**mCRPC**	-	-	No listing for prostate cancer as of Mar. 2022.	

Funding:
Take-home cancer drugs are funded through the Ontario Drug Benefit (ODB) Exceptional Access Program (EAP) for eligible program recipients.
Funding options are also available through CBCRP - Case-by-Case Review Program.

Formularies:
ODB Formulary Search https://www.formulary.health.gov.on.ca/formulary/
EAP https://health.gov.on.ca/en/pro/programs/drugs/eap_mn.aspx#:~:text=The%20Exceptional%20Access%20Program%20(%20EAP,Drug%20Benefit%20(%20ODB%20)%20program
EAP Frequent Requested Drugs https://health.gov.on.ca/en/pro/programs/drugs/docs/frequently_requested_drugs.pdf

DRUG (Brand Name) Manufacturer	Indication	Strength, Route	DIN	Provincial Funding Eligibility Criteria	References

Abiraterone (Zytiga)
Janssen
Generic
	mCRPC
	
	continued
		250 mg Tab
		500 mg Tab
			Multiple	Exceptional Access Program (EAP)[1]: EAP standard form
				
				Eligibility: patients with mCRPC who have not trialed docetaxel[1]
				• For the treatment of mCRPC in patients who meet the following criteria:
				  ○ Used in combination with prednisone
				  ○ Asymptomatic or mildly symptomatic after failure of ADT
				  ○ ECOG PS ≤ 1
				  ○ Patient must not meet any of the exclusion criteria stated below
				
				Exclusion Criteria[1]:
				• Funding for Zytiga will NOT be approved in patients who meet any ONE (or more) of the following exclusion criteria:
				  ○ Patient has viral hepatitis or chronic liver disease;
				  ○ Patient has clinically significant heart disease;
				  ○ Zytiga is being prescribed for combination use with Jevtana or Xtandi for mCRPC;
				  ○ The patient has received prior chemotherapy for mCRPC
				
				Notes:
				• Please provide clinical information as objective evidence that the above criteria are met (e.g., castrate testosterone level, PSA levels, evidence of metastatic disease such as presence and location of lesions, surgical procedures related to the condition, and name(s), date, duration of ADT used details of the response to therapy, labwork or clinical confirmation to support that the patient does not meet any of the exclusion criteria
				• Approved dosage: 1000 mg once daily will be funded until there is evidence of disease progression
				• Duration of Approval: 1 year
				• Renewals will be considered in patients with evidence of not having had disease progression while on Zytiga therapy
				
				…continued
					1. ON EAP-Freq Requested [1-22]
					2. CCO-ABIRPRED [5-21]

Abiraterone (Zytiga)
Janssen
Generic
	continued from previous
	mCRPC
				Eligibility: patients with mCRPC who are requesting Zytiga after a trial of docetaxel[1]
				• For the treatment of mCRPC in patients who meet the following criteria:
				  ○ Zytiga is being used in combination with prednisone
				  ○ Cancer has progressed after having received prior docetaxel containing therapy
				  ○ ECOG PS ≤ 2
				  ○ Patients must not meet ANY of the exclusion criteria for funding stated below
				
				Exclusion Criteria[1]:
				• Funding for Zytiga will NOT be approved in patients who meet any ONE (or more) of the following exclusion criteria:
				  ○ Patient has viral hepatitis or chronic liver disease
				  ○ Patient has clinically significant heart disease
				  ○ Zytiga is being prescribed for combination use with Jevtana or Xtandi for mCRPC
				  ○ Patient has already used Zytiga in the pre-docetaxel setting
				
				Notes:
				• Requests for patients who initiated Jevtana (cabazitaxel) or Xtandi (enzalutamide) therapy within the 3 months preceding the EAP request for Zytiga and who have not had disease progression, will be considered on a case-by-case basis
				• Approved dosage: 1000 mg once daily will be funded until there is evidence of disease progression
				• Duration of Approval: 1 year
				• Renewals will be considered in patients with evidence of not having had disease progression while on Zytiga therapy	

	mCSPC	-	-	Not funded by EAP for newly diagnosed hormone-sensitive high-risk metastatic prostate cancer.	1. CCO-ABIRPRED [6-21]
Alendronate	**Osteoporosis**	10 mg Tab 70 mg Tab	Multiple	ODBF listing	1. ODBF [12-21]

Apalutamide
(Erleada)
Janssen
	nmCRPC	60 mg Cap	Not specified	Exceptional Access Program (EAP)[1,2]: EAP standard form
				
				Eligibility[1]:
				• High risk nmCRPC in patients who meet all the following criteria:
				  ○ Patient using apalutamide (Erleada) in combination with ADT
				  ○ No detectable distant metastases as determined by CT, MRI, or technetium99m bone scan;
				  ○ Castration resistant disease based on meeting all the following indicia observed while on continuous ADT treatment or post orchiectomy:
				  ▪ Castrate serum testosterone levels
				  ▪ Biochemical progression defined as three (3) PSA rises at least 1 week apart, with the last PSA > 2ng/mL
				  ○ High risk for developing metastatic disease based on a PSADT ≤ 10 months during continuous ADT
				  ○ ECOG PS ≤ 2
				
				Exclusion criteria: The following will not be reimbursed[1]
				• The patient received prior chemotherapy for the treatment of prostate cancer, unless it was in the adjuvant or neoadjuvant setting
					1. ON EAP-Freq Requested [1-22]
					2. CCO-APAL [12-21]

			• The patient has experienced disease progression on prior treatment with enzalutamide or darolutamide used for prostate cancer Notes: • The Ministry will fund only one second generation ARI in patients with non-metastatic castrate resistant prostate cancer • Requests for apalutamide in patients who have initiated another ARI therapy in the nmCRPC setting and who have not experienced disease progression will be considered on a case-by-case basis • Patients treated with an ARI as part of a clinical trial may be eligible for apalutamide and will be considered on a case-by-case basis • Approved dosage: 240 mg administered orally once daily • Renewal criteria: Renewals will be considered in patients without evidence of radiographic disease progression or unacceptable toxicity while on apalutamide therapy • Duration of initial and renewal approvals: 1 year	
mCSPC	60 mg Cap	Not specified	Exceptional Access Program (EAP)[1,2]: EAP standard form **Eligibility[1]:** • Patients with mCSPC who meet all the following criteria: ○ In combination with ADT (ADT is not required for patients with bilateral orchiectomy) ○ Metastatic lesions detected on technetium-99m bone scan, CT, and/or MRI ○ Castration sensitive as defined by: ▪ Patient being treatment naïve to an ADT, OR ADT initiated within the prior 6 months before start of therapy with apalutamide , OR ▪ ADT used in the neoadjuvant or adjuvant setting where the patient has been off treatment for 12 months or more prior to start of apalutamide ○ Patient has not experienced disease progression with another ARAT (abiraterone, apalutamide, darolutamide, enzalutamide) for CSPC ○ Patient has good performance status ○ • Baseline levels to be provided with initial application[1] ○ Number of metastatic lesions on bone scan and in soft tissues ○ Testosterone level ○ Baseline (pre-treatment) PSA level ○ Pre-treatment Gleason score (optional) **Exclusion criteria: Patients meeting any of the following will not be funded[1]** • Patients who have previously experienced disease progression on apalutamide or another ARI used in the setting of prostate cancer • Apalutamide will not be funded as combination therapy with another ARAT *…continued*	1. ON EAP-Freq Requested [1-22] 2. CCO-APAL [12-21]

				Notes: • Patients who have previously progressed on an ARI for prostate cancer will not be eligible for apalutamide in mCSPC. The Ministry will fund only one of apalutamide or enzalutamide in patients with mCSPC. • Patients treated with enzalutamide or darolutamide as part of a clinical trial may be eligible for apalutamide and will be considered on a case-by-case basis • Patients who are currently on a treatment regimen with an ARAT for prostate cancer, must meet the initiation criteria if they wish to switch to publicly funded apalutamide for mCSPC • Time limited funding consideration will be prov ided on a case-by-case basis for those patients who are using docetaxel in combination with ADT as long as there has been no progression and the treatment regimen has not been used for more than 6 months • Approved Dosage for Initials and Renewals: 240 mg administered orally once daily • Duration of initial and renewal approvals: 1 year • Renewal Criteria: Renewals will be considered in patients until disease progression (ie,. PSA elevation in addition to radiographic disease progression, or PSA progression in addition to clinical symptoms associated with cancer progression), development of castration resistant disease, or experiencing unacceptable toxicity while on apalutamide	

Darolutamide (Nubeqa) Bayer	**nmCRPC**	300mg Tab	Not specified	Exceptional Access Program (EAP)[1,2]: EAP standard form
				
				Eligibility[1]:
				• High risk nmCRPC in patients who meet all the following criteria:
				  ○ Patient using darolutamide (Nubeqa) in combination with ADT
				  ○ No detectable distant metastases as determined by CT, MRI, or technetium-99m bone scan
				  ○ Patient has castrate resistant disease based on meeting all the following indicia observed while on continuous ADT treatment or post orchiectomy:
				  ▪ Castrate serum testosterone levels
				  ▪ Biochemical progression defined as three (3) PSA rises ≥ 1 week apart, with the last PSA > 2 ng/mL (if the patient has a history of antiandrogen use, the most recent PSA value must be obtained ≥ 4 weeks after anti-androgen withdrawal)
				  ○ Patient is at high risk for developing metastatic disease based on a PSADT ≤ 10 months during continuous ADT
				  ○ ECOG PS ≤ 2
				
				Exclusion criteria: Patients meeting ≥ 1 below exclusion criteria will not be funded[1]
				• The patient received prior chemotherapy or immunotherapy for the treatment of prostate cancer, unless it was in the adjuvant or neoadjuvant setting completed > 2 years previously
				• The patient has experienced disease progression on prior treatment with Erleada (apalutamide) or Xtandi (enzalutamide)
				• The patient has a high risk for disease progression by other definitions (such as a high Gleason score 8-10, high PSA level at diagnosis, etc.) AND has not had a PSA progression in the non-metastatic setting
				
				Notes:
				• The Ministry will fund only one of Nubeqa (darolutamide) or Erleada (apalutamide) or Xtandi (enzalutamide) in patients with nmCRPC
					1. ON EAP-Freq Requested [1-22]
					2. CCO-DARO [11-21]

				• While doses may be withheld or reduced to 300 mg twice daily to manage grade 3 toxicities until symptoms improve, treatment doses should be resumed at a dose of 600 mg twice daily • Requests for Nubeqa in patients who initiated Erleada or Xtandi therapy in the nmCRPC setting and who have not had disease progression will be considered on a case-by-case basis • Following progression on darolutamide in nmCRPC, the patient would not be eligible for darolutamide, apalutamide or enzalutamide in mCRPC state • Approved dosage: 600 mg administered orally twice daily. • Approval duration of initials and renewals: 1 year • Renewal criteria: Renewals will be considered in patients without evidence of radiographic disease progression or unacceptable toxicity while on Nubeqa therapy	

Denosumab (Prolia) Amgen	**Osteoporosis**	60 mg/mL Syr	02343541	Ontario Drug Benefit Formulary - Limited Use
				
				Eligibility: Limited Use Code 515[1]
				• To increase bone mass in males with osteoporosis who meet the following criteria:
				  ○ High risk* for fracture;
				  ○ Failed other available osteoporosis therapy (i.e. fragility fracture OR evidence of a decline in bone mineral density below pre-treatment baseline levels) despite adherence for one year.
				  ○ *High fracture risk is defined as either:
				  ▪ A prior fragility fracture AND a moderate 10-year fracture risk (10% to 20%) based on the CAROC tool or the FRAX tool; OR
				  ▪ A high 10-year fracture risk (greater than or equal to 20%) based on the CAROC or FRAX tool; OR
				  ▪ Where a patient's 10-year fracture risk based on the CAROC or FRAX tool is less than the thresholds defined above, a high fracture risk based on evaluation of clinical risk factors for fracture
				
				Exclusion Criteria[1]:
				• Patients receiving Prolia must not be receiving concomitant bisphosphonate therapy
				
				Notes:
				• Use of the CAROC or FRAX tool may underestimate fracture risk in certain circumstances and may not include all risk factors
				• The recommended dose of PROLIA (denosumab) is a single SC injection of 60 mg, once every 6 months
				• Limited use authorization period: indefinite
				
				Eligibility: Limited Use Code 516[1]
				• To increase bone mass in males with osteoporosis who meet the following criteria:
				  ○ High risk* for fracture;
				  ○ For whom oral bisphosphonates are contraindicated due to hypersensitivity OR abnormalities of the esophagus (e.g., esophageal stricture or achalasia) OR inability to stand or sit upright for at least 30 minutes
				  ○ *High fracture risk is defined as either:
				  ▪ A prior fragility fracture AND a moderate 10-year fracture risk (10% to 20%) based on the CAROC tool or the FRAX tool; OR
					1. ODBF [12-21]

				▪ A high 10-year fracture risk (greater than or equal to 20%) based on the CAROC or FRAX tool; OR ▪ Where a patient's 10-year fracture risk based on the CAROC or FRAX tool is less than the thresholds defined above, a high fracture risk based on evaluation of clinical risk factors for fracture **Exclusion Criteria[1]:** • Patients receiving Prolia must not be receiving concomitant bisphosphonate therapy Notes: • Use of the CAROC or FRAX tool may underestimate fracture risk in certain circumstances and may not include all risk factors • The recommended dose of PROLIA (denosumab) is a single SC injection of 60 mg, once every 6 months • Limited use authorization period: indefinite	
Denosumab (Xgeva) Amgen	**mCRPC with Bone mets**	120 mg per Vial	Not specified	Exceptional Access Program (EAP)[1,2]: Denosumab Form | EAP standard form **Eligibility[1]:** • For the treatment of bony metastases in patients with hormone refractory prostate cancer • Xgeva is considered through CCO for those receiving prostate cancer treatment from a cancer clinic. • Hormone refractory prostate cancer is determined using the following criteria: ○ Patient has an elevated PSA level or evidence of progressive bony disease[a], despite castrate serum testosterone levels (< 1.7 nmol/L or < 50 ng/dL)[b] a. Progressive bony disease is defined as progressive changes in radionucleotide bone scan or clinical signs of disease profession, such as pathologic fracture or increasing bone pain b. Patients who have undergone orchidectomy do not need to provide a serum testosterone level in the request submission Notes: • Approved dosing: 120 mg subcutaneously every four (4) weeks • Duration of approval: 1 Year • Renewals will be considered for patient responding to treatment with Xgeva and who still requires treatment	1. ON EAP-Freq Requested [1-22] 2. CCO DENO [7-18]
Enzalutamide (Xtandi) Astellas	**mCRPC**	40 mg Cap	Not specified	Exceptional Access Program (EAP)[1,2]: EAP standard form **Eligibility[1]:** • For the treatment of metastatic castration resistant prostate cancer (mCRPC) in patients meeting the following criteria: 1. Enzalutamide used in combination with ADT (ADT is not required for patients with bilateral orchiectomy), AND 2. Metastatic lesions detected on a bone scan, CT, and/or MRI, AND 3. Patient has castration resistant disease based on meeting the following indicia observed while on continuous ADT treatment or post orchiectomy ▪ Castrate serum testosterone levels, AND ▪ Biochemical progression defined as three (3) PSA rises at least 1 week apart, with the last PSA greater than 2ng/mL AND/OR radiographic progression of new	1. ON EAP-Freq Requested [1-22] 2. CCO ENZL [12-21]

Enzalutamide (Xtandi) Astellas	*continued from previous*			or pre-existing disease as determined by the detection of 2 or more lesions on bone scan or presence of new soft tissue lesions by RECIST criteria, AND 4. Patient has progressed on a docetaxel-based chemotherapy, OR 5. Patient is using enzalutamide pre-docetaxel for mCRPC and has not previously experienced disease progression on enzalutamide or another second generation ARI (e.g. apalutamide, darolutamide) used for prostate cancer, OR 6. Patient is using enzalutamide pre-docetaxel for mCRPC and has not previously experienced disease progression on abiraterone used in mCRPC sequenced immediately prior to enzalutamide 7. Patient has good performance status defined as ECOG PS ≤ 2	
	mCRPC			**Exclusion Criteria: Patients meeting any of the following will not be funded**[1] • Patient has risk factors for seizures • Enzalutamide will not be funded as combination therapy with another androgen receptor axis targeted therapy or cabazitaxel Notes: • Patients who have progressed on treatment with second generation ARI (e.g., apalutamide, enzalutamide, darolutamide) used in prior stages of prostate cancer will not be eligible for enzalutamide in the metastatic castration resistant setting • Patients treated with apalutamide or darolutamide as part of a clinical trial may be eligible for enzalutamide and will be considered on a case-by-case basis • Requests for enzalutamide in patients who initiated abiraterone therapy and who have not had disease progression while on abiraterone will be considered on a case-by-case basis • Approved dosage for initials and renewals: 160 mg administered orally once daily • Duration of initial and renewal approvals : 1 year • Renewal criteria: Renewals will be considered in patients who have not experienced disease progression while on enzalutamide therapy	
	nmCRPC	40 mg Cap	Not specified	Exceptional Access Program (EAP)[1,2]: EAP standard form **Eligibility**[1]**:** • For the treatment of high risk nmCRPC in patients who meet all the following criteria: 1. Patient using Xtandi in combination with ADT 2. No detectable distant metastases as determined by CT, MRI, or technetium99m bone scan 3. Patient has castrate resistant disease based on meeting all the following indicia observed while on continuous ADT treatment or post orchiectomy: ▪ Castrate serum testosterone levels, AND ▪ Biochemical progression defined as 3 PSA rises ≥ 1 week apart, with the last PSA > 2ng/mL 4. Patient is at high risk for developing metastatic disease based on a PSADT ≤ 10 months during continuous ADT 5. ECOG PS ≤ 2 **Exclusion Criteria**[1]**:** • The patient received prior chemotherapy for the treatment of prostate cancer, unless it was in the adjuvant or neoadjuvant setting • The patient has experienced disease progression on prior treatment with apalutamide or darolutamide • The patient has risk factors for seizures	1. ON EAP-Freq Requested [1-22] 2. CCO_ENZL [12-21]

Enzalutamide (Xtandi) Astellas	*continued from previous* **nmCRPC**			Notes: • The Ministry will fund only one second generation ARI (e.g. apalutamide, darolutamide, or enzalutamide) in patients with nmCRPC • Patients who have progressed on enzalutamide for nmCRPC will not be eligible for enzalutamide in mCRPC • Requests for enzalutamide in patients who initiated another ARI therapy in the nmCRPC setting and who have not had disease progression will be considered on a case-by-case basis • Approved dosage: 160mg administered orally once daily • Approval duration: 1 year • Renewal criteria: Renewals will be considered in patients without evidence of radiographic disease progression or unacceptable toxicity while on enzalutamide therapy	
	mCSPC	40 mg Cap	Not specified	Exceptional Access Program (EAP)[1,2]: EAP standard form **Eligibility[1]:** • For the treatment metastatic castration sensitive prostate cancer (mCSPC) in patients who meet all of the following criteria: 1. Enzalutamide is used in combination with ADT (ADT is not required for patients with bilateral orchiectomy), AND 2. Metastatic lesions detected on technetium-99m bone scan, CT, and/or MRI, AND 3. Castration sensitive as defined by the patient being treatment naïve to an ADT, OR ADT initiated within the prior 6 months before start of therapy with enzalutamide, OR ADT used in the neoadjuvant or adjuvant setting where the patient has been off treatment for 12 months or more prior to start of enzalutamide, AND 4. Has not experienced disease progression with another ARAT for CSPC 5. Patient has good performance status • The following baseline levels are to be provided with the initial application:[1] ○ Number of metastatic lesions on bone scan and in soft tissues ○ Testosterone level ○ Baseline (pre-treatment) PSA level ○ Pre-treatment Gleason score (optional) Exclusion Criteria: Patients meeting any of the following will not be funded[1] • Patients who have previously experienced disease progression on enzalutamide or another ARI used in the setting of prostate cancer • Patients who have risk factors for seizures • Enzalutamide will not be funded as combination therapy with another ARAT Notes: • Patients who have previously progressed on a second-generation ARI (e.g. apalutamide, enzalutamide, darolutamide) for prostate cancer will not be eligible for enzalutamide in mCSPC; the Ministry will fund only one of enzalutamide or apalutamide in patients with mCSPC	3. ON EAP-Freq Requested [1-22] 1. CCO_ENZL [12-21]

Enzalutamide (Xtandi) Astellas	*continued from previous* **mCSPC**	• Patients treated with apalutamide or darolutamide as part of a clinical trial may be eligible for enzalutamide and will be considered on a case-by-case basis • Patients who progress on treatment with enzalutamide or apalutamide mCSPC will not be eligible for enzalutamide in the metastatic castration resistant setting • Patients who are currently on a treatment regimen with an ARAT (e.g. abiraterone or a second-generation ARI) for prostate cancer, must meet the initiation criteria if they wish to switch to publicly funded enzalutamide for mCSPC • Time limited funding consideration will be provided on a case-by-case basis for those patients who are using docetaxel in combination with ADT as long as there has been no progression and the treatment regimen has not been used for more than 6 months • Approved dosage: 160 mg administered orally once daily • Duration of initial and renewal approvals: 1 year • Renewal Criteria: Renewals will be considered in patients until disease progression (i.e. PSA elevation in addition to radiographic disease progression, or PSA progression in addition to clinical symptoms associated with cancer progression), development of castration resistant disease, or experiencing unacceptable toxicity while on enzalutamide	
Olaparib (Lynparza) AstraZeneca	**mCRPC**	Not currently publicly funded for this regimen and intent[1] • Treatment of mCRPC; patients must have confirmation of deleterious or suspected deleterious germline and/or somatic BRCA or ATM mutations before starting treatment	1. CCO_OLAP [10-21]

Funding:
Cancer drugs that are routinely dispensed from community pharmacies are funded by private insurance plans first, and then one or more PEI Pharmacare programs.

Formularies:
PEI Pharmacare Formulary https://www.princeedwardisland.ca/sites/default/files/publications/pei_pharmacare_formulary.pdf
Health PEI Formulary Drugs: Oncology https://www.princeedwardisland.ca/sites/default/files/publications/oncologyformulary.pdf

DRUG (Brand Name) Manufacturer	Indication	Strength, Route	DIN	Provincial Funding Eligibility Criteria	References
Abiraterone (Zytiga) Janssen Generic	**mCRPC**	250 mg Tab 500 mg Tab	Multiple	Special Authorization Status[1,2]: Form Coverage: High-Cost Drug Program, Catastrophic Drug Plan **Special Authorization Criteria[1,2]:** • In combination with prednisone for the treatment of mCRPC in patients who: ○ Are asymptomatic or mildly symptomatic after failure of ADT, OR ○ Have received prior chemotherapy containing docetaxel after failure of ADT Notes[1,2]: • Prescriptions written by PEI oncologists do not require Special Authorization form • Patients must apply for coverage to the High-Cost Drug Program http://healthpei.ca/pharmacareforms	1. PEI Pharmacare Formulary [3-22] 2. PEI Oncology Formulary [4-22]
	mCSPC	250 mg Tab	Multiple	• In combination with androgen deprivation therapy (ADT) for the treatment of patients with mCSPC who have had no prior ADT, or are within 6 months of beginning ADT, in the metastatic setting. Notes[1,2]: • Prescriptions written by PEI oncologists do not require Special Authorization form • Patients must apply for coverage to the High-Cost Drug Program http://healthpei.ca/pharmacareforms	1. PEI Pharmacare Formulary [3-22] 2. PEI Oncology Formulary [4-22]
Alendronate	**Osteoporosis**	10 mg Tab 70 mg Tab	Multiple	Covered under multiple provincial programs including: Generic Drug Program, Senior Drug Program, Family Health Benefit Drug Program (form), Financial Assistance Drug Program, Nursing Home Program or Institutional Pharmacy Program, and Catastrophic Drug Program (form)	1. PEI Pharmacare Formulary [3-22]
Apalutamide (Erleada) Janssen	**nmCRPC**	-	-	No listing information as of Mar. 2022.	1. PEI Pharmacare Formulary [3-22]
	mCSPC	-	-	No listing information as of Mar. 2022.	1. PEI Pharmacare Formulary [3-22]
Darolutamide (Nubeqa) Bayer	**nmCRPC**	-	-	No listing information as of Mar. 2022.	1. PEI Pharmacare Formulary [3-22]

Denosumab (Prolia) Amgen	**Osteoporosis**	60 mg/mL Syr	02343541	Special Authorization Status[1,2]: Form
				Coverage: Senior Drug Program, Family Health Benefit Drug Program (form), Financial Assistance Drug Program, Nursing Home Program or Institutional Pharmacy Program and Catastrophic Drug Program (form)[1,2]
				
				Special Authorization Criteria[1,2]:
				• For the treatment of osteoporosis in men who meet the following criteria:
				  ○ Have a contraindication to oral bisphosphonates
				  High risk for fracture, or refractory or intolerant to other available osteoporosis therapies
				
				Clinical Notes[1,2]:
				• Refractory is defined as a fragility fracture or evidence of a decline in bone mineral density below pre-treatment baseline levels, despite adherence for one year to other available osteoporosis therapies
				• High fracture risk is defined as:
				  ○ Moderate 10-year fracture risk (10% to 20%) as defined by the CAROC tool or the FRAX tool with a prior fragility fracture; OR
				  ○ High 10-year fracture risk (≥ 20%) as defined by the CAROC or FRAX tool
					1. PEI Pharmacare Formulary [3-22]
					2. PEI Oncology Formulary [4-22]

Denosumab (Xgeva) Amgen	**mCRPC with Bone mets**	-	-	No listing information as of Mar. 2022.	

Enzalutamide (Xtandi) Astellas	**mCRPC**	40 mg Cap	02407329	Special Authorization Status[1,2]: Form
				Coverage: High-cost Drug Program (form) and Catastrophic Drug Program (form)[1,2]
				
				Special Authorization Criteria[1,2]:
				• For treatment of patients with mCRPC who:
				  ○ Are asymptomatic or mildly symptomatic after failure of ADT with an ECOG PS ≤ 1 and have not received prior chemotherapy and would be an alternative to abiraterone for patients and not sequential therapy in this asymptomatic or mildly symptomatic patient population; OR
				  ○ Have progressed on docetaxel-based chemotherapy with an ECOG PS ≤ 2 and no risk factors for seizures and would be an alternative to abiraterone for patients and not sequential therapy in this symptomatic post docetaxel chemotherapy setting
				
				Notes[1,2]:
				• Prescriptions written by PEI oncologists do not require Special Authorization
				• Enzalutamide will not be reimbursed in combination with abiraterone
				• Use of enzalutamide in the past docetaxel setting is not permitted if previously used in the prechemotherapy setting
					• PEI Pharmacare Formulary [3-22]
					• PEI Oncology Formulary [4-22]

	nmCRPC			No listing information as of Mar. 2022.	
	mCSPC			No listing information as of Mar. 2022.	
Olaparib (Lynparza) AstraZeneca	**mCRPC**			No listing information as of Mar. 2022.	

High-Cost Drug Program: Approved high-cost medications for persons eligible for PEI Medicare and approved for coverage for one or more of the medications included in the program. Patients must apply for coverage on an annual basis and provide income information to the program.
Catastrophic Drug Program: Once an applicant's out of pocket eligible drug expenses exceed the annual household limit the program will cover any further eligible drug expenses in the program year.

Funding:
Medications that are taken at home may be covered by the provincial drug benefit plan or by private insurance plans.

Formulary:
RAMQ List of Medications [EN] https://www.ramq.gouv.qc.ca/sites/default/files/documents/liste_med_2022-03-02_en.pdf
[FR] https://www.ramq.gouv.qc.ca/sites/default/files/documents/liste_med_2022-03-02_fr.pdf

DRUG (Brand Name) Manufacturer	Indication	Strength, Route	DIN	Provincial Funding Eligibility Criteria	References

Abiraterone (Zytiga)
Janssen
Generic
	mCRPC / CPMRC	250 mg PO
		500 mg PO
			Multiple	Exceptional medication with recognized indications for payment
				
				Eligibility[1]:
				• For patients with mCRPC, in combination with prednisone
				  ○ Asymptomatic or mildly symptomatic after an anti-androgen treatment has failed, AND
				  ○ Never received docetaxel-based chemotherapy, AND
				  ○ ECOG PS is 0 or 1
				• For patients with mCRPC, in combination with prednisone, AND
				  ○ Disease has progressed during or following docetaxel-based chemotherapy, unless there is a contraindication or a serious intolerance, AND
				  ○ ECOG PS is ≤ 2
				
				Notes[1]:
				• The maximum duration of each authorization is four months
				• When requesting continuation of treatment, the physician must provide evidence of a beneficial clinical effect by the absence of disease progression
				• It must be noted that abiraterone is not authorized after failure with an androgen synthesis inhibitor or a second-generation ARI if it was administered for treatment of prostate cancer
				• Abiraterone remains covered by the basic prescription drug insurance plan for those insured persons having used this drug in the three months before 10 July 2019, insofar as the physician provides evidence of a beneficial clinical effect by the absence of disease progression
				
				Critère d'éligibilité[1]:
				• en association avec la prednisone pour le traitement du cancer de la prostate métastatique résistant à la castration, chez les personnes :
				  ○ asymptomatiques ou légèrement symptomatiques après l'échec d'un traitement anti-androgénique; et
				  ○ n'ayant jamais reçu de chimiothérapie à base de docetaxel; et
				  ○ dont le statut de performance selon l'ECOG est de 0 ou 1
				• en association avec la prednisone pour le traitement du cancer de la prostate métastatique résistant à la castration, chez les personnes :
				  ○ dont la maladie a progressé pendant ou à la suite d'une chimiothérapie à base de docetaxel à moins d'une contre-indication ou d'une intolérance sérieuse; et
				  ○ présentant un statut de performance selon l'ECOG de 0 à 2.
					1. RAMQ List of Medications [3-22] Liste des medicaments [3-22]

Abiraterone (Zytiga) Janssen Generic				Remarques[1]: • La durée maximale de chaque autorisation est de 4 mois. • Lors des demandes pour la poursuite du traitement, le médecin devra fournir la preuve d'un effet clinique bénéfique par l'absence de progression de la maladie. • Il est à noter que l'abiratérone n'est pas autorisée à la suite d'un échec avec un inhibiteur de la synthèse des androgènes ou un inhibiteur du récepteur des androgènes de seconde génération s'ils ont été administrés pour le traitement du cancer de la prostate. • Toutefois, l'abiratérone demeure couverte par le Régime général d'assurance médicaments pour les personnes assurées ayant utilisé ce médicament au cours des 3 mois précédant le 10 juillet 2019, en autant que le médecin fournisse la preuve d'un effet bénéfique par l'absence de la progression de la maladie.	
	mCSPC/ CPMSC	-	-	No listing as of Mar. 2022 / Non répertorié en mars 2022	
Alendronate	**Osteoporosis**	5 mg PO 10 mg PO 70 mg PO	Multiple	• Bone resorption inhibitor / inhibiteurs de la résorption osseuse	1. RAMQ List of Medications [3-22] Liste des medicaments [3-22]

Apalutamide (Erleada)
Janssen
	nmCRPC/ CPNMRC	60 mg PO	02478374	Exceptional medication
				
				Eligibility[1]:
				• Patients with nmCRPC
				  ○ At jigh risk of developing distant metastases (PSADT ≤ 10 months) despite an androgenic deprivation treatment, AND
				  ○ Whose ECOG PS is 0 or 1
				
				Notes:
				• The maximum duration of each authorization is four months
				• When requesting continuation of treatment, the physician must provide evidence of a beneficial clinical effect defined by the absence of disease progression
				
				Critère d'éligibilité[1]:
				• pour le traitement du cancer de la prostate non métastatique résistant à la castration, chez les personnes :
				  ○ à risque élevé de développer des métastases à distance malgré un traitement de privation androgénique. Le risque élevé est défini par un temps de doublement de l'antigène prostatique spécifique inférieur ou égal à 10 mois; et
				  ○ dont le statut de performance selon l'ECOG est de 0 ou 1.
				
				Remarques[1]:
				• La durée maximale de chaque autorisation est de 4 mois.
				• Lors des demandes pour la poursuite du traitement, le médecin devra fournir la preuve d'un effet Clinique bénéfique par l'absence de progression de la maladie.
					1. RAMQ List of Medications [3-22]
					Liste des medicaments [3-22]

Apalutamide (Erleada) Janssen	**mCSPC/ CPMSC**	60 mg PO	02478374	Exceptional medication
				
				Eligibility:
				• In association with ADT, for the treatment of mCSPC, in persons:
				  ○ Whose ECOG PS is 0 or 1, AND
				  ▪ Who have not received an ADT for ≥ 3 years for a localized prostate cancer; OR
				  ▪ Who have not received an ADT for ≥ 6 months for a metastatic prostate cancer
				
				Notes:
				• The maximum duration of each authorization is four months
				• When requesting continuation of treatment, the physician must provide evidence of a beneficial clinical effect by the absence of disease progression.
				• Apalutamide is not authorized following failure with an androgen synthesis inhibitor or a second-generation ARI if they have been administered to treat prostate cancer
				
				Critère d'éligibilité[1]:
				• en association avec une thérapie de privation androgénique (TPA), pour le traitement du cancer de la prostate métastatique sensible à la castration, chez les personnes dont le statut de performance selon l'ECOG est de 0 ou 1 :
				  ○ n'ayant pas reçu de TPA pendant plus de 3 ans pour le traitement d'un cancer de la prostate localisé; ou
				  ○ • n'ayant pas reçu de TPA pendant plus de 6 mois pour le traitement d'un cancer de la prostate métastatique.
				
				Remarques[1:]
				• La durée maximale de chaque autorisation est de 4 mois.
				• Lors des demandes pour la poursuite du traitement, le médecin devra fournir la preuve d'un effet clinique bénéfique par l'absence de progression de la maladie.
				• Il est à noter que l'apalutamide n'est pas autorisé à la suite d'un échec avec un inhibiteur de la synthèse des androgènes ou un inhibiteur du récepteur des androgènes de seconde génération s'ils ont été administrés pour le traitement du cancer de la prostate.
					1. RAMQ List of Medications [3-22]
					Liste des medicaments [3-22]

Darolutamide (Nubeqa) Bayer	**nmCRPC/ CPNMRC**	300 mg PO	02496348	Exceptional medication
				
				Eligibility:
				• For the treatment of nmCRPC, in persons:
				  ○ At high risk of developing distant metastases (PSADT ≤ 10 months) despite an androgenic deprivation treatment, AND
				  ○ ECOG PS is 0 or 1
				
				Notes:
				• The maximum duration of each authorization is four months.
				• When requesting continuation of treatment, the physician must provide evidence of a beneficial clinical effect defined by the absence of disease progression.
				
				Critère d'éligibilité[1]:
				• pour le traitement du cancer de la prostate non métastatique résistant à la castration, chez les personnes :
					1. RAMQ List of Medications [3-22]
					Liste des medicaments [3-22]

				○ à risque élevé de développer des métastases à distance malgré un traitement de privation androgénique. Le risque élevé est défini par un temps de doublement de l'antigène prostatique spécifique inférieur ou égal à 10 mois; et ○ dont le statut de performance selon l'ECOG est de 0 ou 1. Remarques[1:] • La durée maximale de chaque autorisation est de 4 mois. • Lors des demandes pour la poursuite du traitement, le médecin devra fournir la preuve d'un effet clinique bénéfique par l'absence de progression de la maladie.	
Denosumab (Prolia) Amgen	**Osteoporosis / ostéoporose**	S.C. Inj. Sol. (syr) 60 mg/mL	02343541	Exceptional medication **Eligibility:** • Osteoporosis in men at high risk of fracture who cannot receive an oral bisphosphonate because of serious intolerance or a contraindication. **Critère d'éligibilité[1]:** • pour le traitement de l'ostéoporose chez les hommes à risque élevé de fractures ne pouvant recevoir un bisphosphonate oral en raison d'une intolérance sérieuse ou d'une contre-indication.	1. RAMQ List of Medications [3-22] Liste des medicaments [3-22]
Denosumab (Xgeva) Amgen	**mCRPC + bone mets / CPRC + métastase osseuse**	Inj. Sol. 120 mg /1.7mL	02368153	Exceptional medication **Eligibility:** • Prevention of bone events in persons suffering from mCRPC with at least one bone metastasis **Critère d'éligibilité[1]:** • pour la prévention des événements osseux chez les personnes atteintes d'un cancer de la prostate resistant à la castration et présentant au moins une métastase osseuse.	1. RAMQ List of Medications [3-22] Liste des medicaments [3-22]
Enzalutamide (Xtandi) Astellas	**mCRPC/ CPMRC**	40 mg PO	02407329	Exceptional medication **Eligibility:** • For the treatment of mCRPC in persons: ○ Whose cancer progressed during or following docetaxel-based chemotherapy, unless there is a contraindication or serious intolerance, AND ○ ECOG PS is ≤ 2 • For the treatment of mCRPC in persons: ○ Who are Asymptomatic or mildly symptomatic after an anti-androgen treatment has failed, AND ▪ Never received docetaxel-based chemotherapy, AND ▪ ECOG PS is 0 or 1 Notes: • The maximum duration of each authorization is four months. • When requesting continuation of treatment, the physician must provide evidence of a beneficial clinical effect by the absence of disease progression • Enzalutamide is not authorized after failure with an androgen synthesis inhibitor or a second-generation ARI if it was administered for treatment of prostate cancer.	1. RAMQ List of Medications [3-22] Liste des medicaments [3-22]]

Enzalutamide
(Xtandi)
Astellas
	**mCRPC/
	CPMRC**
				Critère d'éligibilité[1]:
				• en monothérapie pour le traitement du cancer de la prostate métastatique résistant à la castration chez les personnes :
				  ○ dont la maladie a progressé pendant ou à la suite d'une chimiothérapie à base de docetaxel à moins d'une contre-indication ou d'une intolérance sérieuse; et
				  ○ dont le statut de performance selon l'ECOG est de 0 à 2.
				
				Remarques[1:]
				• La durée maximale de chaque autorisation est de 4 mois.
				• Lors des demandes pour la poursuite du traitement, le médecin devra fournir la preuve d'un effet clinique bénéfique par l'absence de progression de la maladie.
				• Il est à noter que l'enzalutamide n'est pas autorisé à la suite d'un échec avec un inhibiteur de la synthèse des androgènes ou un inhibiteur du récepteur des androgènes de seconde génération s'ils ont été administrés pour le traitement du cancer de la prostate.	

	**nmCRPC/
	CPNMRC**
		40 mg PO	02407329	Exceptional medication
				
				Eligibility:
				• For the treatment of nmCRPC, in persons:
				  ○ Exposed to a high risk of developing metastases despite ADT (PSADT ≤ 10 months)
				  ○ ECOG PS is 0 or 1
				
				Notes:
				• The maximum duration of each authorization is four months
				• When requesting continuation of treatment, the physician must provide evidence of a beneficial clinical effect defined by the absence of disease progression
				
				Critère d'éligibilité[1]:
				• pour le traitement du cancer de la prostate non métastatique résistant à la castration, chez les personnes :
				  ○ exposées à un risque élevé de développer des métastases à distance malgré un traitement de privation androgénique. Le risque élevé est défini par un temps de doublement de l'antigène prostatique spécifique inférieur ou égal à 10 mois; et
				  ○ dont le statut de performance selon l'ECOG est de 0 ou 1.
				
				Remarques[1:]
				• La durée maximale de chaque autorisation est de 4 mois.
				• Lors des demandes pour la poursuite du traitement, le médecin devra fournir la preuve d'un effet clinique bénéfique par l'absence de progression de la maladie.
					1. RAMQ List of Medications [3-22]
					Liste des medicaments [3-22]

	**mCSPC/
	CPMSC**
		40 mg PO	02407329	Exceptional medication
				
				Eligibility:
				• In association with ADT for treatment of mCSPC in persons:
				  ○ Whose ECOG PS is 0 or 1, AND
				  ▪ Who have not received an ADT for ≥ 3 years for the treatment of localized prostate cancer, OR
				  ▪ Who have not received an ADT for ≥ 6 months for the treatment of metastatic prostate cancer
					1. RAMQ List of Medications [3-22]
					Liste des medicaments [3-22]

	continued from previous			Notes: • The maximum duration of each authorization is four months • When requesting continuation of treatment, the physician must provide evidence of a beneficial clinical effect by the absence of disease progression • Enzalutamide is not authorized following failure with an androgen synthesis inhibitor or a second-generation androgen receptor inhibitor if they have been administered to treat prostate cancer **Critère d'éligibilité[1]:** • en association avec une thérapie de privation androgénique (TPA), pour le traitement du cancer de la prostate métastatique sensible à la castration, chez les personnes dont le statut de performance selon l'ECOG est de 0 ou 1 : o n'ayant pas reçu de TPA pendant plus de 3 ans pour le traitement d'un cancer de la prostate localisé; ou o n'ayant pas reçu de TPA pendant plus de 6 mois pour le traitement d'un cancer de la prostate métastatique. Remarques[1]: • La durée maximale de chaque autorisation est de 4 mois. • Lors des demandes pour la poursuite du traitement, le médecin devra fournir la preuve d'un effet clinique bénéfique par l'absence de progression de la maladie. • Il est à noter que l'enzalutamide n'est pas autorisé à la suite d'un échec avec un inhibiteur de la synthèse des androgènes ou un inhibiteur du récepteur des androgènes de seconde génération s'ils ont été administrés pour le traitement du cancer de la prostate.
Enzalutamide (Xtandi) Astellas	**mCSPC/ CPMSC**			
Olaparib (Lynparza) AstraZeneca	**mCRPC**	-	-	No listing as of Mar. 2022 / Non répertorié en mars 2022

Funding:
The Cancer Agency through funding from the government of Saskatchewan pays for all approved cancer drugs for patients with a valid health card and registered with the Cancer Agency. This includes drugs administered by injection or oral cancer treatments taken at home.

Formularies:
Saskatchewan Drug Plan Formulary: https://formulary.drugplan.ehealthsask.ca/SearchFormulary/BG/693949
Saskatchewan Cancer Agency (SCA) Drug Formulary http://www.saskcancer.ca/health-professionals-article/drug-formulary
Exception Drug Status Program https://formulary.drugplan.ehealthsask.ca/PDFs/APPENDIXA.pdf

DRUG (Brand Name) Manufacturer	Indication	Strength, Route	DIN	Provincial Funding Eligibility Criteria	References

Abiraterone (Zytiga) Janssen Generic	**mCRPC**	250 mg tab
		500 mg tab
			Not specified	**Eligibility:**
				• mCRPC, in combination with prednisone
				  ○ CRPC defined as 3 consecutive rises in PSA ≥1 week apart with the last PSA >2 mcg/L, OR
				  ○ Progression or appearance of ≥ 2 lesions on bone scan or in soft tissue, during continuous ADT with castrate testosterone levels (<1.7 nmol/L)
				
				Notes:
				• Funded in patients who have experienced disease progression after prior treatment with other ARATs (e.g., enzalutamide) in patients who are unable to tolerate or are not candidates for other therapeutic choices (ie, chemotherapy)
					1. SCA Drug Formulary [3-22]

	mCSPC	250 mg tab 500 mg tab	Not specified	**Eligibility:** • mCSPC, in combination with prednisone and ADT in patients who: ○ Had no prior ADT in the metastatic setting or initiated ADT within 6 months in the metastatic setting with no disease progression • Abiraterone may continue until disease progression or unacceptable toxicity Notes: • Metastatic prostate cancer is interpreted as distant metastatic disease (ie, positive bone scan or metastatic lesions on radiologic imaging for soft tissue; patients with disease limited to regional pelvic lymph nodes only are not eligible) • Patients who previously received adjuvant ADT in the non-metastatic setting are eligible as long as ADT was completed >1 year prior to initiation of abiraterone • Patients who received recent docetaxel chemotherapy for the treatment of mCSPC within the past 3 months are eligible if they have not experienced disease progression • Patients unable to tolerate abiraterone plus prednisone may be switched to either apalutamide or enzalutamide for treatment of mCSPC if there is no disease progression • Patients who experience disease progression on abiraterone plus prednisone for treatment of mCSPC are eligible for enzalutamide for treatment of mCRPC if they are unable to tolerate or are not candidates for other therapeutic choices (ie, chemotherapy) provided they have previously not experienced disease progression after prior treatment with other ARATs (e.g., apalutamide, darolutamide) in any setting	1. SCA Drug Formulary [3-22]

Alendronate	**Osteoporosis**	10 mg PO
		70 mg PO
			Multiple	Exception Drug Status Program[1,2]
				
				Eligibility[1,2]:
				• For the treatment of osteoporosis in patients with a 20% or greater 10-year fracture risk (determined by FRAX, CAROC tools)
				  ○ The Drug Plan will not require FRAX or CAROC documentation to be included with EDS applications for oral bisphosphonates
				OR
				• For the treatment of osteoporosis in patients with:
				  ○ Pre-existing and/or recent fragility fractures, OR
				  ○ Glucocorticoid treatment for a duration of 3 months or longer, OR
				  ○ Men on ADT for prostate cancer, OR
				  ○ Women on aromatase inhibitor therapy for breast cancer.
				OR
				• For treatment of osteogenesis imperfecta
					1. SK Drug Plan
					2. Exception Drug Status Program [2-22]

Apalutamide (Erleada) Janssen	**nmCRPC**	60 mg tab	Not specified	STEP special status*
				
				Eligibility[1]:
				• nmCRPC in combination with ADT in patients who:
				  ○ Have histologically or cytologically confirmed adenocarcinoma of the prostate without neuroendocrine differentiation, signet cell features, or small cell features
				  ○ Have no detectable distant metastases by either CT, MRI or technetium-99m bone scan, including any CNS, vertebral or meningeal involvement, but excluding pelvic lymph nodes <2 cm in short axis (N1) located below the common iliac vessels
				  ○ Are at high risk of developing metastases (PSADT of ≤ 10 months during continuous ADT)
				  ○ (if applicable) have demonstrated a further rise in PSA measured ≥ 6 weeks after discontinuing treatment with a first generation anti-androgen (e.g., bicalutamide)
				• Apalutamide may continue until radiographic disease progression or unacceptable toxicity
				
				Notes:
				• CRPC defined as 3 consecutive rises in PSA ≥1 week apart with the last PSA >2 mcg/L, during continuous ADT with castrate testosterone levels (<1.7 nmol/L)
				• If biochemical progression (rising PSA) occurs while on apalutamide, appropriate clinical evaluation and/or investigations for metastatic disease should be conducted in a timely manner
				• If progression to mCRPC occurs during apalutamide treatment for nmCRPC, abiraterone (not enzalutamide) is funded as a subsequent treatment option in patients who are unable to tolerate or are not candidates for other therapeutic choices (ie, chemotherapy)
				• If apalutamide was discontinued in the nmCRPC setting (e.g., due to intolerance) prior to development of metastatic disease, either abiraterone or enzalutamide is funded as an option for treatment at the time of progression to mCRPC
					1. SCA Drug Formulary [3-22]

	mCSPC	60 mg tab	Not specified	**Eligibility[1]:** • mCSPC in combination with ADT in patients who had no prior ADT in the metastatic setting or initiated ADT within 6 months in the metastatic setting with no disease progression • Apalutamide may continue until radiographic disease progression or unacceptable toxicity	2. SCA Drug Formulary [3-22] 1.

continued

Apalutamide (Erleada) Janssen	*continued from previous* **mCSPC**			Notes: • Metastatic prostate cancer is interpreted as distant metastatic disease (ie, positive bone scan or metastatic lesions on radiologic imaging for soft tissue; patients with disease limited to regional pelvic lymph nodes only are not eligible) • Patients who previously received adjuvant ADT in the non-metastatic setting are eligible as long as ADT was completed >1 year prior to initiation of apalutamide • Patients who received recent docetaxel chemotherapy for the treatment of mCSPC within the past 3 months are eligible if they have not experienced disease progression • Patients unable to tolerate apalutamide may be switched to either enzalutamide or abiraterone plus prednisone for treatment of mCSPC if there is no disease progression • Patients who experience disease progression on apalutamide for treatment of mCSPC are eligible for abiraterone plus prednisone for treatment of mCRPC if they are unable to tolerate or are not candidates for other therapeutic choices (ie, chemotherapy) provided they have previously not experienced disease progression on abiraterone in any setting	

Darolutamide (Nubeqa) Bayer	**nmCRPC**	300 mg PO	Not specified	STEP special status*
				
				Eligibility[1]:
				• nmCRPC in combination with ADT in patients who:
				  ○ Have histologically or cytologically confirmed adenocarcinoma of the prostate without neuroendocrine differentiation or small cell features
				  ○ Have no detectable distant metastases by either CT, MRI or technetium-99m bone scan, including any CNS, vertebral or meningeal involvement, but excluding pelvic lymph nodes <2 cm in short axis (N1) located below the common iliac vessels
				  ○ Are at high risk of developing metastases, defined as PSADT ≤10 months during continuous ADT
				  ○ (if applicable) have demonstrated a further rise in PSA, measured ≥ 6 weeks after discontinuing treatment with a first generation anti-androgen (e.g., bicalutamide)
				• Darolutamide may continue until radiographic disease progression or unacceptable toxicity
				
				Notes:
				• CRPC defined as 3 consecutive rises in PSA ≥1 week apart with the last PSA >2 mcg/L, during continuous ADT with castrate testosterone levels (<1.7 nmol/L)
				• If biochemical progression (rising PSA) occurs while on darolutamide, appropriate clinical evaluation and/or investigations for metastatic disease should be conducted in a timely manner
				• If progression to mCRPC occurs during darolutamide treatment for nmCRPC, abiraterone is funded as a treatment option
				• If darolutamide was discontinued in the nmCRPC setting (e.g., patient choice, intolerance) prior to the development of metastatic disease, either abiraterone or enzalutamide is funded as an option for treatment at the time of progression to mCRPC
					1. SCA Drug Formulary [3-22]

Denosumab (Prolia) Amgen	**Osteoporosis**	60 mg/mL Pre-filled Syringe	02343541	Exception Drug Status Program[1,2]
				
				Eligibility[1,2]:
				• To increase bone mass in men with osteoporosis who are at high risk for fracture or who have failed or are intolerant to other available osteoporosis therapy, where the following clinical criteria are met:
				  ○ High fracture risk defined as either:
				  ▪ Moderate 10-year fracture risk (10% to 20%) as defined by CAROC tool or the FRAX tool with a prior fragility fracture, OR
					1. SK Drug Plan
					2. Exception Drug Status Program

	continued from previous			▪ High 10-year fracture risk (≥ 20%) as defined by either the CAROC tool or the FRAX tool AND contraindication to oral bisphosphonates ○ Contraindication to oral bisphosphonates	
Denosumab (Prolia) Amgen	**Osteoporosis**			• For treatment of osteoporosis in patients with a moderate – high 10-year fracture risk (10% or more) and one of the following: ○ Men on androgen deprivation therapy for prostate cancer; OR ○ Women on aromatase inhibitor therapy for breast cancer. Notes[1,2]: • Bisphosphonate failure will be defined as a fragility fracture and/or evidence of a decline in bone mineral density below pre-treatment baseline levels, despite adherence for one year • Contraindication to oral bisphosphonates will be considered. Contraindications include renal impairment, hypersensitivity, and abnormalities of the esophagus (e.g., esophageal stricture or achalasia)	
Denosumab (Xgeva) Amgen	**mCRPC with Bone mets**	-	-	No listing as of Mar. 2022.	
Enzalutamide (Xtandi) Astellas	**mCRPC**	40 mg cap	Not specified	**Eligibility:** • mCRPC in patients who: ○ Have not previously received and experienced disease progression during apalutamide, enzalutamide or darolutamide used in any prior treatment setting ○ Have no risk factors for seizure Notes: • CRPC is defined as 3 consecutive rises in PSA ≥ 1 week apart with the last PSA >2 mcg/L, or progression or appearance of >2 lesions on bone scan or in soft tissue, during continuous ADT with castrate testosterone levels (<1.7 nmol/L)	1. SCA Drug Formulary [3-22]
	nmCRPC	40 mg cap	Not specified	STEP special status* **Eligibility:** • nmCRPC in combination with ADT in patients who: ○ Have histologically or cytologically confirmed adenocarcinoma of the prostate without neuroendocrine differentiation, signet cell features or small cell features ○ Have no detectable distant metastases by either CT, MRI or technetium-99m bone scan, including any CNS, vertebral or meningeal involvement, but excluding pelvic lymph nodes <2 cm in short axis (N1) located below the common iliac vessels ○ Are at high risk of developing metastases, defined as PSADT ≤10 months during continuous ADT ○ Have no risk factors for seizure ○ (if applicable) have demonstrated a further rise in PSA, measured ≥6 weeks after discontinuing treatment with a first generation anti-androgen (e.g., bicalutamide) • Enzalutamide may continue until radiographic disease progression or unacceptable toxicity. Notes: • CRPC is defined as 3 consecutive rises in PSA ≥1 week apart with the last PSA >2 mcg/L, during continuous ADTwith castrate testosterone levels (<1.7 nmol/L)	1. SCA Drug Formulary [3-22] •

Enzalutamide (Xtandi) Astellas	*continued from previous* **nmCRPC**			• If biochemical progression (rising PSA) occurs while on enzalutamide, appropriate clinical evaluation and/or investigations for metastatic disease should be conducted in a timely manner • If progression to mCRPC occurs during enzalutamide treatment for nmCRPC, abiraterone is funded as a treatment option • If enzalutamide was discontinued in the nmCRPC setting (e.g., patient choice, intolerance) prior to the development of metastatic disease, either abiraterone or enzalutamide is funded as an option for treatment at the time of progression to mCRPC	
	mCSPC	40 mg cap	-	**Eligibility:** • mCSPC in combination with ADT in patients who: o Have had no prior ADT in the metastatic setting, or initiated ADT within 6 months in the metastatic setting with no disease progression o Have no risk factors for seizure Notes: • Metastatic prostate cancer is interpreted as distant metastatic disease (ie, positive bone scan or metastatic lesions on radiologic imaging for soft tissue; patients with disease limited to regional pelvic lymph nodes only are not eligible) • Patients who previously received adjuvant ADT in the non-metastatic setting are eligible as long as ADT was completed >1 year prior to initiation of enzalutamide • Patients who received recent docetaxel chemotherapy for the treatment of mCSPC within the past 3 months are eligible if they have not experienced disease progression • Patients unable to tolerate enzalutamide may be switched to either apalutamide or abiraterone plus prednisone for treatment of mCSPC if there is no disease progression • Patients who experience disease progression on enzalutamide for treatment of mCSPC are eligible for abiraterone plus prednisone for treatment of mCRPC if they are unable to tolerate or are not candidates for other therapeutic choices (ie, chemotherapy) provided they have previously not experienced disease progression on abiraterone in any setting	1. SCA Drug Formulary [3-22]
Olaparib (Lynparza) AstraZeneca	**mCRPC**	-	-	No listing in prostate cancer as of Mar. 2022.	

*STEP (SCA Treatment Evaluation Program) is a special status designation within the Cancer Agency which is an internal registration or approval process to support the ability of the P&T Committee to monitor drug program use when required.

PATIENT ASSISTANCE PROGRAMS

HOME

Drug, Company	Indication	Program Name	Contact Information	Strength	DIN	Eligibility Criteria & Window	Support Offered
Abiraterone (Zytiga) Janssen Inc.	mCRPC	Janssen BioAdvance Patient Assistance Program	Phone: 1-844-511-2616 Fax: 1-855-629-7100 Email : zytiga@bioadvancemail.ca	250 mg PO 500mg PO	02371065 02457113	• Contact program	• Compassionate supply may be available • Financial assistance for patients with or without private insurance may be available
Abiraterone JAMP	mCRPC mCSPC	https://jampcare.ca/	Phone: 1-844-445-5267 Fax: 1-833-580-1263 Email :	250 mg PO	02502305	• Contact program	• No compassionate supply available • Financial assistance for patients with or without private insurance may be available (Copay Card)
Abiraterone PMS	mCRPC mCSPC	Ally Patient Support Program	Phone : 1-833-255-9100 Fax : 1-833-255-9544 Email: ally@patientassistance.ca	250 mg PO 500mg PO	02492601 02501503	• Contact program	• Compassionate supply may be available • Financial assistance for patients with or without private insurance may be available
Abiraterone Sandoz	mCRPC mCSPC		Phone: 1-888-672-6369 Fax: 1-833-835-6637 Email: support.continum@sandoz.com	250 mg PO	02486393	• Contact program	• No compassionate supply available • Financial assistance for patients with or without private insurance may be available
Apalutamide (Erleada) Janssen Inc.	nmCRPC mCSPC	Janssen BioAdvance Patient Assistance Program	Phone : 1-844-511-2616 Fax: 1-855-629-7100 Email: erleada@bioadvancemail.ca	60mg PO	02478374	• Contact program	• Compassionate supply may be available • Financial assistance for patients with or without private insurance may be available
Darolutamide (Nubeqa) Bayer Inc.	nmCRPC	DART: Darolutamide Access & Reimbursement Touchpoint	Dispensary: Shoppers Drug Mart Specialty Health Network Phone: 1-833-955-DART (3278) Fax: 1-877-208-4393 Email: info@dartsupport.ca	300mg PO	2496348	• Contact program • Program enrolment requires the completion of: **DART Enrolment form EN; DART Enrolment form FR**	• Compassionate supply may be available • Financial assistance for patients may be available • Reimbursement navigation support • Bridging may be available
Denosumab (Xgeva) Amgen Canada Inc.	Bone health mCRPC	VICTORY Program	Phone: 1-888-706-4717 Fax: 1-833-884-5608 Email: victory@adjuvantz.com	120 mg /1.7 mL SC	02368153	• Program enrolment requires the completion of: **VICTORY Enrolment form EN; VICTORY Enrolment form FR**	• No compassionate supply available • Financial assistance for patients with or without private insurance is available • Injection training support, reimbursement, and coverage navigation
Enzalutamide (Xtandi) Astellas Pharma Canada Inc.	mCSPC nmCRPC mCRPC	Xtandi Patient Assistance Program (XPAP)	Phone: 1-855-982-6348 Fax: 1-855-982-6349 Email: info@XTANDIassistanceprogram.ca	40 mg PO	02407329	• All mCSPC, high-risk nmCRPC, chemo naive mCRPC and post chemo mCRPC • Program enrolment only requires the completion of the **XPAP form EN; XPAP form FR**	• Compassionate supply may be available • Financial assistance for patients with or without private insurance may be available • Reimbursement services, speciality pharmacy services, nurse support services

continued

Olaparib (Lynparza) **AstraZeneca Canada Inc.**	BRCAm or ATMm mCRPC	AstraZeneca and Merck's Oncology Patient Support Program	Phone: 1-877-280-6208 Fax: 1-877-280-6221 Email: enrollment@azoncologypsp.ca	100 mg PO 150 mg PO	02475200 02475219	• Patients with mCRPC who have progressed on NHA (new hormonal agent) in any setting • ECOG PS 0-2 • Identified with a germline and/or somatic BRCA or ATM* (deleterious or suspected deleterious mutation by a validated laboratory test, no VUS) • Enrollment requires a validated lab report showing BRCA or ATM result and completed PSP enrolment form • Open: 25-January-2021 • Closed: 29-April-2022 *ATM testing all provinces except Quebec • †Closed in Alberta	• Patients who meet criteria are eligible for drug free of charge • Program will screen for insurance coverage • Co-pay assistance

Patient assistance program information can be found at: http://www.bccancer.bc.ca/systemic-therapy-site/Documents/Policy%20and%20Forms/Patient%20assistance%20programs.pdf [3-22]

DART PROGRAM ENROLMENT FORM

Phone: 1-833-955-DART (3278) Email: info@dartsupport.ca

Please fax completed form, including back page with patient signature, to 1-877-208-4393

DART
Darolutamide Access & Reimbursement Touchpoint
PATIENT SUPPORT PROGRAM

NUBEQA® (darolutamide) is indicated for the treatment of patients with non-metastatic castration resistant prostate cancer (nmCRPC).
NUBEQA has not been studied in patients with nmCRPC at low risk of developing metastasis. The benefit and risk profile in these patients is unknown.

PATIENT INFORMATION (must be completed – please print)

Last name	First name	Birth date DD / MM / YYYY	Language ☐ English ☐ French ☐ Other:
Address	City	Province/Territory	Postal code
Email		Messages may be left at: ☐ Home ☐ Cell/Alternate ☐ Email ☐ Text or SMS	
Home phone number	Cell/Alternate	Best time to call ☐ Morning ☐ Afternoon ☐ Evening	
Primary contact	Phone	Relationship	
Patient has private insurance ☐ Yes ☐ No ☐ Unknown		Required program services ☐ Bridging ☐ Financial assistance	

REFERRING CENTRE'S INFORMATION

Prescribing physician	License #
Clinic/treatment centre (address, floor, room number)	
Clinic phone / Clinic fax / Clinic email	
Nurse or drug access navigator (DAN) name: ☐ Same as clinic information above	
Nurse/DAN phone / Nurse/DAN fax / Nurse/DAN email	
Preferred method of contact ☐ Phone ☐ Fax ☐ Email	Preferred time of day for contact ☐ Morning ☐ Afternoon ☐ Evening

PRESCRIPTION INFORMATION (to be completed by the prescribing physician or sent as an attachment)

Medical diagnosis
☐ non-metastatic castration resistant prostate cancer

Prescription
☐ NUBEQA 300 mg tablet

Quantity/supply: Refills:

Dosing instructions
☐ 600 mg (two tablets of 300 mg) NUBEQA taken twice daily (1200 mg daily)
☐ Other (please specify):

Allergies: ☐ No ☐ Yes (please specify):

Physician signature

Date DD / MM / YYYY

MEDICAL INFORMATION (to be completed by the prescribing physician)

Prostate-Specific Antigen Doubling Time (PSADT) of ≤10 months: ☐ Yes ☐ No

Prescribed NUBEQA in combination with Androgen Deprivation Therapy (ADT): ☐ Yes ☐ No

Eastern Cooperative Oncology Group (ECOG) status:

Please refer to the Product Monograph for complete details on dosing and administration.

PATIENT AUTHORIZATION AND CONSENT TO ENROLMENT
(verbal authorization and HCP signature required if NOT signed by patient)

The DART Patient Support Program ("Program") is funded by Bayer Inc., 2920 Matheson Blvd. E, Mississauga, ON L4W 5R6 ("Bayer"). The service provider acting on behalf of Bayer is Shoppers Drug Mart Specialty Health Network, 1685 Tech Avenue, Mississauga, Ontario, L4W 0A7 ("Service Provider").

You are being invited to take part in the DART Patient Support Program for patients who have been prescribed NUBEQA (darolutamide) for the treatment of non-metastatic castration resistant prostate cancer (nmCRPC). Before you decide whether to participate or not, please take the time to read the following information to understand why this program has been set up and what it will involve.

The purpose of the Program is to provide reimbursement navigation assistance, education, and in certain circumstances financial support during your treatment with NUBEQA.

It is up to you whether or not you want to take part in this program. If you decide not to participate, this will not affect your standard medical care. You can change your mind at any time during the program without giving a reason. Ask your treating healthcare professional/program contact partner if there is anything that is not clear or if you would like more information. If you wish to participate in the program, you will be given a copy of this information sheet to keep and be asked to sign the consent section. There will be no additional cost to you for your participation in the Program.

WHAT WILL HAPPEN WITH YOUR PERSONAL DATA IF YOU JOIN THE PROGRAM

Personal Data

If you wish to participate in this program, it will be necessary to handle your personal data in order to run the program. Below, you will be asked to provide your consent for processing of your personal data. Your data is also processed to ensure high standards of quality and safety of medicinal products and to ensure the scientific integrity of the program.

For this program, "personal data" can include any information relating to you. It may include, for example: information to arrange your participation in the program that directly identifies you (such as your name, address, telephone number, health insurance number, age, gender); information on your health and medical condition including your medical history; your treatments and your response to treatments.

"Handling of your personal data" means collecting, storing, analyzing or transmitting your personal data to the Service Provider

Your personal data is confidential and will only be shared with your treating healthcare professional(s) and their staff and the Service Provider. In addition, some of your personal data may be shared with:

- Bayer's Pharmacovigilance Departments for processing and reporting obligations in the event that you have an adverse event, product technical complaint or usability issue or other safety-related event. Processing of respective personal data may be supported by Bayer entities or service providers in countries that have a different data privacy level than your country. In this case, Bayer will contractually ensure an appropriate data protection level;
- Bayer's auditors for audit and inspection reasons to ensure the program is run properly;
- Regulatory Authorities to comply with legal requirements like reporting of adverse events, and to make sure the program is run properly;
- And with a new Service Provider in case the services under the program are transferred to a new provider.

These people must keep your data private.

The Service Provider, program contact partner and/or treating healthcare professional may share aggregated data about the program with Bayer to improve patient care; plan future programs; create educational and informative materials; and publish results or presentations. This aggregated data will not identify you.

Your data will be locally stored by the Service Provider for at least 7 years after the end of the Program, or longer if needed for the purposes above or for legal reasons.

Your rights with respect to your personal data

To take part in this program means you need to agree to the collection and handling of your personal data as described above. Once collected, your personal data is required to meet obligations from regulatory health authorities and help develop programs to high standards of safety and quality.

Your personal data are protected by data privacy laws which ensure you have the following rights to:

- Withdraw your consent to handle your personal data at any time without having to justify your decision. This would mean that you cannot continue to participate in the program and no further personal data about you will be collected. Please note the data already collected so far based on your initial consent may not be deleted if required for regulatory purposes like adverse event reporting obligations, or to ensure the scientific integrity of the program;
- Request information about the handling of your personal data, a copy of your personal data collected or deletion of your data. Please note, to ensure compliance with regulatory requirements like adverse event reporting obligations, a deletion may not be possible;
- Request correction of your personal data if it is wrong or not complete;
- Request to limit the handling of your personal data. This may mean that you cannot further participate in the program. Where the handling of your personal data is required to fulfill regulatory obligations like adverse event reporting, a limitation may not be possible;
- File a complaint with a data protection authority.

For any information about your data and your rights or if you want to exercise any of your rights with respect to your personal data, please address your request to the Service Provider's Privacy Officer at 1-855-454-3800.

INFORMED CONSENT

Patient Declaration:

I confirm that:

- I have had the opportunity to discuss the Program with my healthcare provider, have read this document and understand the program being offered, and I have had all of my questions answered
- I understand that I will receive a copy of this Form once I have signed it
- I understand that Program services begin after the physician's prescription and enrolment into the program
- The Service Provider may reach out to me to discuss my personal insurance information, and for the administration of patient satisfaction surveys
- I understand that the service is provided free of charge by the Service Provider on behalf of Bayer and that Bayer can modify or cancel this Program and the associated service(s) at any time
- The Service Provider may communicate with me via phone, SMS text message and/or e-mail in order to support my participation in the Program
- The Service Provider may contact me for the follow-up of adverse events, product technical complaints and/or usability issues or other safety related events
- Bayer Pharmacovigilance Department may contact the Service Provider and/or my treating healthcare professional for the follow-up of adverse events, product technical complaints and/or usability issues or other safety related events
- If I am enrolled in a Bayer-led NUBEQA study, and any adverse events are reported, Bayer Pharmacovigilance may cross-reference for reported events through the study
- I understand that my decision to take part in the Program is entirely voluntary. I can decide to leave the Program at any time without affecting my standard of medical care.
- I agree to participate in the Program as described in this document

Declaration concerning data protection:

My consent to the following allows for the handling of my personal data. My consent is voluntary. It will allow my participation in the Program. Once my personal data has been collected, it may be required for ensuring high standards of quality and safety of medicinal products and to ensure the scientific integrity of the program:

- I consent to the processing of my personal data as described in this document. Personal data includes the following sensitive data: health related data.
- I agree that in case of any adverse event/product technical complaint/usability issue or other safety and quality related events, necessary information will be forwarded to Bayer's local Pharmacovigilance unit and health authorities, as required for reporting purposes
- I agree that in case of audit or inspection, necessary information will be shared with auditors and/or health authorities, as required
- I am aware that I may withdraw my participation in the program and my consent to the further processing of my personal data without any impact on my standard medical care at any time without justifying my decision. The withdrawal of my consent for processing my data does not affect the lawfulness of the processing of my personal data collected before the withdrawal.
- I am aware that in case of withdrawal, my already collected personal data may be further processed in accordance with applicable laws, if required to meet obligations from health authorities

I, the undersigned, have read and agree to the terms of this consent form, including the privacy terms, and I understand and agree to the services offered by the DART Patient Support Program.	
Patient signature	Date DD / MM / YYYY
If your patient is unable to provide a signature but would still like to participate, please check the box below: ☐ I confirm that my patient is unable to provide a signature but has verbally provided consent to participate in the Program.	Date DD / MM / YYYY

Consult the Product Monograph at https://www.bayer.com/sites/default/files/2020-11/nubeqa-pm-en.pdf for contraindications, warnings, precautions, adverse reactions, interactions, dosing and conditions of clinical use. The Product Monograph is also available by calling Bayer Medical Information at 1-800-265-7382.

PP-NUB-CA-0141-1
NBQ029E

NUBEQA® (darolutamide) 300 mg tablets

FORMULAIRE D'INSCRIPTION AU PROGRAMME DART

Téléphone : 1-833-955-DART (3278) Adresse électronique : info@dartsupport.ca

DART
Darolutamide–Accès et Remboursement Tout-en-un
PROGRAMME DE SOUTIEN AUX PATIENTS

Veuillez envoyer le formulaire dûment rempli par télécopieur, y compris la page du verso portant la signature du patient, au 1-877-208-4393.

NUBEQA® (darolutamide) est indiqué pour le traitement des patients atteints de cancer de la prostate résistant à la castration non métastatique (CPRCnm).
NUBEQA n'a pas été étudié chez les patients atteints de CPRCnm à faible risque de métastases. Le profil bienfaits-risques chez ces patients est inconnu.

RENSEIGNEMENTS SUR LE PATIENT

Nom de famille	Prénom DD	Date de naissance MM / YYY /	Langue ☐ Anglais ☐ Français ☐ Autre :
Adresse		Ville	Province/Territoire / Code postal
Adresse électronique		Possibilité de laisser un message : ☐ Tél. à domicile ☐ Cellulaire/Autre tél. ☐ Courriel ☐ Message texte ou SMS	
Téléphone à domicile	Cellulaire/Autre	Meilleur moment pour appeler : ☐ Matin ☐ Après-midi ☐ Soir	
Principale personne-ressource	Téléphone	Lien	
Le patient souscrit une assurance privée ☐ Oui ☐ Non ☐ Renseignements non disponibles		Services du programme demandés ☐ Transition ☐ Aide financière	

RENSEIGNEMENTS SUR LE CENTRE ORIENTEUR

Médecin prescripteur		Numéro de permis d'exercice :
Clinique/centre de traitement (adresse, étage, numéro de pièce)		
Téléphone de la clinique	Télécopieur de la clinique	Adresse électronique de la clinique
Nom de l'infirmière ou de l'intervenant en accès aux médicaments : ☐ Identique aux renseignements de la clinique ci-dessus		
Téléphone de l'infirmière ou de l'intervenant en accès aux médicaments	Télécopieur de l'infirmière ou de l'intervenant en accès aux médicaments	Adresse élec. de l'infirmière ou de l'intervenant en accès aux médicaments
Mode de contact de préférence ☐ Téléphone ☐ Télécopieur ☐ Courriel	Moment préféré de la journée pour prendre contact ☐ Matin ☐ Après-midi ☐ Soir	

RENSEIGNEMENTS SUR L'ORDONNANCE (à remplir par le médecin prescripteur ou envoyer en pièce jointe)

Diagnostic médical
☐ cancer de la prostate résistant à la castration non métastatique

Ordonnance
☐ Comprimé de NUBEQA à 300 mg

Quantité/approvisionnement : Renouvellements :

Posologie
☐ 600 mg (deux comprimés de 300 mg) de NUBEQA, deux fois par jour (1 200 mg par jour)
☐ Autre (veuillez préciser) :

Allergies : ☐ Non ☐ Oui (préciser) :

Signature du médecin

Date
JJ / MM / AAAA

RENSEIGNEMENTS MÉDICAUX (à remplir par le médecin prescripteur)

Temps de doublement de l'antigène prostatique spécifique (TDAPS) ≤ 10 mois : ☐ Oui ☐ Non

NUBEQA prescrit en combinaison avec un traitement antiandrogénique (TAT) : ☐ Oui ☐ Non

État de l'Eastern Cooperative Oncology Group :

Consulter la monographie pour obtenir tous les renseignements concernant la posologie et l'administration.

AUTORISATION DU PATIENT ET CONSENTEMENT À L'INSCRIPTION

(L'autorisation verbale et la signature d'un professionnel de la santé sont exigées si le patient N'A PAS signé l'autorisation et le consentement.)

Le Programme de soutien aux patients DART (le « programme ») est financé par Bayer Inc., dont les bureaux sont situés au 2920, boulevard Matheson Est, Mississauga (Ontario) L4W 5R6 (« Bayer »). Le fournisseur de services agissant au nom de Bayer est le Réseau de santé spécialisé Shoppers Drug Mart/Pharmaprix, dont les bureaux se trouvent au 1685, avenue Tech, Mississauga (Ontario) L4W 0A7 (le « fournisseur de services »).

Vous êtes invité à participer au programme de soutien aux patients DART destiné aux patients à qui l'on a prescrit NUBEQA (darolutamide) pour traiter un cancer de la prostate résistant à la castration non métastatique (CPRCnm). Avant de décider de participer ou non, prenez le temps de lire les renseignements suivants sur le programme pour bien comprendre les raisons qui ont mené à son existence et ce qu'il implique.

L'objectif de ce programme est de fournir de l'assistance en matière de remboursement, des renseignements et, dans certaines circonstances, une aide financière pendant votre traitement par NUBEQA.

Votre participation à ce programme est volontaire. Votre refus d'y participer n'aura aucun effet sur les soins médicaux standards que vous recevez. Vous pouvez changer d'avis à n'importe quel moment pendant le programme, sans avoir à donner de raison. Si vous souhaitez obtenir des précisions ou de plus amples renseignements, adressez-vous à votre professionnel de la santé ou à la personne-ressource du programme. Si vous désirez participer au programme, vous recevrez une copie du présent feuillet d'information, que vous pourrez garder. On vous demandera aussi de signer la section afférente au consentement. La participation à ce programme n'entraîne aucuns frais supplémentaires.

QUE FERONS-NOUS DE VOS DONNÉES PERSONNELLES SI VOUS VOUS INSCRIVEZ AU PROGRAMME?

Données personnelles

Si vous souhaitez participer à ce programme, il sera nécessaire d'obtenir vos données personnelles aux fins de gestion du programme. On vous demandera ci-dessous de consentir au traitement de vos données personnelles. Vos données sont également traitées pour garantir des normes élevées en matière de qualité et d'innocuité des produits médicaux et assurer l'intégrité scientifique du programme.

Dans le cadre de ce programme, les « données personnelles » comprennent toute information qui vous concerne. Il s'agit, entre autres, de renseignements permettant d'assurer votre participation au programme et qui vous identifient directement (comme votre nom, votre adresse, votre numéro de téléphone, votre numéro d'assurance maladie, votre âge et votre sexe); de renseignements sur votre santé et votre problème médical, y compris vos antécédents médicaux; de renseignements sur vos traitements et sur votre réponse aux traitements.

Le « traitement de vos données personnelles » signifie la collecte, la conservation, l'analyse et la transmission de vos données personnelles au fournisseur de services.

Vos données personnelles sont confidentielles et ne seront communiquées qu'aux professionnels de la santé qui vous traitent et leur personnel, ainsi qu'au fournisseur de services. De plus, certaines de vos données personnelles pourraient être communiquées :

- au Service de la pharmacovigilance de Bayer, pour répondre à nos obligations sur le plan du traitement et du signalement des effets indésirables, des plaintes techniques liées au produit, de problèmes d'utilisation ou de tout autre effet en lien avec l'innocuité du produit. Le traitement des données personnelles respectives pourrait être réalisé par des entités de Bayer ou des fournisseurs de service faisant affaire avec Bayer situés dans des pays offrant une protection différente de celle de votre pays de résidence en matière de confidentialité. Dans un tel cas, Bayer sera contractuellement tenue d'assurer un niveau de protection approprié;
- aux vérificateurs de Bayer à des fins de vérification et d'inspection dans le but d'assurer le déroulement adéquat du programme;
- aux autorités sanitaires pour se plier aux exigences légales, comme le signalement des effets indésirables, et veiller au bon fonctionnement du programme; et
- à un nouveau fournisseur de services dans le cas où les services du programme seraient transférés à un autre fournisseur.

Ces personnes sont tenues d'assurer la confidentialité de vos données personnelles.

Le fournisseur de services, la personne-ressource du programme et/ou le professionnel de la santé qui vous traite pourraient communiquer des données groupées sur le programme à Bayer dans le but d'améliorer les soins prodigués aux patients, de mettre sur pied d'autres programmes à l'avenir, de créer des documents de formation et d'information et de publier des résultats ou de faire des présentations. Les données groupées ne permettront en aucun cas de vous identifier.

Vos données seront conservées localement par le fournisseur de services pendant au moins 7 ans après la fin du programme, ou pendant plus longtemps aux fins décrites ci-dessus ou pour des raisons d'ordre juridique.

Vos droits en ce qui concerne les données personnelles

Pour participer à ce programme, vous devez autoriser la collecte et le traitement de vos données personnelles, de la manière décrite ci-dessus. Une fois recueillies, vos données personnelles sont nécessaires pour répondre aux exigences des autorités de réglementation de la santé et mettre au point des programmes selon des normes d'innocuité et de qualité élevées.

Vos données personnelles sont protégées par les lois relatives à la protection des données, qui vous garantissent les droits suivants :

- Le droit de retirer votre consentement en vue du traitement de vos données personnelles en tout temps, sans avoir à justifier votre décision. Si vous exercez ce droit, vous ne pourrez pas continuer de participer au programme et aucune autre donnée personnelle ne sera recueillie à votre sujet. Veuillez noter que les données déjà recueillies conformément à votre consentement initial pourraient ne pas être supprimées si elles sont exigées à des fins réglementaires, comme le signalement d'effets indésirables, ou pour assurer l'intégrité scientifique du programme.
- Le droit de demander de l'information sur le traitement de vos données personnelles, un exemplaire des données personnelles recueillies ou la suppression de vos données. Veuillez noter que pour assurer le respect des exigences réglementaires, comme le signalement des effets indésirables, il pourrait ne pas être possible de supprimer les données.
- Le droit de demander de corriger vos données personnelles si elles sont erronées ou incomplètes.
- Le droit de limiter le traitement de vos données personnelles. Ce faisant, il est possible que vous ne puissiez pas continuer de participer au programme. Lorsque le traitement de vos données personnelles est nécessaire pour répondre aux exigences réglementaires, comme le signalement des effets indésirables, une utilisation limitée pourrait s'avérer impossible.
- Le droit de déposer une plainte auprès d'une autorité responsable de la protection des données.

Pour toute information au sujet de vos données et de vos droits, ou si vous souhaitez exercer vos droits en ce qui a trait aux données personnelles, veuillez acheminer votre demande à l'agent de protection des renseignements personnel du fournisseur de services au 1-855-454-3800.

CONSENTEMENT ÉCLAIRÉ

Déclaration du patient :
Je confirme ce qui suit :

- J'ai eu l'occasion de discuter du programme avec mon professionnel de la santé, j'ai lu ce document et je comprends le programme offert et j'ai obtenu des réponses à toutes mes questions.
- Je comprends que je recevrai une copie du présent formulaire une fois que je l'aurai signé.
- Je comprends que les services du programme commenceront après que le médecin m'aura prescrit le médicament et que je serai inscrit au programme.
- Le fournisseur de services pourrait communiquer avec moi pour discuter de mes renseignements personnels pour ce qui est de mes assurances et pour des sondages sur la satisfaction du patient.
- Je comprends que ce service est donné sans frais par le fournisseur de services au nom de Bayer, et que Bayer peut modifier ou annuler ce programme et les services associés en tout temps.
- Le fournisseur de services pourrait communiquer avec moi par téléphone, message texte et/ou courriel afin de soutenir ma participation au programme.
- Le fournisseur de services pourrait communiquer avec moi pour effectuer un suivi concernant des effets indésirables, des plaintes techniques sur le produit et/ou des problèmes d'utilisation ou d'autres effets liés à l'innocuité.
- Le Service de la pharmacovigilance de Bayer pourrait communiquer avec le fournisseur de services et/ou le professionnel de la santé qui me traite pour effectuer un suivi des effets indésirables, des plaintes techniques sur le produit et/ou des problèmes d'utilisation ou d'autres effets liés à l'innocuité.
- Si je suis inscrit à une étude sur NUBEQA menée par Bayer et qu'un quelconque effet indésirable est signalé, le Service de la pharmacovigilance de Bayer pourra effectuer un recoupement des effets signalés durant toute l'étude.
- Je comprends que ma décision de participer au programme est entièrement volontaire. Je peux décider de quitter le programme en tout temps, sans compromettre la qualité de mes soins.
- J'accepte de participer au programme tel qu'il est décrit dans le présent document.

Déclaration concernant la protection des données :

Mon consentement aux suivantes permet le traitement de mes renseignements personnels. Mon consentement est volontaire. Il permettra ma participation au programme. Une fois mes données personnelles recueillies, celles-ci pourraient également être traitées pour garantir des normes élevées en matière de qualité et d'innocuité des produits médicaux et pour assurer l'intégrité scientifique du programme :

- Je consens au traitement de mes données personnelles de la manière décrite dans le présent document. Les données personnelles incluent les données sensibles suivantes : renseignements relatifs à la santé.
- J'accepte que, dans l'éventualité d'un effet indésirable, d'une plainte technique sur le produit, d'un problème d'utilisation ou d'un autre effet en lien avec l'innocuité et la qualité, les renseignements nécessaires soient envoyés au Service local de la pharmacovigilance de Bayer et aux autorités sanitaires, aux fins de production des rapports exigés.
- J'accepte que, dans l'éventualité d'une vérification ou d'une inspection, les renseignements nécessaires soient transmis aux vérificateurs et/ou aux autorités sanitaires, comme exigé.
- Je sais que je peux me retirer du programme et retirer mon consentement au traitement futur de mes données personnelles sans que cela ait des répercussions sur mes soins médicaux standards, et ce, à n'importe quel moment et sans avoir à justifier ma décision. Le retrait de mon consentement au traitement de mes données n'a pas de répercussions sur la légalité du traitement de mes données personnelles recueillies avant le retrait.
- Je sais que dans le cas où je retirerais mon consentement, les données personnelles déjà recueillies à mon sujet pourraient continuer d'être traitées, conformément aux lois applicables, comme exigées pour remplir les obligations des autorités sanitaires.

Je, soussigné, ai lu et accepte les modalités et conditions de ce formulaire de consentement, y compris les conditions concernant le respect de la vie privée, et je comprends et accepte les services offerts par le programme de soutien aux patients DART.	
Signature du patient	Date JJ / MM / AAAA
Si votre patient n'est pas en mesure de fournir une signature, mais qu'il souhaite malgré tout participer, veuillez cocher la case ci-dessous : ☐ Je confirme que mon patient n'est pas en mesure de fournir une signature, mais qu'il a donné son consentement verbal pour participer au programme.	Date JJ / MM / AAAA

Veuillez consulter la monographie au https://www.bayer.com/sites/default/files/2020-11/nubeqa-pm-fr.pdf pour connaître les contre-indications, les mises en garde, les précautions, les réactions indésirables, les interactions, la posologie et les conditions de l'utilisation clinique. Vous pouvez également obtenir la monographie en téléphonant au Service de l'information médicale de Bayer au 1-800-265-7382.

PP-NUB-CA-0141-1
NBQ029F

MEMBRE DE MÉDICAMENTS NOVATEURS CANADA

RÉVISÉ PAR CCPP

NUBEQA® (darolutamide) Comprimé pelliculé à 300 mg

Patient Enrolment Form for the VICTORY® Program
(by Amgen Entrust™ Patient Support Services*)

VICTORY® Program
Patient Assistance Program
By AMGEN Entrust™

Instructions

Enrol your patient in the VICTORY® Program by:

Having them download and complete the form available at VictoryAssist.ca and faxing it to **1-833-884-5608**

or

Completing this form and faxing it to **1-833-884-5608**

or

Contacting a VICTORY® Program Reimbursement Specialist by phone at **1-888-706-4717**

A VICTORY® Program Reimbursement Specialist will call the patient within one business day.

Prescriber information:

Name of physician _____ Phone _____

Name of pharmacist _____ Phone _____

Office contact person _____ Email _____ Phone _____

Patient information:

Name _____

Date of birth (DD / MM / YYYY) _____

Address _____

City _____ Province _____ Postal code _____

Home phone _____ Business phone _____

Preferred time to call: ❑ a.m. ❑ p.m. ❑ Okay to leave a message

Please specify primary language (or provide an alternate contact who speaks English/French for purposes relating to your enrolment). _____

Email† _____

*Amgen Entrust™ is our new, unified patient support services platform, built on the legacy of our branded support programs.

†I agree to receive electronic communications from McKesson Canada Corporation ("McKesson") acting on behalf of Amgen Canada Inc. containing information and updates relating to my enrolment in the VICTORY® Program. I understand that I may withdraw my consent to such communications at any time by providing notice to McKesson at 70 Wynford Drive, P.O. Box 383, North York, ON M3C 2S7 or via email at victory@adjuvantz.com.

Prescribed treatment:

❑ **PrAranesp®** (darbepoetin alfa)
[ ] DIN: 02391775 (100 mcg/syringe)
[ ] DIN: 02391783 (130 mcg/syringe)
[ ] DIN: 02391791 (150 mcg/syringe)
[ ] DIN: 02391805 (200 mcg/syringe)
[ ] DIN: 02391821 (300 mcg/syringe)
[ ] DIN: 02392364 (500 mcg/syringe)
[ ] Other: _____mcg/syringe

❑ **PrBLINCYTO®** (blinatumomab)
[ ] DIN: 02450283 (38.5 mcg/vial)

❑ **PrKANJINTI®** (trastuzumab for injection)
[ ] DIN: 02496690 (420 mg/vial)

❑ **PrKyprolis®** (carfilzomib for injection)
[ ] DIN: 02459930 (10 mg/vial)
[ ] DIN: 02459949 (30 mg/vial)
[ ] DIN: 02451034 (60 mg/vial)
[ ] KRd twice weekly
[ ] Kd twice weekly
[ ] Kd once weekly
[ ] KdD twice weekly

❑ **PrLUMAKRAS™** (sotorasib tablets)
[ ] DIN: 02520095 (120 mg)

❑ **PrMVASI®** (bevacizumab for injection)
[ ] DIN: 02470748 (100 mg [25 mg/mL])
[ ] DIN: 02470756 (400 mg [25 mg/mL])

❑ **PrNeulasta®** (pegfilgrastim injection)
[ ] DIN: 02249790 (6 mg [10 mg/mL])

❑ **PrNEUPOGEN®** (filgrastim injection)
Vials:
[ ] DIN: 01968017 (300 mcg/1.0 mL)
[ ] DIN: 01968017 (480 mcg/1.6 mL)
Pre-filled syringes:
[ ] DIN: 02420104 (300 mcg/0.5 mL)
[ ] DIN: 02420112 (480 mcg/0.8 mL)

❑ **PrNplate®** (romiplostim for injection)
[ ] DIN: 02322854 (250 mcg/0.5mL)
[ ] DIN: 02322862 (500 mcg/1.0mL)

❑ **PrRIABNI™** (rituximab for injection)
[ ] DIN: 02513447 (100 mg [10 mg/mL])
[ ] DIN: 02513447 (500 mg [10 mg/mL])

❑ **PrVectibix®** (panitumumab)
[ ] DIN: 02308487 (100 mg [20 mg/mL])
[ ] DIN: 02308509 (400 mg [20 mg/mL])
[ ] 6 mg/kg

❑ **PrXGEVA®** (denosumab injection)
[ ] DIN: 02368153 (120 mg/1.7 mL)

Is the patient covered by a private drug insurance plan?

❑ Yes ❑ No ❑ Unsure

Is the patient covered by a public plan?

❑ Yes ❑ No ❑ Unsure

If YES, has an application been sent to request the treatment authorization?

❑ Yes ❑ No

Consent:

By signing this form, I acknowledge that I have read and understand the legal information (as described in full on the back of this form) and consent to the collection, use, and disclosure of my personal information, including personal health information, by McKesson, Amgen, and Amgen's agents and service providers, as explained on the back of this form. I further consent to being contacted from time to time by McKesson, Amgen, or Amgen's agents and service providers for the above-noted purposes.

Patient signature _____ Date _____

We thank you for your cooperation and assistance.

AMGEN®

Legal Information:

The VICTORY® Program ("Program") is sponsored by Amgen Canada Inc. ("Amgen") and administered by McKesson, a third-party service provider, on behalf of Amgen. Other service providers may be appointed by Amgen to administer the Program from time to time. The personal information that you and/or your healthcare providers (including your doctor and pharmacy), insurers, or payers provide to the Program, including your name, contact information, and prescription information, will be used to manage and administer the Program, including provision of Program services to you, such as reimbursement assistance and administering, training or assisting in therapy (e.g. self-injection training), and provision of information about the Program to you.

Amgen has a legal obligation to report adverse drug events to various local and international health authorities and to monitor product complaints. Personal information provided to the Program may be (i) monitored by Amgen or its service providers for safety-related data and product complaints in order to ensure compliance with these legal reporting requirements, and (ii) reported to local or international health authorities. Amgen may contact you or your physician for additional information to fulfill its reporting obligations. Your personal information may be combined with the information of others who participate in the Program in order to generate aggregated data that does not contain identifying information ("Aggregated Data"). Aggregated Data may be used by Amgen and its service providers to improve and/or refine the Program, to design and implement other patient programs, and for research purposes, including the identification of trends such as product utilization, adherence, or outcomes.

For these sole purposes, McKesson may, on a confidential basis, collect your personal information and share it with your healthcare providers, insurers and/or other payers, and Amgen and/or Amgen's agents and service providers (e.g. information technology providers). If, from time to time, another service provider is appointed by Amgen to administer the Program, your personal information will be transferred to this service provider to ensure the continuity of the Program services to you. Please note that Amgen and its service providers may store or process your personal information outside of Canada (including in the United States), where local laws may require the disclosure of personal information to governmental authorities under circumstances that are different than those that apply in Canada. In addition, your personal information may be used or disclosed to third parties when permitted or required by applicable laws, court orders, or government regulations (collectively, "Applicable Laws").

Your personal information will be retained only for as long as is needed to fulfill the purposes for which it was collected and in order to comply with Applicable Laws. Industry-standard safeguards will be used to protect the security of the personal information that is collected. You may contact the Program's Privacy Officer at any time to update or access your personal information, modify or withdraw your consent (in part or in full), express a privacy-related concern, or inquire about the privacy practices of the Program (including those related to foreign processing). The Privacy Officer can be reached by email at privacycanada@amgen.com or by mail at Amgen Canada Inc., Attn: Chief Privacy Officer, 6775 Financial Drive, Suite 100, Mississauga, ON L5N 0A4. Please note that if you modify or withdraw your consent, your ability to receive the Program services may be limited.

MEMBER OF INNOVATIVE MEDICINES CANADA

REVIEWED BY PAAB

AMGEN®

Formulaire d'inscription du patient au programme VICTOIRE[MD] (par l'entremise des services de soutien aux patients Amgen Entrust[MC] *)

Programme **VICTOIRE**[MD]
Programme d'aide aux patients
par AMGEN Entrust[MC]

Instructions

Inscrivez votre patient au programme VICTOIRE[MD] comme suit :

Demandez-lui de télécharger et de remplir le formulaire disponible en ligne au VictoireAide.ca et télécopiez-le au **1-833-884-5608**

ou

Remplissez le présent formulaire et télécopiez-le au **1-833-884-5608**

ou

Communiquez avec un spécialiste en remboursement des médicaments du programme VICTOIRE[MD] au **1-888-706-4717**

Un spécialiste en remboursement des médicaments du programme VICTOIRE[MD] appellera le patient dans un délai d'un jour ouvrable.

Renseignements sur le médecin prescripteur :

Nom du médecin _____ Téléphone _____

Nom du pharmacien _____ Téléphone _____

Nom de la personne-ressource _____ Courriel _____ Téléphone _____

Renseignements sur le patient :

Nom _____

Date de naissance (AAAA / MM / JJ) _____

Adresse _____

Ville _____ Province _____ Code postal _____

Téléphone (résidence) _____ Téléphone (travail) _____

Meilleur moment pour appeler : ❑ Matin ❑ Après-midi ❑ Permission de laisser un message

Veuillez préciser votre langue maternelle (ou indiquer les coordonnées d'une personne-ressource anglophone ou francophone que nous pourrions contacter au sujet de votre inscription). _____

Courriel† _____

* Amgen Entrust[MC] est notre nouvelle plateforme intégrant tous les services de soutien aux patients, bâtie sur l'héritage des programmes de soutien de nos marques.

† J'accepte de recevoir, par voie électronique, des renseignements et des mises à jour au sujet de mon inscription au programme VICTOIRE[MD] provenant de la Corporation McKesson Canada (« McKesson »), agissant au nom d'Amgen Canada Inc. Je sais que je peux, en tout temps, retirer mon consentement à recevoir ces renseignements en avisant McKesson par la poste, au 70 Wynford Drive, B.P. 383, North York (Ontario) M3C 2S7, ou par courriel, à l'adresse victory@adjuvantz.com.

Traitement prescrit :

❑ **[Pr]Aranesp[MD]** (darbépoétine alfa)
- [ ] DIN : 02391775 (100 µg/seringue)
- [ ] DIN : 02391783 (130 µg/seringue)
- [ ] DIN : 02391791 (150 µg/seringue)
- [ ] DIN : 02391805 (200 µg/seringue)
- [ ] DIN : 02391821 (300 µg/seringue)
- [ ] DIN : 02392364 (500 µg/seringue)
- [ ] Autre : _____µg/seringue

❑ **[Pr]BLINCYTO[MD]** (blinatumomab)
- [ ] DIN : 02450283 (38,5 mcg/flacon)

❑ **[Pr]KANJINTI[MD]** (trastuzumab pour injection)
- [ ] DIN : 02496690 (420 mg/flacon)

❑ **[Pr]Kyprolis[MD]** (carfilzomib pour injection)
- [ ] DIN : 02459930 (10 mg/flacon)
- [ ] DIN : 02459949 (30 mg/flacon)
- [ ] DIN : 02451034 (60 mg/flacon)
  - [ ] KRd deux fois par semaine
  - [ ] Kd deux fois par semaine
  - [ ] Kd une fois par semaine
  - [ ] KdD deux fois par semaine

❑ **[Pr]LUMAKRAS[MC]** (comprimés de sotorasib)
- [ ] DIN : 02520095 (120 mg)

❑ **[Pr]MVASI[MD]** (bevacizumab pour injection)
- [ ] DIN : 02470748 (100 mg [25 mg/mL])
- [ ] DIN : 02470756 (400 mg [25 mg/mL])

❑ **[Pr]Neulasta[MD]** (pegfilgrastim injection)
- [ ] DIN : 02249790 (6 mg [10 mg/mL])

❑ **[Pr]NEUPOGEN[MD]** (filgrastim injection)

Flacons :
- [ ] DIN : 01968017 (300 mcg/1,0 mL)
- [ ] DIN : 01968017 (480 mcg/1,6 mL)

Seringues préremplies :
- [ ] DIN : 02420104 (300 mcg/0,5 mL)
- [ ] DIN : 02420112 (480 mcg/0,8 mL)

❑ **[Pr]Nplate[MD]** (romiplostim pour injection)
- [ ] DIN : 02322854 (250 mcg/0,5mL)
- [ ] DIN : 02322862 (500 mcg/1,0mL)

❑ **[Pr]RIABNI[MC]** (rituximab pour injection)
- [ ] DIN : 02513447 (100 mg [10 mg/mL])
- [ ] DIN : 02513447 (500 mg [10 mg/mL])

❑ **[Pr]Vectibix[MD]** (panitumumab)
- [ ] DIN : 02308487 (100 mg [20 mg/mL])
- [ ] DIN : 02308509 (400 mg [20 mg/mL])
  - [ ] 6 mg/kg

❑ **[Pr]XGEVA[MD]** (denosumab injection)
- [ ] DIN : 02368153 (120 mg/1,7 mL)

Le patient est-il couvert par un régime privé d'assurance médicaments?

❑ Oui ❑ Non ❑ Incertain

Le patient est-il assuré par un régime public?

❑ Oui ❑ Non ❑ Incertain

DANS L'AFFIRMATIVE, est-ce qu'une demande d'autorisation du traitement a été envoyée?

❑ Oui ❑ Non

Consentement :

En signant ce formulaire, je reconnais avoir lu et compris l'information juridique (telle qu'elle est décrite en détail au verso du présent formulaire) et j'accepte que McKesson, Amgen et les agents et fournisseurs de services autorisés d'Amgen recueillent, utilisent et divulguent mes renseignements personnels, y compris mes renseignements médicaux, comme il est expliqué au verso. J'accepte aussi que McKesson, Amgen ou les agents et fournisseurs de services autorisés d'Amgen communiquent avec moi de temps à autre pour les raisons susmentionnées.

Signature du patient _____ Date _____

Nous vous remercions de votre coopération.

AMGEN[MD]

Information juridique :

Le programme VICTOIRE[MD] (« Programme ») est commandité par Amgen Canada Inc. (« Amgen ») et administré par McKesson, un tiers fournisseur, au nom d'Amgen. D'autres fournisseurs de services pourraient être désignés par Amgen pour administrer le Programme selon les besoins. Les renseignements personnels que vous, vos fournisseurs de soins de santé (y compris votre médecin et votre pharmacie), les assureurs ou les payeurs avez divulgués au Programme, y compris votre nom, vos coordonnées et vos renseignements d'ordonnance, seront utilisés afin de faciliter la gestion et l'administration du Programme, y compris la prestation de services tels que la gestion du remboursement ou l'aide au remboursement, la formation ou l'assistance concernant le traitement (p. ex., une formation sur l'auto-injection), et le fait que des renseignements relatifs au Programme vous ont été communiqués.

Amgen a une obligation légale de déclarer les effets indésirables des médicaments à divers organismes de réglementation en matière de santé locaux et internationaux et de surveiller les plaintes relatives aux produits. Les renseignements personnels fournis au Programme peuvent être i) utilisés par Amgen ou ses fournisseurs de services pour surveiller les risques associés aux médicaments et les plaintes relatives aux produits afin d'assurer le respect de ses obligations de déclaration en vertu de la loi, et ii) divulgués aux organismes de réglementation en matière de santé locaux et internationaux. Amgen peut communiquer avec vous ou votre médecin pour obtenir des informations supplémentaires pour s'acquitter de ses obligations de déclaration. Vos renseignements personnels pourraient être combinés à ceux d'autres participants dans le but d'obtenir des données agrégées ne contenant aucune information d'identification (« données agrégées »). Les données agrégées peuvent être utilisées par Amgen et ses fournisseurs de services pour améliorer ou parfaire le Programme, pour concevoir et mettre en œuvre d'autres programmes à l'intention des patients et pour des fins de recherche, y compris le repérage de tendances comme l'utilisation, l'observance ou les résultats liés à un produit.

À ces fins uniquement, McKesson pourrait, de façon confidentielle, recueillir vos renseignements personnels et les communiquer à vos fournisseurs de soins de santé, assureurs et/ou à d'autres payeurs, à Amgen ou à ses agents et fournisseurs de services (p. ex., les fournisseurs de technologies de l'information). Si, selon les besoins, un autre fournisseur de services est désigné par Amgen pour administrer le Programme, vos renseignements personnels seront transférés à ce fournisseur de services afin d'assurer la continuité des services du Programme. Veuillez noter qu'Amgen et ses fournisseurs de services peuvent conserver ou traiter vos renseignements personnels à l'extérieur du Canada (y compris aux États-Unis), où les lois peuvent obliger la divulgation de renseignements personnels aux autorités gouvernementales dans des circonstances différentes de celles exigées au Canada. De plus, vos renseignements personnels peuvent être utilisés ou divulgués à d'autres tiers lorsque les lois, les ordonnances d'un tribunal ou la réglementation gouvernementale (collectivement appelées « lois applicables ») le permettent ou l'exigent.

Vos renseignements personnels seront conservés uniquement pendant la période de temps nécessaire pour atteindre le but dans lequel ils ont été recueillis et pour se conformer aux lois applicables. Les mesures de protection habituelles de l'industrie seront utilisées pour protéger la confidentialité des renseignements personnels recueillis. Vous pouvez communiquer en tout temps avec l'agent de la protection des renseignements personnels du Programme pour accéder à vos renseignements personnels, les mettre à jour, modifier ou retirer votre consentement (en partie ou en totalité), faire part d'une inquiétude concernant la confidentialité de vos renseignements, ou pour vous renseigner sur les pratiques en matière de protection des renseignements personnels du Programme (y compris celles relatives au traitement des renseignements de source étrangère). Vous pouvez communiquer avec l'agent de la protection des renseignements personnels par courriel à l'adresse privacycanada@amgen.com ou par la poste à l'adresse suivante : Amgen Canada inc., à l'attention du directeur de la protection des renseignements personnels, 6775 Financial Drive, bureau 100, Mississauga (Ontario) L5N 0A4. Veuillez noter que le retrait ou la modification de votre consentement peut limiter votre admissibilité aux services du Programme.

MEMBRE DE MÉDICAMENTS NOVATEURS CANADA

RÉVISÉ PAR CCPP

AMGEN[MD]

Clear

PATIENT ENROLMENT AND CONSENT FORM

Phone: 1-855-982-6348 • Fax to: 1-855-982-6349

XPAP Xtandi Patient Assistance Program
Surround yourself with support

astellas ONCOLOGY

Patient Information

Patient name: _____ (First) _____ (Middle) _____ (Last)

Date of birth: _____ (MM) | _____ (DD) | _____ (YYYY) **Language:** ○ English ○ French

Contact: _____ (Home Phone #) _____ (Alternate Phone # please indicate ○ Work ○ Cell) _____ (Email)

By providing your email address you consent to receiving emails for the purposes of administering the Program

_____ (Address) _____ (City) _____ (Province) _____ (Postal code)

Best time for contact: ○ Morning ○ Afternoon ○ Evening **Can the Program team leave you a message?** ○ Yes ○ No

Service Offerings (check all service offerings you would like the Program to provide):

○ Reimbursement Services ○ Specialty Pharmacy Services (counselling & dispensing options) ○ Nurse Support Services

Medical Diagnosis

○ Metastatic CSPC
○ Non-metastatic CRPC
○ Metastatic CRPC (chemotherapy-naïve)
○ Metastatic CRPC (post-docetaxel)

Notes: _____

Official Pharmacy Prescription (optional) Only complete if patient is ready to initiate therapy.

Prescription: ○ Xtandi 160 mg PO QD ○ Xtandi _____ mg PO QD

Supply: ○ 30 days **Repeats:** _____

Please refer to the Product Monograph for complete details on dosing and administration.

Prescriber signature: _____ **Date:** _____ (MM) | _____ (DD) | _____ (YYYY)

This prescription above is recognized as an original prescription and has been faxed only to be filled by the single regional pharmacy receiving it directly from the Xtandi Patient Assistance Program, if the patient chooses to opt for that service. The original of this prescription has been securely filed and will not be faxed elsewhere at another time.

Treating Physician Information

Name: _____ (First) _____ (Last) **Licence #:** _____

Practice address: _____ (Hospital/clinic name, floor, room #)

_____ (Address) _____ (City) _____ (Province) _____ (Postal code)

Contact: _____ (Phone #) _____ (Fax #) _____ (Email address)

Preferred method of contact: ○ Phone ○ Fax ○ Email

I hereby consent to the collection of information by the Xtandi Patient Assistance Program, its use to facilitate the functions and activities of the Program, and the disclosure of information collected to Astellas Pharma Canada, Inc., and its affiliates for the purposes of regulatory reporting requirements, program monitoring and evaluation and the collection, use and disclosure of the information as permitted or required by law. My signature acknowledges that I am the treating physician of this patient. I confirm that the patient is aware and has agreed to be contacted by the Program Administrator.

Prescriber signature: _____ **Date:** _____ (MM) | _____ (DD) | _____ (YYYY)

Additional Information for Personnel Coordinating Treatment (if applicable)

Name: _____ (First) _____ (Last) **Licence #:** _____

Title: _____ (e.g., Drug Access Navigator, Pivot Nurse)

Contact: _____ (Phone #) _____ (Fax #) _____ (Email address)

Preferred method of contact: ○ Phone ○ Fax ○ Email

I hereby consent to the collection of information by the Xtandi Patient Assistance Program, its use to facilitate the functions and activities of the Program, and the disclosure of information collected to Astellas Pharma Canada, Inc., and its affiliates for the purposes of regulatory reporting requirements, program monitoring and evaluation and to the collection, use and disclosure of the information as permitted or required by law. My signature acknowledges that I am coordinating reimbursement and access to Xtandi for this patient.

Coordinator signature: _____ **Date:** _____ (MM) | _____ (DD) | _____ (YYYY)

Patient Consent to Participate in the Program

Please ensure that your patient has read the important information on the reverse side of this form about the protection of their Personal Information provided on the "PERSONAL INFORMATION" section. Their signature below indicates their consent to the terms and conditions included on this form regarding "PATIENT CONSENT TO PARTICIPATE IN THE PROGRAM" and "PERSONAL INFORMATION".

If your patient is unable to provide a signature but would still like to participate, please check the box below:

○ I confirm that my patient is unable to provide a signature but has verbally provided consent to participate in the Program.

FOR THE PATIENT

By providing a signature below, you are confirming that you:

- Have been informed of the Program purpose and have been given the opportunity to discuss this program with your health care team
- Authorize the Program team to communicate with your doctor with regards to the service offerings selected
- Allow your patient file to be updated, if and when appropriate

_____
Signature of Patient or Legal Representative

_____
Printed Name of Patient or Legal Representative

_____
Legal Representative's relationship to patient

_____
Date (MM/DD/YYYY)

Patient Consent to Participate in the Program

The **Xtandi Patient Assistance Program** (the "**Program**") provides patients who have been prescribed Xtandi with support services, including reimbursement services, specialty pharmacy services (such as counselling & dispensing options), and in-home nurse follow-up.

The Program is managed by **Astellas Pharma Canada, Inc.**, its affiliates and agents ("**Astellas Canada**") and is administered by McKesson Canada Corporation ("**Program Administrator**"). In the event that McKesson Canada Corporation ceases to be the Program Administrator, **Astellas Canada** may appoint a replacement Program Administrator to administer the Program, and I agree that my Information may be transferred to and used by the replacement Program Administrator in the manner described on this form, to continue to administer the Program and provide me with support services.

I understand that for the purposes of the Program, my personal information, including the information that I provide by completing this form, and information about my insurance, prescriptions, medical condition, and health ("**Personal Information**"), will be collected, used, shared and stored as described on this form.

I authorize my health care provider(s) and their staff and my health insurer(s), as applicable, to disclose my Personal Information to the **Program Administrator** and its agents for the purposes of my enrolment and participation in the Program and as otherwise permitted or required under law.

Personal Information

I understand that my Personal Information will be used by the Program Administrator to:

- Contact me and complete my enrolment in the Program;
- Provide me with support services that are part of the Program;
- Provide my caregiver, if caregiver information is specified, support services that are part of the Program;
- Communicate with my medical insurance provider(s) to determine if I am eligible for reimbursement;
- Share my information, including date of birth and diagnosis, with my medical insurance provider(s) in order to establish insurance reimbursement;
- Communicate with my physician, nurse, pharmacist, or their staff, when appropriate;
- Coordinate fulfillment of my prescription; and
- Perform internal evaluation and assessments of the Program.

My Personal Information may be communicated to **Astellas Canada** in a de-identified or aggregated manner (in non-personally identifiable form) and used for the purposes of Program assessment, improvement and financial administration, for regulatory purposes, for product or program development or in order to comply with applicable laws.

My Personal Information may also be provided to and used by **Astellas Canada** in the context of reporting any adverse drug events to Health Canada or other government agencies in and outside of Canada, or as otherwise may be required by law. **Astellas Canada** may also be required to review my Program file (with my initials only to identify me) in order to audit the Program and confirm the accuracy of the data collected through the Program.

I understand that privacy laws require the Program Administrator to protect my privacy by requiring that it collect, use and disclose my Personal Information only for the purposes described herein or as permitted or required by law.

My Personal Information will be stored by the Program Administrator in a secure and confidential database, with access to the database restricted to authorized employees and agents. Safeguards are used to protect my Personal Information against unauthorized access, disclosure, copying, use or modification. I understand that my Personal Information may be stored or processed outside of Canada. If this is the case, it would be subject to the laws of that country where it is stored. That country may have laws that require that Personal Information be disclosed to the government under different circumstances than would Canada.

I understand that I have the right to revoke this consent at any time by contacting the Program Administrator at 70 Wynford Dr P.O. Box 383, North York, Ontario, M3C 2S7 and **1-855-982-6348**. I may access my Personal Information held by the **Program Administrator** and may rectify or request corrections using the contact information above. If I wish to make inquiries or complaints or have other concerns about the Program Administrator's personal information practices, I can contact the Program Administrator.

I authorize the Program Administrator to contact me in relation to these services by mail, email, fax, telephone call or text message. I authorize you to leave messages at the provided phone number or email address, and I understand that such messages may mention the name of Astellas Canada' products or services, details about my medical condition and insurance coverage and my doctor's name.

I UNDERSTAND THAT:

- By signing this form, I agree to be enrolled into the Program.
- Participation in the Program is not required for me to receive my medication.
- I am not required to sign this consent form. If I choose not to consent to the collection use and disclosure of my Personal Information, I will not be able to participate in the Program.
- I am responsible for ensuring that I meet any requirements and conditions related to public drug program enrolment (e.g. Ontario's Trillium Drug Program) where applicable.
- Signing this form will not affect my medical treatment and is not a requirement for coverage by my insurance provider and will not affect my insurance enrolment or eligibility for insurance benefits.
- My Personal Information may be transferred and stored outside of Canada.
- I authorize my health care provider to provide the Program Administrator with this completed form on my behalf so that a Program nurse and coordinator can contact me in connection with the Program.
- Unless and until revoked, this consent is valid for the duration of the Program.

Astellas Canada reserves the right to modify, suspend or terminate the Program, or any part thereof, in its sole discretion.

The Program is not intended to provide medical advice or medical diagnoses. Always seek the advice of your physician, pharmacist or other qualified health provider if you have any health concerns. Never disregard professional medical advice or delay in seeking it because of something you have read or other information conveyed as a result of this Program.

Xtandi® (enzalutamide capsules) is indicated for the treatment of patients with metastatic castration-sensitive prostate cancer (mCSPC).

Xtandi® (enzalutamide capsules) is indicated for the treatment of patients with non-metastatic castration-resistant prostate cancer (nmCRPC). Xtandi has not been studied in patients with nmCRPC at low risk of developing metastatic disease. The benefit and risk profile in these patients is unknown.

Xtandi is indicated in the setting of medical or surgical castration for the treatment of metastatic castration-resistant prostate cancer (mCRPC) in patients who:

- Are chemotherapy-naïve with asymptomatic or mildly symptomatic disease after failure of androgen deprivation therapy.
- Have received docetaxel therapy.

Consult the Xtandi Product Monograph at https://www.astellas.com/ca/system/files/2020-06/Xtandi_PM_EN_June2020.pdf for important information relating to contraindications, warnings, precautions, adverse reaction, interactions, dosing and conditions of clinical use. The Product Monograph is also available through Medical Information at 1-888-338-1824.

Xtandi Patient Assistance Program
70 Wynford Dr., P.O. Box 383, North York, ON, M3C 2S7
Phone: 1-855-982-6348 (1-855-Xtandi-8)
Fax: 1-855-982-6349 (1-855-Xtandi-9)
Email: info@XTANDIassistanceprogram.ca

XPAP | Xtandi Patient Assistance Program
Surround yourself with support

MEMBER OF INNOVATIVE MEDICINES CANADA

PAAB

astellas ONCOLOGY

076-5095-PM-EN

Clear

FORMULAIRE D'INSCRIPTION ET DE CONSENTEMENT DU PATIENT

Téléphone : 1 855 982-6348 • Télécopieur : 1 855 982-6349

XPAP | Programme d'assistance pour le patient Xtandi
Entourez-vous de soutien

astellas ONCOLOGIE

Renseignements sur le patient

Nom du patient : _____ (Prénom) _____ (Second prénom) _____ (Nom de famille)

Date de naissance : _____ (MM) | _____ (JJ) | _____ (AAAA) **Langue :** ○ Anglais ○ Français

Contact : _____ (N° Téléphone à domicile) _____ (Autre N° de téléphone, veuillez préciser ○ Travail ○ Cellulaire) _____ (Courriel)

En fournissant votre adresse de courriel, vous consentez à recevoir des courriels aux fins d'administration du Programme.

_____ (Adresse) _____ (Ville) _____ (Province) _____ (Code postal)

Meilleur moment pour me contacter : ○ Matin ○ Après-midi ○ Soirée **L'équipe du Programme peut-elle vous laisser un message?** ○ Oui ○ Non

Services offerts (cochez les services que vous souhaitez recevoir dans le cadre du Programme) :

○ Services de remboursement ○ Services de pharmacie spécialisés (options de counseling et de délivrance) ○ Services de soutien infirmier

Diagnostic médical

○ CPSC métastatique
○ CPRC non métastatique
○ CPRC métastatique (patients n'ayant jamais reçu de chimiothérapie)
○ CPRC métastatique (post-docétaxel)

Remarques : _____

Ordonnance officielle de pharmacie (optionnelle)

Veuillez remplir cette section uniquement si le patient est prêt à commencer le traitement.

Ordonnance : ○ Xtandi 160 mg P.O. 1x/jour ○ Xtandi _____ mg P.O. 1x/jour

Approvisionnement : ○ 30 jours **Renouvellements :** _____

Veuillez consulter la monographie de produit pour obtenir les informations complètes concernant la posologie et l'administration.

Signature du médecin traitant : _____ **Date :** _____ (MM) | _____ (JJ) | _____ (AAAA)

L'ordonnance ci-dessus est reconnue à titre d'ordonnance originale et elle a été télécopiée afin d'être exécutée uniquement par une seule pharmacie régionale qui l'a reçue directement de la part du Programme d'assistance pour le patient sous Xtandi, si le patient a choisi d'avoir recours à ce service. La copie originale de cette ordonnance a été archivée de façon sécurisée et elle ne sera pas télécopiée ailleurs à un autre moment.

Information au sujet du médecin traitant

Nom : _____ (Prénom) _____ (Nom de famille) **N° Permis :** _____

Adresse de pratique : _____ (Nom de l'hôpital/clinique, étage, n° de salle)

_____ (Adresse) _____ (Ville) _____ (Province) _____ (Code postal)

Contact : _____ (N° téléphone) _____ (N° télécopieur) _____ (Courriel)

Mode de contact préféré : ○ Appel téléphonique ○ Télécopie ○ Courriel

Par la présente, je consens à ce que le Programme d'assistance pour le patient sous Xtandi recueille de l'information, qu'il utilise cette information afin de faciliter les fonctions et les activités du Programme et que cette information soit divulguée à Astellas Pharma Canada, Inc., et ses sociétés affiliées afin de satisfaire aux exigences des rapports réglementaires, aux activités de surveillance, d'évaluation et de collecte des données dans le cadre du programme ainsi que l'utilisation et la divulgation de l'information telle que permise ou exigée par la loi. Ma signature ci-dessous confirme que je suis le médecin traitant de ce patient. Je confirme que le patient a été informé du programme et qu'il est d'accord pour être contacté par l'Administrateur du Programme.

Signature du médecin traitant : _____ **Date :** _____ (MM) | _____ (JJ) | _____ (AAAA)

Information additionnelle pour le personnel coordonnant le traitement (si applicable)

Nom : _____ (Prénom) _____ (Nom de famille) **N° Permis :** _____

Titre : _____ (ex., Coordonnateur d'accès aux médicaments, infirmière pivot)

Contact : _____ (N° téléphone) _____ (N° télécopieur) _____ (Courriel)

Mode de contact préféré : ○ Appel téléphonique ○ Télécopie ○ Courriel

Par la présente, je consens à ce que le Programme d'assistance pour le patient sous Xtandi recueille de l'information, qu'il utilise cette information afin de faciliter les fonctions et les activités du Programme et que cette information soit divulguée à Astellas Pharma Canada, Inc., et ses sociétés affiliées afin de satisfaire aux exigences des rapports réglementaires, aux activités de surveillance, d'évaluation et de collecte des données dans le cadre du programme ainsi que l'utilisation et la divulgation de l'information telle que permise ou exigée par la loi. Ma signature ci-dessous confirme que je coordonne le remboursement et l'accès à Xtandi pour ce patient.

Signature du coordonnateur : _____ **Date :** _____ (MM) | _____ (JJ) | _____ (AAAA)

Consentement du patient à participer au Programme

Prière de veiller à ce que le patient lise l'information importante au verso de ce formulaire dans la section « INFORMATION PERSONNELLE » qui porte sur la protection des renseignements personnels. Sa signature ci-dessous indique qu'il consent aux modalités stipulées dans ce formulaire au sujet du « CONSENTEMENT DE PARTICIPATION DU PATIENT AU PROGRAMME » et de l'« INFORMATION PERSONNELLE ».

Si votre patient n'est pas en mesure de signer mais aimerait néanmoins participer au Programme, veuillez cocher la case ci-dessous :

○ Je confirme que mon patient n'est pas en mesure de poser sa signature, mais qu'il a verbalement donné son consentement pour participer au Programme.

POUR LE PATIENT

En signant le formulaire ci-dessous, vous confirmez que :

- On vous a renseigné sur l'objectif du Programme et vous avez eu l'occasion d'en discuter avec votre équipe de professionnels en soins de santé;
- Vous autorisez l'équipe du Programme à communiquer avec votre médecin en ce qui a trait aux services offerts sélectionnés;
- Vous permettez que votre dossier patient soit mis à jour, au besoin.

_____
Signature du patient ou de représentant légal

_____
Nom du patient ou de son représentant légal en caractères d'imprimerie

_____
Lien du représentant légal avec le patient

_____
Date (MM/JJ/AAAA)

Consentement du patient à participer au Programme

Le **Programme d'assistance pour le patient sous Xtandi** (le « **Programme** ») procure des services de soutien aux patients à qui Xtandi a été prescrit, notamment des services de remboursement, des services de pharmacie spécialisés (options de counseling et de délivrance) et des services de suivi infirmier à domicile.

Le Programme est géré par **Astellas Pharma Canada, Inc.**, ses sociétés affiliées et ses agents (« **Astellas Canada** ») et il est administré par McKesson Canada Corporation (« **l'Administrateur du Programme** »). Dans l'éventualité où McKesson Canada Corporation cesserait d'être l'administrateur du Programme, **Astellas Canada** pourrait nommer un remplaçant à titre d'Administrateur du Programme pour gérer le Programme, et je consens à ce que mes renseignements soient transférés à l'administrateur remplaçant et utilisés par celui-ci conformément à la manière décrite dans ce formulaire, afin de continuer à gérer le Programme et à me fournir des services de soutien.

Je comprends que, aux fins du Programme, mes renseignements personnels, y compris l'information que je fournis en remplissant le présent formulaire ainsi que l'information sur mon assurance, mes ordonnances, mes problèmes médicaux et mon bilan de santé (« **Information personnelle** ») seront recueillis, utilisés, partagés et entreposés de la manière décrite dans le présent formulaire.

J'autorise mon fournisseur/mes fournisseurs de soins de santé et leur personnel ainsi que mon fournisseur/mes fournisseurs d'assurance maladie, le cas échéant, à divulguer mon information personnelle à l'**Administrateur du Programme** et ses mandataires aux fins de mon inscription et de ma participation au Programme et selon ce qui est permis ou exigé par la loi.

Information personnelle

Je comprends que mon Information personnelle puisse être utilisée par l'Administrateur du Programme pour :

- Communiquer avec moi et effectuer mon inscription au Programme;
- Me fournir des services de soutien qui font partie du Programme;
- Fournir à mon aidant, si l'information au sujet de mon aidant est disponible, des services de soutien qui font partie du Programme;
- Communiquer avec mon fournisseur/mes fournisseurs d'assurance médicale afin de déterminer si je suis admissible à un remboursement;
- Partager mon information, incluant ma date de naissance et mon diagnostic, avec mon fournisseur/mes fournisseurs d'assurance médicale afin de déterminer le remboursement d'assurance auquel j'ai droit;
- Communiquer avec mon médecin, mon infirmier/infirmière, mon pharmacien, ou leur personnel lorsque cela est approprié;
- Coordonner la délivrance de mon ordonnance; et
- Effectuer des évaluations internes du Programme.

Mon Information personnelle peut être divulguée à **Astellas Canada** de manière anonymisée ou sous forme de données cumulatives (ne permettant pas une identification personnelle) et utilisée aux fins d'évaluation et d'amélioration du Programme, ainsi que d'administration financière, de conformité réglementaire, de mise au point de produits ou de programmes ou pour se soumettre aux lois en vigueur.

Mon Information personnelle peut également être divulguée à **Astellas Canada**, et utilisée par elle, dans une situation où il convient de signaler des effets indésirables à Santé Canada ou à toute autre agence gouvernementale au Canada et à l'extérieur du pays ou selon toute situation où un tel signalement est exigé par la loi. **Astellas Canada** pourrait également être tenu de réviser mon dossier dans le cadre du Programme (portant mes initiales seulement dans le but de m'identifier) afin d'effectuer un audit du Programme et de confirmer l'exactitude des données recueillies par le Programme.

Je comprends que les lois sur la vie privée exigent que l'Administrateur du Programme protège ma confidentialité en recueillant, utilisant et divulguant mon Information personnelle uniquement aux fins décrites dans le présent document ou comme permis ou requis par la loi.

Mon Information personnelle sera enregistrée par l'Administrateur du Programme dans une banque de données sécurisée et confidentielle et l'accès à cette banque de données sera réservé uniquement aux employés et aux agents autorisés. Des mesures de protection sont utilisées pour protéger mon Information personnelle contre l'accès, la divulgation, la reproduction, l'utilisation ou la modification non autorisés. Je comprends que mon Information personnelle pourrait être conservée ou traitée à l'extérieur du Canada. Si tel est le cas, l'information est alors assujettie aux lois du pays dans lequel elle est conservée. En vertu de ses propres lois, ce pays pourrait exiger la divulgation de l'Information personnelle à son gouvernement selon des critères qui diffèrent de ceux en vigueur au Canada.

Je comprends que j'ai le droit de retirer mon consentement en tout temps en communiquant avec l'Administrateur du Programme : 70 Wynford Dr, Case postale 383, North York (Ontario) M3C 2S7; **1-855-982-6348**. Je peux accéder à mon Information personnelle détenue par l'**Administrateur du Programme** et je peux la corriger ou demander qu'elle soit corrigée en communiquant avec l'Administrateur aux coordonnées fournies ci-dessus. Si je désire poser des questions ou déposer une plainte ou si j'ai d'autres inquiétudes au sujet des pratiques de l'Administrateur du Programme en matière de traitement de l'information personnelle, je peux contacter l'Administrateur du Programme.

J'autorise l'Administrateur du Programme à communiquer avec moi par la poste, par courriel, par télécopie, par téléphone ou par texto en ce qui concerne les services offerts par le Programme. Je vous autorise à me laisser des messages au numéro de téléphone fourni ou à m'envoyer des messages à l'adresse courriel fournie et je comprends que ces messages pourraient mentionner le nom des produits et services d'Astellas Canada, comporter des renseignements sur mes problèmes de santé et sur la couverture de mon assurance ainsi que mentionner le nom de mon médecin.

JE COMPRENDS QUE :

- En signant ce formulaire, je consens à mon inscription au Programme;
- Ma participation au Programme n'est pas un prérequis afin que je puisse recevoir mon médicament;
- Je ne suis pas tenu de signer ce formulaire de consentement; Si je décide de ne pas consentir à la collecte, utilisation et divulgation de mon Information personnelle, je ne pourrai pas participer au Programme;
- J'ai la responsabilité de veiller à ce que je réponde aux critères et exigences reliés à l'inscription à un programme public de médicament (p. ex., le Programme de médicaments Trillium de l'Ontario), le cas échéant;
- Le fait de signer ce formulaire n'aura aucune répercussion sur mon traitement médical et n'est pas une exigence pour ma couverture par mon fournisseur d'assurance; cela n'aura pas non plus de répercussions sur mon admissibilité à mon régime d'assurance ni sur mon admissibilité à des prestations d'assurance;
- Mon Information personnelle pourrait être transférée et conservée à l'extérieur du Canada;
- J'autorise mon fournisseur de soins de santé à fournir en mon nom, à l'Administrateur du Programme, le présent formulaire dûment rempli afin que le personnel infirmier ou le coordonnateur du Programme puisse me contacter dans le cadre du Programme;
- Sauf si je le révoque ou jusqu'à ce que je le révoque, ce consentement est valide pour la durée du Programme.

Astellas Canada se réserve le droit de modifier ou suspendre le Programme, dans son ensemble ou en partie, ou encore d'y mettre fin, à son entière discrétion.

Le Programme n'a pas été conçu pour fournir des conseils médicaux ni de diagnostic médical. Veuillez consulter votre médecin, votre pharmacien ou un autre fournisseur de soins de santé qualifié si vous avez des inquiétudes concernant votre santé. N'ignorez jamais les recommandations médicales d'un professionnel de la santé et ne tardez pas à consulter un tel professionnel afin d'obtenir son avis médical en raison de quelque chose que vous avez lu ou de toute autre information que vous avez obtenue dans le cadre de ce Programme.

Xtandi[MD] (capsules d'enzalutamide) est indiqué pour le traitement des patients atteints d'un cancer de la prostate métastatique sensible à la castration (CPSCm).

Xtandi[MD] (capsules d'enzalutamide) est indiqué pour le traitement des patients atteints d'un cancer de la prostate résistant à la castration non métastatique (CPRCnm). Xtandi n'a pas fait l'objet d'études chez les patients atteints d'un CPRCnm à faible risque de progression vers une maladie métastatique. Chez ces patients, le profil d'avantages et de risques n'est pas connu.

Xtandi est indiqué dans un contexte de castration médicale ou chirurgicale pour le traitement du cancer de la prostate métastatique résistant à la castration (CPRCm) chez les patients qui :

- n'ont jamais reçu de chimiothérapie et sont asymptomatiques ou légèrement symptomatiques après échec d'un traitement antiandrogénique;
- ont reçu un traitement par le docétaxel.

Veuillez consulter la monographie de Xtandi à l'adresse https://www.astellas.com/ca/system/files/xtandi_pm_fr_june2020.pdf pour obtenir des renseignements importants sur les contre-indications, les mises en garde et précautions, les effets indésirables, les interactions, la posologie et les conditions d'utilisation clinique. La monographie du produit peut également être obtenue en communiquant avec le service d'Information médicale au 1 888 338-1824.

Programme d'assistance pour le patient sous Xtandi
70 Wynford Dr., C.P. 383, North York, ON, M3C 2S7
Téléphone : 1 855 982-6348 (1-855-Xtandi-8)
Télécopieur : 1 855 982-6349 (1-855-Xtandi-9)
Courriel : info@XTANDIassistanceprogram.ca

XPAP | Programme d'assistance pour le patient Xtandi
Entourez-vous de soutien

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