DART PROGRAM ENROLMENT FORM

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

DART
Darolutamide Access & Reimbursement Touchpoint
PATIENT SUPPORT PROGRAM

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

PATIENT INFORMATION (must be completed – please print)

Language ❑ Eng ❑ Fr

Last name _____ First name _____ Birth date DD/MM/YYYY

Address _____ City _____ Province/Territory _____ Postal code _____

Email _____ Home phone _____ Cell/Alternate _____ Messages may be left at ❑ Voicemail ❑ Email

Primary contact _____ Phone _____ Relationship _____

PRESCRIBING 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) ❑ Same as clinic information above _____ Nurse/DAN phone _____ Nurse/DAN fax _____ Nurse/DAN email _____

Preferred method of contact ❑ Phone ❑ Fax ❑ Email Primary point of contact ❑ Nurse/DAN ❑ Physician ❑ Both

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

Consult the Product Monograph for complete dosing and administration information.

Prescription: NUBEQA® 300 mg tablet

NUBEQA® (darolutamide) is indicated for the treatment of patients with metastatic castration-sensitive prostate cancer (mCSPC)[1]

Dosing instructions

❑ 600 mg (two 300 mg tablets) BID (1200 mg/day)

❑ Other (please specify) _____

Quantity/supply ❑ 30 days

Refills _____

The DART Patient Support Program does not guarantee or warrant that this enrolment form constitutes a valid prescription. Its validity, as mandated by relevant laws and professional standards, is determined by the pharmacist's and/or physician's professional judgment and responsibility.

MEDICAL INFORMATION (*ALL* fields to be completed)

Medical diagnosis: mCSPC **Regimen: NUBEQA® plus ADT (doublet)**

Confirmed presence of metastases beyond regional lymph nodes by imaging ❑ Yes

Volume of disease
❑ High volume* ❑ Low volume

Risk stratification
❑ High risk† ❑ Low risk

Stage of diagnosis
❑ De novo ❑ Recurrent

Choose at least one of the below:

❑ Patient has not received ADT in the metastatic setting

❑ Patient initiated ADT within the prior 6 months, in the metastatic setting

❑ It has been ≥1 year since prior ADT for early-stage disease

AND

Choose one of the below:

❑ Has not received prior ARPi in mCSPC setting

❑ Has received prior ARPi and requires switch due to intolerance or drug-drug interaction

* High volume defined (from CHAARTED) as having ≥1 of the following: ≥4 bone lesions with ≥1 beyond the vertebral bodies and pelvis; or visceral metastases.[2]

† High risk defined (from LATITUDE) as having ≥2 of the following: ≥3 bone metastases; and/or visceral metastases; and/or Gleason score ≥8.[2]

For patients with HIGH RISK and/or HIGH VOLUME disease only (complete below)

Patients with mCNPC/mCSPC should be assessed in a multidisciplinary manner whenever possible (Level 3 evidence, Strong recommendation). In patients who can safely tolerate docetaxel and in whom docetaxel is appropriate, a triplet regimen (docetaxel plus ARPi and ADT) should be the treatment option, and not docetaxel and ADT alone (Level 1 evidence, Strong recommendation).[2]

Will the patient be referred/considered for assessment of early eligibility of chemotherapy (docetaxel)?

❑ Yes ❑ No; please specify reason for chemo-ineligibility: _____

The DART program will follow up in 6 weeks to confirm if the patient has started or will be starting chemotherapy (if above is checked "yes").

Patient Consent

My signature certifies that I have read and understand the Patient Consent to Collect, Use and Disclose Personal Information (or "Authorization") on the reverse of this form and I agree to the outlined terms.

Patient full name (print) _____ Date DD/MM/YYYY

Patient or Patient Representative* signature _____ Relationship to patient _____

* NOTE: a Patient Representative must be a person who is legally entitled and authorized to make decisions on behalf of the Patient with regard to their personal information and health care in cases where the Patient is not legally capable of doing so.

Physician Consent

By signing below, I acknowledge that the patient has been prescribed NUBEQA® (darolutamide) for the indication noted above and that I have read and understand the information provided in the Physician Authorization on the reverse of this form.

Physician signature _____ **Date** DD/MM/YYYY

BID=twice daily; ADT=androgen deprivation therapy; mCNPC=metastatic castration-naive prostate cancer; ARPi=androgen receptor pathway inhibitor.

PATIENT CONSENT TO COLLECT, USE AND DISCLOSE PERSONAL INFORMATION ("AUTHORIZATION")

The DART Patient Support Program (the "**Program**") is sponsored and offered by Bayer Inc., 2920 Matheson Boulevard East, Mississauga, Ontario, L4W 5R6, Canada ("**Bayer**"). I understand that the Program is administered by Bayer and a third-party service provider contracted by Bayer to administer the Program (the "**Program Administrator**"). The current Program Administrator is Shoppers Drug Mart Specialty Health Network, 1685 Tech Avenue, Mississauga, Ontario, L4W 0A7.

I have been prescribed by my healthcare provider NUBEQA® (darolutamide) (the "**Product**") for the treatment of metastatic castration-sensitive prostate cancer (mCSPC), for which Bayer is the manufacturer.

The Program includes services such as reimbursement navigation assistance, education and, in certain circumstances financial support during my treatment with the Product.

Bayer reserves the right to terminate or change the Program or its criteria at any time without prior notice or delay, including by moving the Program to a new Program Administrator or to add Program Administrators for certain services under the Program, including to receive or process my Personal Information.

I have been given the opportunity to discuss this Program with my healthcare provider, I have been given a copy of the Authorization, and I understand that participation in the Program is voluntary and at no additional cost.

By signing this Authorization, I hereby consent to the Program collecting, using, disclosing and storing my Personal Information (as defined below) to determine my eligibility for and in connection with my participation in the Program and to provide me with Program services as outlined herein.

My Personal Information

Program Purposes

I understand that in order to be enrolled in the Program, I or my healthcare provider must provide certain information about me for the purposes set out in the next paragraph and that the Program Administrator on behalf of Bayer may collect other information from me or my healthcare provider including my personal information and personal health information (e.g., name, gender, age, address, telephone number, email, health information and medical condition as it affects my therapy) (collectively, my "**Personal Information**"). I understand that, absent exceptional circumstances such as regulatory requirements, the information received by Bayer from the Program Administrator will not include direct identifiers such as my name and address, rather, Bayer receives my information in a coded, de-identified format that references a unique patient number assigned to me.

I authorize and consent to the disclosure of my Personal Information to Bayer and its Program Administrator for the purposes of the Program, and authorize Bayer and its Program Administrator to collect, use, and disclose my Personal Information, including with my healthcare provider(s), in order to:

- Manage and administer the Program, including to enroll me in the Program, which may also include contacting me about the Program, online support, financial assistance services, co-pay assistance, and compliance and persistency services.
- Communicate with my healthcare provider about benefits, coverage and medical care.
- Fulfill any legal reporting obligations (e.g., to report adverse events to Regulatory Authorities).
- Locate pharmacies that can fill my prescription and facilitate dispensing of my prescription by a pharmacy of my choice.
- Provide me with educational materials, information, and services related to my treatment experience with my medication/condition.
- Conduct patient satisfaction surveys, data analytics, and other internal business activities related to the evaluation, refinement and improvement of the Program and its associated Products and services.

Optional: Uses for Other Programs and General Research

I also understand that, unless I opt out of such uses by checking the box below, my Personal Information may be used and analyzed by Bayer and its Program Administrator for other purposes not directly related to program administration, including:

- to assist in the design and implementation of other patient programs;
- for general research purposes, including for example:
  - Understanding how patients use the Product and Program and how this may relate to the use of other and related products and programs;
  - Evaluating trends related to patient adherence to treatment regimens and the effectiveness of such treatment regimens;
  - Contacting me about potential participation in research or study initiatives related to the Product and/or Program.

In the course of using the Personal Information for program development and research purposes, Bayer and its Program Administrator may combine my Personal Information with the information of others who participate in the Program and other Bayer-sponsored programs, in order to generate anonymized and aggregated data that may be used by Bayer and/or disclosed to third parties for research, including future scientific research and publications. I understand that my information will only be disclosed for research or published in an aggregated format, and never in a manner that will identify me by name or other identifiers.

I understand that the uses of my Personal Information as described in this paragraph are optional and not required for my participation in the Program.

❑ **I do not wish for my Personal Information to be used by Bayer for the optional purposes described in this section entitled *Optional: Uses for Other Programs and General Research.***

Confidentiality and Disclosure

I understand that Bayer and the Program Administrator will keep my Personal Information confidential and will use it only for the purposes set out in this Authorization. From time to time, I also understand that Bayer and the Program Administrator may need to disclose my Personal Information to third parties who are involved in delivering the Program or for health and safety, regulatory and legal purposes, including:

- My healthcare provider(s) for the purposes of the Program;
- Bayer's authorized third-party services providers (including any new or different Program Administrator) to perform services on behalf of Bayer for the purposes set out in this Authorization;
- Bayer's Pharmacovigilance Departments in order to comply with reporting obligations, including as a result of any adverse event, product technical complaint or usability issue or other safety-related event;
- Bayer's auditors for audit and inspection purposes to ensure the Program is properly managed and administered; and
- Law enforcement and other government agencies to comply with legal obligations and respond to lawful requests.

I understand that my Personal Information may be collected, used and disclosed and/or stored outside of my region/country, and that the privacy laws of those jurisdictions may be less stringent than the laws of Canada and/or my region/country. I also understand that my Personal Information will be kept for at least seven (7) years after the end of the Program or as may be required thereafter in order to comply with legal requirements.

My Privacy Rights

I understand that I may refuse to sign this Authorization, and that, subject to legal and contractual restrictions, I may withdraw consent to Bayer's and the Program Administrator's further collection, use and disclosure of my Personal Information relating to all or any of the services or uses at any time by contacting the Program Administrator. My choice about whether to provide my consent or later revoke it will not change the way my healthcare provider administers treatment to me, but may affect my ability to participate or receive assistance from the Program from the date of withdrawal. The effect of my withdrawal of consent in whole or in part on my participation in the Program will be explained to me at the time I indicate my wish to withdraw consent.

I understand that, if permitted by and subject to applicable law, I may contact the Program Administrator to exercise additional privacy rights, including the right to access, correct/rectify, or request deletion of my Personal Information, the right to obtain information about the processing of my Personal Information, the right to request that my Personal Information be communicated or transferred to me or a third party in a structured and commonly used technological format, and the right to lodge a complaint with the appropriate data protection authority.

I can contact the Program Administrator for any information about my Personal Information, my privacy rights or this Authorization at: Phone: 1-833-955-DART (3278) or Email: info@dartsupport.ca.

Physician Authorization

Please review the information in the Patient Authorization, above, for a description of the DART Patient Support Program (the "Program"). By signing where indicated, you agree that:

- The Personal Information you provide is collected, used, and disclosed by Program Administrator to meet the Program Purposes set out in the Patient Authorization.
- Unless you are located in British Columbia, your name, specialty, coarse geographic location (FSA), and number of patient enrolments will be shared with Bayer to use solely for purposes of Program monitoring, oversight, improvement, and quality assurance ("Optional Uses").
- Your Personal Information will be kept confidential, but may be disclosed and/or transferred outside your region/country as described in the "Confidentiality and Disclosure" section of the Patient Authorization.
- Subject to legal and contractual restrictions, you may opt out of the Optional Uses or modify your consent preferences by contacting the Program Administrator. If permitted by and subject to applicable law, you may contact the Program Administrator to exercise additional privacy rights, as described in the My Privacy Rights section of the Patient Authorization.
- Your choice about whether to provide or revoke your consent to the Optional Uses will not affect your patients' ability to participate in or receive assistance from the Program. If you opt out, Bayer will cease processing your Personal Information, and only coded, de-identified information will be shared with Bayer going forward.

If unable to obtain written consent from patient, please document verbal consent.

Name of the person who obtained the verbal consent _____

Signature of the person who obtained the verbal consent _____

Relationship to patient _____

Date on which verbal consent was obtained DD/MM/YYYY (*Verbal consent only applies to provinces outside of Alberta. Under Alberta law, verbal consent is not permitted.*)

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.

References: 1. NUBEQA Product Monograph, Bayer Inc. **2.** So AI, et al. 2025 Canadian Urological Association-Canadian Uro-oncology Group Guideline: Metastatic castration-naïve and castration-sensitive prostate cancer (Update). *CUAJ* 2025;19(5):E142–52.

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NUBEQA® (darolutamide) 300 mg tablets