

**From Director of Hospital Care  
Paul Cavanagh**



Department of  
**Health**

An Roinn Sláinte

Máinnstríe O Poustie

[www.health-ni.gov.uk](http://www.health-ni.gov.uk)

**By email**

**Chief Executives of Trusts - for cascade to:**

Medical Directors  
Directors of Nursing  
Directors of Acute Services  
Heads of Pharmacy & Medicines Management  
Clinical & Social Governance Leads

**Strategic Planning and Performance Group**

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Date: 4 December 2023

**Director of Primary Care, SPPG - for cascade to:**

Head of Pharmacy & Medicines Management

Dear Colleague,

**SERVICE NOTIFICATION FOR NICE TECHNOLOGY APPRAISAL TA903 –  
DAROLUTAMIDE WITH ANDROGEN DEPRIVATION THERAPY AND DOCETAXEL FOR  
TREATING HORMONE-SENSITIVE METASTATIC PROSTATE CANCER**

**Background**

The Department's Medicines Policy Branch (MPB) in the Chief Medical Officer's Group has recently reviewed the above NICE guidance and has formally endorsed it as applicable in Northern Ireland.

In line with Circular HSC (SQSD) 12/22, the SPPG is required to issue a Service Notification to HSC Trusts and other relevant providers and stakeholders, including Family Practitioners, setting out the expectations for implementation.

**Commissioning Arrangements**

This regimen will be formally commissioned by the SPPG initially on a cost-per-case (CPC) basis. Thereafter, numbers of patients who received or are receiving treatment will be reviewed and consideration will be given to moving to recurrent funding to support this regimen.

Any changes to the commissioning arrangements on this treatment will be updated on the SPPG NI formulary Managed Entry Decisions webpage:

<https://niformulary.hscni.net/managed-entry/managed-entry-decisions/>

**Resource Implications**

Any resources associated with the introduction of the technology in line with the commissioning arrangements set out above will be incorporated in the Trust financial allocation for the appropriate financial year.

The company (Bayer) have commercial arrangements (simple discount patient access scheme), which makes darolutamide available with a discount. The size of the discount is commercial in confidence.

Any additional infrastructure requirements will be subject to agreement with the relevant SPPG Service Team.

## **Legislative/Policy Caveats**

This advice does not override or replace the individual responsibility of health professionals to make appropriate decisions in the circumstances of their individual patients, in consultation with the patient and/or guardian or carer. This would, for example, include situations where individual patients have other conditions or complications that need to be taken into account in determining whether the NICE guidance is fully appropriate in their case.

The Rural Needs Act (NI) 2016 has been considered and this guidance, which is purely of a technical nature, is not regarded as falling within the scope of the Act.

## **Licencing**

This treatment is licenced for use in Northern Ireland. The SPPG have identified licence divergence for this treatment.

NICE TA903 recommends darolutamide for the treatment of adult men with metastatic hormone-sensitive prostate cancer (mHSPC) in combination with docetaxel which is line with the GB Marketing authorisation for darolutamide. However, the EMA marketing authorisation requires darolutamide to be used in combination with both docetaxel *and androgen deprivation therapy*.

Where NICE recommendations represent an off-label use of a medicine then clinicians prescribing this treatment should ensure that they abide by extant HSC Trust governance procedures in relation to the prescribing of off-label medicines.

## **Action required by Health and Social Care Trusts**

Trusts should now take forward the implementation of the TA in accordance with Circular HSC (SQSD) 12/22. The SPPG's expectation is that proportionate implementation arrangements will be established on receipt of this correspondence.

In particular, within three months ensure that: targeted dissemination takes place; a clinical/management change leader has been agreed; and a proportionate implementation plan is in place.

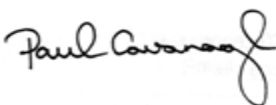
## **SPPG Monitoring and Assurance arrangements**

The SPPG will seek direct assurances from Trusts on an ongoing basis regarding the actions outlined above in advance of the scheduled SPPG/Trust Service Issues and Performance meetings.

The SPPG cost per case process will generate regular reports on the number of applications for this treatment.

Thank you for your attention with this matter. If you have any queries please email SPPG Hospital Care directorate via [SPPG-NICEInbox@hscni.net](mailto:SPPG-NICEInbox@hscni.net) in the first instance.

Yours sincerely



**Paul Cavanagh**  
**Director of Hospital Care**

**CC:**

Chief Medical Officer

Chief Pharmaceutical Officer

Chief Executive Patient and Client Council

Chief Executive/Postgraduate Dean, NIMDTA

Chief Executive, NICPLD

Chief Executive, NIPEC

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