

## NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

### Interventional procedures consultation document

# Electrically stimulated intravesical chemotherapy for non-muscle-invasive bladder cancer

Non-muscle-invasive bladder cancer is only in the lining of the bladder. It has not grown into the deeper muscle layer. This procedure is used before or after surgery. A catheter (tube) is inserted into the bladder through the urethra (the tube that carries urine out of the body from the bladder). Chemotherapy drugs are passed through this tube into the bladder (intravesical therapy). An electrode is also passed into the bladder, to create a small electrical current. The aim is to make the chemotherapy work better.

The National Institute for Health and Care Excellence (NICE) is looking at electrically stimulated intravesical chemotherapy for non-muscle-invasive bladder cancer. NICE's interventional procedures advisory committee has considered the evidence and the views of specialist advisers, who are consultants with knowledge of the procedure.

The committee has made draft recommendations and we now want to hear your views. The committee particularly welcomes:

- comments on the draft recommendations
- information about factual inaccuracies
- additional relevant evidence, with references if possible.

**This is not our final guidance on this procedure. The recommendations may change after this consultation.**

After consultation ends:

- The committee will meet again to consider the original evidence and its draft recommendations in the light of the consultation comments.
- The committee will prepare a second draft, which will be the basis for NICE's guidance on using the procedure in the NHS.

For further details, see the [Interventional Procedures Programme process guide](#).

Through our guidance, we are committed to promoting race and disability equality, equality between men and women, and to eliminating all forms of discrimination. One of the ways we do this is by trying to involve as wide a range of people and interest groups as possible in developing our interventional procedures guidance. In particular, we encourage people and organisations from groups who might not normally comment on our guidance to do so.

To help us promote equality through our guidance, please consider the following question:

Are there any issues that require special attention in light of NICE's duties to have due regard to the need to eliminate unlawful discrimination, advance equality of opportunity, and foster good relations between people with a characteristic protected by the equalities legislation and others?

Please note that we reserve the right to summarise and edit comments received during consultations or not to publish them at all if in the reasonable opinion of NICE, there are a lot of comments, or if publishing the comments would be unlawful or otherwise inappropriate.

Closing date for comments: 18 October 2018

Target date for publication of guidance: January 2019

## 1 Draft recommendations

- 1.1 Current evidence on electrically stimulated intravesical chemotherapy for non-muscle-invasive bladder cancer shows there are no major safety concerns. Evidence on efficacy is limited in quantity and quality. Therefore, this procedure should only be used in the context of [research](#).
- 1.2 Further research should include randomised controlled trials compared with standard care, which should report details of patient selection.

## **2 The condition, current treatments and procedure**

### ***The condition***

- 2.1 The most common form of bladder cancer is transitional cell carcinoma (TCC). Non-muscle-invasive TCC is classified as stage Ta when the tumour is confined to the urothelium with no spread into the wall of the bladder or beyond, and stage T1 when there is spread into the connective tissue layer between the urothelium and the muscle wall. It is graded from G1 (low grade, least aggressive) to G3 (high grade, most aggressive). Another type of non-muscle-invasive cancer is carcinoma in situ, in which aggressive cancer cells spread within the surface lining of the bladder.

### ***Current treatments***

- 2.2 Conventional treatment for non-muscle-invasive cancer is transurethral resection of bladder tumour (TURBT), in which malignant tissue is removed with an electrocautery device during cystoscopy. Intravesical chemotherapy with Bacillus Calmette-Guérin (BCG) vaccine or other chemotherapeutic drugs may also be used. The drug is instilled directly into the bladder, either alone or as adjuvant therapy after TURBT. The aim is to reduce the risk of cancer recurrence. Intravesical microwave hyperthermia may also be used, in combination with intravesical chemotherapy. Cystectomy may be needed in some patients.

### ***The procedure***

- 2.3 Electrically stimulated intravesical chemotherapy (also known as electromotive drug administration) can be used as neoadjuvant treatment before TURBT, or as adjuvant treatment after TURBT. The procedure involves the use of a device to create an electric field across the bladder wall, with the aim of stimulating directional

ionic and solute movement of the intravesical fluid. This increases absorption of the drug into the bladder lining.

- 2.4 The procedure is usually done using local anaesthesia. With the patient in a supine position, electrode pads are placed on the skin of the lower abdomen and a catheter (with an intravesical electrode) is inserted into the bladder through the urethra. When the catheter and electrodes are in place the chemotherapeutic drug solution (usually mitomycin C in saline or distilled water) is instilled into the bladder through the catheter. The cutaneous and intravesical electrodes are connected to a generator that creates a current of up to 25 milliamps. Treatment sessions last about 30 minutes and are repeated, often weekly, for 4 to 8 weeks or longer for adjuvant treatment. After the procedure, the bladder is drained and the catheter is removed.

### **3 Committee considerations**

#### ***The evidence***

- 3.1 To inform the committee, NICE did a rapid review of the published literature on the efficacy and safety of this procedure. This comprised a comprehensive literature search and detailed review of the evidence from 6 sources, which was discussed by the committee. The evidence included 1 systematic review, 2 non-randomised controlled trials and 3 case series and is presented in table 2 of the [interventional procedures overview](#). Other relevant literature is in the appendix of the overview.
- 3.2 The specialist advisers and the committee considered the key efficacy outcomes to be: time to disease progression, progression-free survival and quality of life.
- 3.3 The specialist advisers and the committee considered the key safety outcomes to be: infection and bleeding.

- 3.4 This guidance is a review of NICE's interventional procedures guidance on [electrically-stimulated intravesical chemotherapy for superficial bladder cancer](#).

### ***Committee comments***

- 3.5 The committee was informed that the procedure may have a role when treatment with Bacillus Calmette-Guérin (BCG) vaccine is contraindicated or has been unsuccessful, and in patients who are unable to have a cystectomy.
- 3.6 The committee noted that the authors of the Cochrane review described the studies for this procedure as being poorly reported.

Tom Clutton-Brock

Chairman, interventional procedures advisory committee

September 2018

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