INTRAVESICAL IMMUNOTHERAPY WITH BCG
INFORMATION FOR PATIENTS

What evidence is this information based on?
This booklet includes advice from consensus panels, the British Association of Urological Surgeons, the Department of Health and other sources. As such, it is a reflection of best urological practice in the UK. You should read this booklet with any advice your GP or other healthcare professional may already have given you. We have outlined alternative treatments below that you can discuss in more detail with your urologist or specialist nurse.

What does the procedure involve?
It involves putting the BCG vaccine into the bladder to treat aggressive bladder cancer or superficial cancer that returns.

What are the alternatives to this procedure?
Alternatives to this procedure include repeated cystoscopy, radiotherapy, surgical removal of the bladder with urinary diversion or bladder reconstruction and systemic chemotherapy.

What should I expect before the procedure?
Your Consultant Urologist has referred you for treatment of your superficial bladder cancer. Superficial bladder cancer affects the inner surface of the bladder only, but can progress to more aggressive disease.

The aim of the treatment is to stop or slow down re-growth of the cancer by putting a drug into the bladder. The treatment recommended for you is BCG. BCG is a commonly used vaccine against tuberculosis (TB) and contains a bacterium from the same family as the TB bacterium. This bacterium has been altered to reduce the risk of infection but can still produce the immune reaction needed to have a beneficial effect. It has been shown that putting liquid containing BCG vaccine into the bladder is an effective treatment for bladder cancer.

Like all powerful treatments, it comes with some possible side-effects (see below) and you should balance these risks against the risk of the bladder cancer itself.

Please note
Some preparations of BCG may interact with influenza vaccine so should not be used within six weeks of having the vaccination. Although OncoticeBCG®, which is
currently the only form of BCG available in the UK, does not carry this warning from the manufacturer (Merck Sharp & Dohme), similar precautions should be taken.

The first course of treatment is called the **induction course** and lasts for six weeks. Once you have completed this, you will enter a program of **maintenance treatment** lasting approximately three years. This will include several doses of BCG with a flexible cystoscopy before each one. The main reasons for patients failing to complete the full course are the side-effects (see below) or the disease progressing (or both).

You should limit how much fluid you drink for six hours before each treatment. Your first treatment will take up to three hours. Depending on how well you tolerate this treatment, future visits to the clinic should take about 30 minutes.

When you arrive in the clinic, you will be asked to do a urine sample which will be tested to make sure that you do not have a urine infection. If you do have an infection, your treatment will need to be postponed for one week while you are treated with antibiotics.

Please tell your surgeon (before your surgery) if you have any of the following:

- An artificial heart valve
- A coronary artery stent
- A heart pacemaker or defibrillator
- An artificial joint
- An artificial blood-vessel graft
- A neurosurgical shunt
- Any other implanted foreign body
- A regular prescription for warfarin, aspirin or clopidogrel (Plavix®)
- A previous or current MRSA infection
- A high risk of variant-CJD (if you have had a corneal transplant, a neurosurgical dural transplant or injections of human-derived growth hormone).

When you are admitted to hospital, you will be asked to sign the second part of your operation consent form giving permission for your operation to take place, showing you understand what is to be done and confirming that you want to go ahead. Make sure that you are given the opportunity to discuss any concerns and to ask any questions you may still have before signing the form.

**What happens during the procedure?**

A fine plastic tube (catheter) will be passed into your bladder and the liquid containing the vaccine (approximately half a cup of fluid) will be given through it. The catheter will then be removed. You will be asked not to pass urine for two hours to allow the medication to treat the bladder lining.

On your first visit, you will be asked to stay in the clinic until the treatment is completed and you will be asked to pass urine before you go home. If you live within easy reach of the hospital and have your
own transport, you may be allowed to go home with the medication in your bladder and pass urine at home after two hours.

**What happens immediately after the procedure?**
You should be told how the procedure went and you should:

- ask the surgeon if it went as planned;
- let the medical staff know if you are in any discomfort;
- ask what you can and cannot do;
- feel free to ask any questions or discuss any concerns with the ward staff and members of the surgical team; and
- make sure that you are clear about what has been done and what happens next.

Once the treatment has been completed, you will be able to go home.

All the urine you pass during the first 6 hours after treatment should be disinfected by pouring undiluted household bleach (equal to the amount of urine passed) into the toilet; you should leave this for 15 minutes before flushing the toilet.

You should drink plenty of fluids (two to three litres) for the first few days after the treatment. Some patients find that a glass of cranberry juice every day eases any bladder symptoms. However, do not drink cranberry juice if you are taking warfarin.

**Are there any side-effects?**
Most procedures have possible side-effects. But, although the complications listed below are well-recognised, most patients do not suffer any problems.

**Common (greater than 1 in 10)**
- Urinary tract infection (if you get an infection, the next dose of BCG will have to be postponed).
- Some bladder discomfort.
- Flu-like symptoms which can last for two to three days.
- Urgently needing to pass urine, and wanting to pass urine more frequently, which can last for two to three days.
- Failure to complete the course of treatment due to discomfort in the bladder.
- Blood in the urine.
- Debris in the urine.

**Occasional (between 1 in 10 and 1 in 50)**
- Narrowing of the urethra (water pipe) following repeated use of a catheter.
- Inflammation which can affect various parts of the body (the liver, joints and the back of the eye).

**Rare (less than 1 in 50)**
- Persistent or severe pain after treatment, sometimes leading to removal of the bladder.
- Generalised and possibly serious infection with the BCG bacteria needing treatment in hospital with powerful antibiotics. This is not TB and there is no risk of catching TB from the treatment.
Hospital-acquired infection

- Colonisation with MRSA (0.9% - 1 in 110).
- Clostridium difficile bowel infection (0.01% - 1 in 10,000).
- MRSA bloodstream infection (0.02% - 1 in 5000).

The rates for hospital-acquired infection may be greater in high-risk patients, for example those patients
- with long-term drainage tubes;
- who have had their bladder removed due to cancer;
- who have had a long stay in hospital; or
- who have been admitted to hospital many times.

What should I expect when I get home?
When you are discharged from hospital, you should:

- be given advice about your recovery at home;
- ask when you can begin normal activities again, such as work, exercise, driving, housework and sex;
- ask for a contact number if you have any concerns once you return home;
- ask when your follow-up will be and who will do this (the hospital or your GP); and
- be sure that you know when you get the results of any tests done on tissues or organs which have been removed.

If you think you have a urine infection (pain when passing urine, passing urine more frequently or foul-smelling urine) or if you develop a high temperature with backache, it is important to contact your GP and get treatment with antibiotics.

What else should I look out for?
Because this treatment is put directly into the bladder and not into the blood stream, you will not experience the side effects often associated with other cancer drug treatments.

Are there any other important points?
You should wash your hands and genitals after you have passed urine. We also advise you to bring a wash bag with you to hospital when you come for the treatment.

Men should pass urine sitting down the first time they go to the toilet after the treatment. After that, they can pass urine in the usual way (standing).

It is best not to have sex for at least 24 hours after the treatment as this can cause some discomfort. During the treatment, and for one week afterwards, you should use a condom during sex.

If you are a smoker, you should be aware that smoking seems to encourage the return of bladder cancer.
Driving after surgery
It is your responsibility to make sure you are fit to drive following your surgery. You do not normally need to tell the DVLA that you have had surgery, unless you have a medical condition that will last for longer than three months after your surgery and may affect your ability to drive. You should, however, check with your insurance company before returning to driving. Your doctors will be happy to give you advice on this.

Is any research being carried out in this area?
Before your operation, your surgeon or specialist nurse will tell you about any relevant research studies taking place. In particular, they will tell you if any tissue that is removed during your surgery will be stored for future study. If you agree to this research, you will be asked to sign a special form giving your consent.

All surgical procedures, even those not currently undergoing research, are audited so that we can analyse our results and compare them with those of other surgeons. In this way, we learn how to improve our techniques and results; this means that our patients will then get the best treatment available.

What should I do with this information?
Thank you for taking the trouble to read this booklet. If you want to keep a copy for your own records, please sign below. If you would like a copy of this booklet filed in your hospital records for future reference, please let your urologist or specialist nurse know. However, if you do agree to go ahead with the scheduled procedure, you will be asked to sign a separate consent form that will be filed in your hospital records; we can give you a copy of this consent form if you ask.

I have read this booklet and I accept the information it provides.

Signature--------------------------------------------------------------------------------Date--------------------------------------------------------------------------------
How can I get information in alternative formats?
Please ask your local NHS Trust or PALS network if you require this information in other languages, large print, Braille or audio format.

Most hospitals are smoke-free. Smoking can make some urological conditions worse and increases the risk of complications after surgery. For advice on stopping, contact your GP or the free NHS Smoking Helpline on 0800 169 0 169

Disclaimer
While we have made every effort to be sure the information in this booklet is accurate, we cannot guarantee there are no errors or omissions. We cannot accept responsibility for any loss resulting from something that anyone has, or has not, done as a result of the information in this booklet.

The NHS Constitution
Patients’ Rights & Responsibilities

Following extensive discussions with staff and the public, the NHS Constitution has set out new rights for patients that will help improve your experience within the NHS. These rights include:

- a right to choice and a right to information that will help you make that choice;
- a right to drugs and treatments approved by NICE when it is considered clinically appropriate;
- a right to certain services such as an NHS dentist and access to recommended vaccinations;
- the right that any official complaint will be properly and efficiently investigated, and that patients will be told the outcome of the investigations; and
- the right to compensation and an apology if you have been harmed by poor treatment.

The constitution also lists patients’ responsibilities, including:

- providing accurate information about their health;
- taking positive action to keep yourself and your family healthy.
- trying to keep appointments;
- treating NHS staff and other patients with respect;
- following the course of treatment that you are given; and
- giving feedback (both positive and negative) after treatment.

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Published: March 2014
Due for review: March 2015