NHS
Greater Glasgow and Clyde

CLINICAL GUIDELINE

Intravesical Gentamicin for the management of resistant urinary tract infection in patients aged ≥ 18 years

A guideline is intended to assist healthcare professionals in the choice of disease-specific treatments.

Clinical judgement should be exercised on the applicability of any guideline, influenced by individual patient characteristics. Clinicians should be mindful of the potential for harmful polypharmacy and increased susceptibility to adverse drug reactions in patients with multiple morbidities or frailty.

If, after discussion with the patient or carer, there are good reasons for not following a guideline, it is good practice to record these and communicate them to others involved in the care of the patient.

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Important Note:

The online version of this document is the only version that is maintained.
Any printed copies should therefore be viewed as 'Uncontrolled' and as such, may not necessarily contain the latest updates and amendments.

Intravesical Gentamicin for the management of resistant urinary tract infections in patients aged ≥ 18 years

1. Rationale for Use

There are small groups of patients who have repeated frequent urinary tract infections (UTIs) that cause systemic upset and which require either oral or parenteral antibiotics to achieve symptom relief. These patients have to repeatedly attend both primary and secondary care for treatment and their quality of life is poor, both because of the symptoms the infection has caused, and because of their repeated need to seek medical treatment. Some of these patients have had ileocystoplasties for bladder reconstructions, others have intact bladders but need to perform intermittent catheterisation or have indwelling catheters with repeat sepsis.

The purpose of this guideline is to provide a framework to ensure that intravesical gentamicin is prescribed appropriately and used safely.

2. Unlicensed indication

While gentamicin intravenous injection possesses a UK Marketing Authorisation, its use for intravesical administration in the management of resistant urinary tract infections is an unlicensed indication. A patient information leaflet on the use on unlicensed medicines is available here: GGC Medicines: Unlicensed or off-label medicines

3. Allowed Prescribers and responsibilities

Within NHS GG&C, intravesical gentamicin will only be initiated by a Consultant Urologist.

The Urology Consultant initiating therapy will:

- consent in writing the patient / guardian
- provide the patient with written and verbal information about the treatment
- ensure the patient has been adequately trained to administer the treatment,
- prescribe gentamicin for so long as it is indicated
- send a standard letter to patient's GP on commencement of intravesical Gentamicin including the rationale for treatment, treatment regimen, potential complications, and contact numbers.

4. Eligible patients

Adult patients who have an intact bladder **and** suffer repeated, difficult to treat, urinary tract infections. Infections should be proven by MSSU.

- These patients may have failed on long term oral antibiotic prophylaxis or be intolerant to the oral agents currently available for this indication.
- The treatment should usually only be used when all conventional measures to reduce the frequency of urinary tract infections have failed, including a trial of methenamine hippurate, long term, low dose antibiotic prophylaxis; Cystistat® or iAluril® instillations, use of cranberry juice or capsules; high fluid intake and frequent voiding' and a check of intermittent self catheterisation technique where applicable. An underlying treatable cause for infections will also have been ruled out with upper tract imaging and cystoscopy.
- The patient should be made aware by the clinicians responsible for ongoing care that

the treatment may be of limited benefit and has not been subjected to detailed research. They should then take part in a full discussion and decide for themselves whether they want to use this novel treatment. This discussion must be documented in the patient's medical notes along with the patient's consent if they decide to proceed.

- The patient's technique in performing intermittent self catheterisation should be checked and found to be satisfactory. If not already able to self-catheterise or if technique is poor, patients or a carer must be taught self catheterisation technique by a Urology Specialist Nurse.
- Patients will be asked about pre-existing hearing impairment and the risks of ototoxicity with gentamicin discussed before proceeding with treatment

5. Exclusion Criteria

- Previous microbiology which shows that the patient has gentamicin resistant organisms
- Patients with a gentamicin allergy. Consideration also must be given to whether there are any relatives in the immediate household with a gentamicin allergy and any necessary precautions
- Patients with myasthenia gravis
- Patient/carer unable to self-catheterise

6. Dosage and method of administration

Dosage: Gentamicin 80mg instilled intravesically once daily (at night) for 60 days. The frequency will then be reduced to twice every week for the next 60 days, then to once per week for 60 days and then treatment stopped (6 month treatment duration in total).

Duration: Therapy is intended to continue for 6 months in the absence of complications or a change in circumstances.

Administration: Gentamicin 80mg diluted in 50ml of sterile sodium chloride 0.9% should be instilled in the bladder nightly, after completion of a conventional bladder washout, and the catheter withdraw, leaving the solution in the bladder overnight.

The solution will be voided spontaneously in the morning, or be removed by routine self catheterisation.

Patients will be provided a patient information leaflet with detailed steps on method of administration.

7. Prescription and supply

- Prescriptions will be written by the Urology Consultants only.
- Initially one month's supply will be issued followed by 1 to 3 monthly prescriptions to meet with the patient's clinic appointments. Details of when the patient is due to collect will be written on the prescription (see appendix one)
- Gentamicin 80mg/2mls injection (for intravesical use) should be prescribed at rate of 30 amps/month for the first 60 days then reduced as dosing frequency is reduced. Sodium chloride 0.9% in ampoules or sterile bottles should be prescribed as required.

- Equipment to facilitate intravesical administration will initially be provided by the Specialist Nurse (for up to 1 month) and the patient's GP will prescribe subsequent supplies. In addition to catheter supply equipment will include: 1000ml bottle NaCl 0.9% (100ml/treatment – 50ml wash then 50ml for treatment), sharps box, 50ml catheter tip syringe, needles and syringes to extract gentamicin dose from vial, alcohol wipes, foil bowl.

For disposal of waste products see GGC Medicines Update: Safe disposal of sharps waste in primary care. Available on the intranet via Safe disposal of sharps waste

8. Response Criteria/ monitoring

Patients will be reviewed initially at Day 7 at urology clinic to assess technique and if they are tolerating the treatment. A gentamicin level will also be checked. Treatment will be discontinued if gentamicin level >1mg/L. These will be rechecked if the treatment is continued beyond the initial six months.

The patient will be reviewed again at 1 month, 3 months and 6 months either at clinic or via telephone consultation.

At each review, patients will be assessed for clinical benefits of treatment, reduction in hospital/ high level of care with sepsis admissions, adverse drug reactions and a decision made regarding continuation of treatment. Signs of ototoxicity will also be checked (e.g. changes in hearing or balance) and treatment stopped/audiology contacted if there are any concerns.
At the 3 month review (after stepping down from daily to twice weekly) clinical benefit will be reviewed and decision made to complete 6 month treatment or stop treatment (e.g. episodes of UTI, not tolerating treatment).

If during the treatment period, the patient experiences signs of UTI then a urine sample should be taken for culture and sensitivities.

9. Discontinuation Criteria

If no clinical benefit is demonstrated at the 3 month review, or any reviews thereafter, intravesical gentamicin will be discontinued.

If gentamicin resistance or adverse effects develop at any time during treatment, then intravesical gentamicin will be discontinued.

10. Adverse Drug Reactions

Gentamicin may cause local irritation in the bladder. Ototoxicity and nephrotoxicity are unlikely adverse effects.

The Medicines and Healthcare products Regulatory Agency (MHRA) yellow card scheme should be used to report any adverse effects which are serious, medically significant or result in harm from intravesical gentamicin. This will be done online at www.mhra.gov.uk/yellowcard, via Yellow Card mobile app or via paper Yellow Card form found in BNFs.

11. Audit

An audit of all patients commenced on intravesical gentamicin will be undertaken within the urology department. Data recorded will include; efficacy of treatment, number/ type of hospital admissions due to UTIs, number of episode of symptomatic UTIs, side effects (including neurotoxicity and ototoxicity) and the development of any gentamicin resistance. Results will be shared with the NHS GGC: Antibiotic Utilisation Committee.

12. References

- Summary of Product Characteristics for SPC for Cidomycin 80mg/2ml Solution for Injection (gentamicin) SANOFI Last updated on eMC: Accessed via www.medicines.org.uk/emc (accessed 9.10.23)
- SIGN 160 Management of suspected bacterial urinary tract infection in adults July 2006, Updated July 2012 available via Management of suspected bacterial lower urinary tract infection in adult women (sign.ac.uk)
- European Association of Urology (EAU) guideline on urological infections) available via http://uroweb.org/guideline/urological-infections/
- Royal Devon and Exeter NHS Foundation Trust. Intravesical gentamicin guideline May 2011. Date Due for revision June 2012.
- The use of intravesical gentamicin to treat recurrent urinary tract infections in lower urinary tract dysfunction. Abrams P., Hashim H., Tomson C., Macgowan A., Skews R., Warren K. Neurourology and Urodynamics. 36 (8) (pp 2109-2116), 2017.
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- Gentamicin bladder instillations decrease symptomatic urinary tract infections in neurogenic bladder patients on intermittent catheterization. Cox L., He C., Bevins J., Clemens J.Q., Stoffel J.T., Cameron A.P. Canadian Urological Association Journal 2017; 11 (9): E350-E354.
- McPhee S, Bekarma H, Meddings R, et al. Intravesical Gentamicin (IVG) installations improve QOL and reduce micro-organism resistance in patient with recurrent UTI's. Abstract 109. International Continence Society Conference, Gothenburg 2019. Available from: https://www.ics.org/2019/abstract/109
- NHS GGC ADTC. Medicines blog: Safe disposal of sharps waste in primary care. Last updated 26/07/23. Accessed via GGC Medicines: Safe disposal of sharps waste in primary care. Accessed 9.11.23

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Appendix 1

Instalment Prescription form - Intravesical Gentamicin

Patient:		**Date of Birth**	
CHI:		**Ward/Hospital**	
Address:		**Patient Contact details**	

Responsible Consultant	

Month	Prescription	Duration	Instalments	Date dispensed Disp/Checked by
1	Gentamicin 80mg vial ONCE daily Sodium Chloride 0.9% 20ml amp	30 days	30 amps supplied 8x20 20ml amp supplied	
2	Gentamicin 80mg vial ONCE daily Sodium Chloride 0.9% 20ml amp	30 days	30 amps supplied 8x20 20ml amp supplied	
3&4	Gentamicin 80mg vial TWICE weekly Sodium Chloride 0.9% 20ml amp	60 days	20 amps supplied 5x20 20ml amp supplied	
5&6	Gentamicin 80mg vial ONCE weekly Sodium Chloride 0.9% 20ml amp	60 days	10 amps supplied 3x20 20ml amp supplied	

At the 3 month review the patient is assessed for clinical benefit. If decision is to stop treatment then the reviewer must send an email to the local pharmacy department to cancel the remaining instalments.

Prescriber signature _____ Date _____

Prescriber's name _____ Designation_____

Contact number/Email_____

Clinical Pharmacist Check _____ Date _____