

## **Appendix 4 – Paediatric cystic fibrosis intravenous aminoglycoside consent form**

The following information explains the aims, benefits, and risks of aminoglycoside antibiotics.

### **What are intravenous (IV) aminoglycosides?**

Aminoglycosides are antibiotics (given into a vein), used in children with cystic fibrosis (CF), to treat serious lung infections caused by bacteria such as *Pseudomonas aeruginosa* and *Mycobacterium abscessus* complex. The aminoglycoside antibiotics we use are tobramycin and amikacin.

### **Reasons for starting aminoglycoside therapy**

Both *Pseudomonas* and *Mycobacterium abscessus* complex infections are hard to eradicate and require treatment with more than one antibiotic. There is strong evidence that aminoglycosides are one of the most effective types of antibiotics for children with CF, so it is our standard practice to use them. This is in line with recommendations from both the UK CF Trust and the European Cystic Fibrosis Society. We use these antibiotics when we believe the potential benefits of this treatment outweigh the risks, which are outlined below.

### **Side effects**

Like many important medicines, aminoglycosides have side effects and can affect your child's kidneys and hearing, and therefore we always monitor drug levels in your child's blood to minimise the possibility of these occurring.

Although theoretically this is possible with a single aminoglycoside course, it is usually the accumulation of many courses (usually over several years), that increases the risk of hearing problems, even if every blood test for the drug concentration was within the normal range.

It should be emphasised that the possibility of significant hearing problems is small, even with many aminoglycoside courses. Some children may be more sensitive to these antibiotics than others, but this is still a new area of research.

### **Monitoring**

Regular blood tests (weekly) will be done to ensure that the correct dose of antibiotic is given to help minimise the risk of side effects.

We will also arrange for children to have a baseline hearing test at their local hospital if they need amikacin for *Mycobacterium abscessus* complex infections; or are starting regular 3-monthly courses of IV antibiotics, and this will be repeated every year or sooner if concerns arise.

If symptoms such as hearing difficulties, tinnitus (ringing sound in the ears), dizziness or problems with balance are noticed, please tell your doctor as soon as possible. We will be monitoring for kidney problems, but it is most important to stay well hydrated (drink plenty) especially in hot weather. If there are concerns, we will stop the aminoglycosides and use an alternative antibiotic, although the alternative antibiotics may not be quite as effective in treating the infection.

**Child or Parent/Carer name**

**Child or Parent/Carer signature**

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Date.....

I agree to the treatment outlined above and have read and understood the information given to me and my questions have been answered.

**Interpreter name**

**Interpreter signature**

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Date.....

I have explained the information above to the patient/parent/carer to the best of my ability and in a way in which I believe he / she can understand.

**Doctor name**

**Doctor signature**

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Date .....

I have discussed the side effects with the patient and answered his / her questions.

Patient / parent / carer has given consent to treatment with IV aminoglycosides

Patient / parent / carer has declined treatment with IV aminoglycosides

Copy into patient notes

Copy given to patient/parent/carer

Copy into Audit Folder