Christopher Feinmann
Technology Appraisal Project Manager
NICE
Peter House
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10th December 2007

Dear Mr Feinmann,

Juvenile Diabetes Research Foundation
Response to Appraisal Consultation Document:
Continuous subcutaneous insulin infusion for the treatment of diabetes mellitus (review of technology appraisal guidance)

Thank you for the opportunity to feedback on this draft guidance. We believe that this is, in general, a positive outcome for people with type 1 diabetes, particularly children.

Firstly, a response to your specific questions:

i. We are satisfied that all the relevant evidence has been taken into account.
ii. We have no further comment about the summaries of clinical and cost effectiveness of CSII treatment
iii. Whilst we concur with the main conclusions we have some reservations that are outlined below. We hope that these will be taken into consideration when preparing final guidance
iv. There are no equality related issues that we believe need special consideration.

Further comments

Children

Juvenile Diabetes Research Foundation is delighted to note the improved access to pumps for children which we believe will go some way to addressing the gap between levels of care for children with type 1 diabetes in the UK and those in Europe and the USA. This development has met with approval by all parents of children with type 1 diabetes who have taken part in JDRF's review process.

We would like NICE to consider changing the age limits to recommend insulin pump therapy as a treatment option for children **up to 12 years** old to ensure that CSII treatment is available for all children of primary school age. The current draft guidance could be interpreted to restrict this access to children of 10 and under.

We are concerned that there is no guidance about continuation of CSII use for children once they reach the cut off age. The current wording allows for interpretation and could be used to withdraw or refuse funding either as a child reaches 11 or on moving to practitioner who does not support pump use. It would be

very alarming to the child and detrimental to blood glucose control to ask a child who has grown up using pump therapy to switch suddenly to MDI. We very much hope that any child who has been started on pump therapy will have the right to continue this method of treatment as long as they wish/it is suitable.

HbA1c levels

We are extremely worried about the increase in HbA1c levels needed for CSII therapy in children over 11 and adults. Medical guidelines in the UK give a target HbA1c level of 7.5% and this is even lower in other countries (the USA is moving towards levels of 6.5%). This increase will have three outcomes:

a) People who have improved their control through pump use may now not be eligible for CSII treatment.
b) This infers the message that HbA1c levels of 8.5% are adequate although evidence shows that the closer people with type 1 diabetes can get to normal blood sugar levels (range in people without the condition is usually 4-6.1), the smaller the risk of complications. Setting this higher level sends mixed messages.
c) People with type 1 diabetes struggling to maintain levels of 7.5% will be tempted to let their sugar levels 'float up' in order to qualify for a pump causing damage to their bodies during this period.

By setting levels at 8.5% these guidelines effectively tie the hands of practitioners and people struggling to achieve that final drop to recommended HbA1c levels. If medical guidance advises a certain target then people with type 1 diabetes who are engaged in achieving the recommended levels should have access to all technology and support to do so.

Hypoglycaemia

JDRF would like to recommend a change in wording for point 1.3 to read:

The person *has experienced* disabling hypoglycaemia

This is because anecdotal evidence suggests that many people with type 1 diabetes who have experienced a traumatic hypoglycaemic episode may keep their blood sugars high in order to prevent the experience ever happening again. Thus they may run at 8-8.5% constantly without experiencing hypos but causing damage to their bodies and living with the acute and life affecting fear of hypoglycaemia.

Targets

JDRF would like NICE to further consider setting targets for implementation of CSII use in the UK. This is because past behaviour indicates that some diabetes practitioners do not keep up to date with technology developments and are unwilling to instigate pump use. We have examples of parents shifting their children's diabetes care centre because they are unable to access pumps although their child qualifies under current guidance. It has taken three years to reach the current NICE target of two percent of people with type 1 diabetes on pumps and removing this target may actually reduce this number. We would like to see a target figure of 15-20 percent of people with type 1 diabetes on CSII therapy to bring us in line with Europe and the

USA. Furthermore we would ask that this be audited to ensure that the diabetes community is responding proactively.

Yours sincerely,

[redacted]
Director of Policy & Communications

cc: [redacted], Juvenile Diabetes Research Foundation

[redacted], Juvenile Diabetes Research Foundation

[redacted], King's College London
[redacted], JDRF UK Scientific Advisory Committee