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Dear Sir/ Madam

Continuous subcutaneous insulin infusion (CSII) for the treatment of diabetes mellitus (review of technology appraisal guidance 57)

Thank you for the opportunity to respond to the appeal made by the British Dietetic Association (BDA) to the final appraisal determination (FAD) for the above technology appraisal. As is noted in the Appeal Panel Chair's response to the appellant, only the appeal point lodged under ground 1 will be heard.

FAD section 1.2 recommends CSII therapy as a treatment option for children younger than 12 years with type 1 diabetes mellitus provided that:

- *MDI therapy is considered to be impractical or inappropriate, and*
- ***children on insulin pumps would be expected to undergo a trial of MDI therapy between the ages of 12 and 18 years.***

The BDA appealed against this recommendation on the ground that "*the institute has failed to act fairly and in accordance with the appraisal procedure set out in the institute's Guide to the Technology Appraisal Process*" because *"the recommendation contained in Section 1.2 has suddenly appeared in the FDA. This recommendation was not evident in any of the preliminary drafts sent out for consultation. We therefore feel the consultees have not been given a fair opportunity to comment on this aspect of the guidance."*

When accepting this appeal point the Chair of the Appeal Panel noted that "*it is inherent in a consultation exercise that the documents under consultation may change so the simple fact that the FAD differs from the earlier documentation sent to consultees will not, of itself, establish unfairness.*"

Concerning the acceptability of making this sort of change at the FAD stage: the Committee is required to consider responses to consultation, make changes to their preliminary recommendations if they decide these are appropriate and clarify any areas of ambiguity. This is normally undertaken without a further round of consultation.

The part of the recommendation that is subject to appeal was added to the guidance as a result of a comment received during ACD consultation. In its response to consultation, the Juvenile Diabetes Research Foundation raised the concern *" 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."*

As concerns the substantive logic of the change considered at the FAD meeting, the Committee considered the following:

- There is little evidence in the literature of clinical effectiveness of CSII in young children – most trials were in older people.

However, children, especially young children, were considered by the committee to merit special consideration. The following factors were considered:

- The factors relevant to favouring CSII therapy for adults in whom MDI therapy had failed to achieve an acceptable HbA1c level, or who experienced disabling hypoglycaemia, applied as least as much to children.

- The paediatric clinical expert's commentary of the importance of insulin pumps in managing diabetes in the very young due to the ability to deliver very small amounts of insulin and to titrate insulin dose to a child's irregular pattern of daily activities. Furthermore, young children would not be expected to self-inject.

The committee concluded that children who have an onset of type 1 diabetes before age 12 should have the option to use CSII without a trial of MDI.

- Children above the age of 12 years are expected to be able to self-inject. Therefore children, who have an onset of type 1 diabetes after the age of 12 would undergo a trial of MDI, and CSII considered if MDI does not provide acceptable glycaemic control, that is in the same way as recommended for adults (FAD section 1.1).
- When children who have started with CSII before the age of 12,without a trial of MDI reach age 12 and beyond, CSII could become an inefficient use of NHS resources without a trial of MDI at that point. Therefore, continuation of CSII beyond age 12 could not be supported without a trial of MDI.

The Committee formulated a position on the management of the transition from childhood to adulthood. The Committee considered the need for flexibility in view of other life events that may occur around this time and concluded that such a trial of MDI could be undertaken at any time until a child (adolescent) reached adulthood at the age of 18 years (see also FAD sections 4.3.8 and 4.3.9).

Without the recommendation in FAD section 1.2 that children on insulin pumps would be expected to undergo a trial of MDI therapy between the ages of 12 and 18 years, a situation would arise in the future in which those adults who received CSII treatment as children would not have a trial of MDI. The evidence for this appraisal has shown that using CSII in all these adults would not be an efficient use of NHS resources. Without the ability of specifying this recommendation the Appraisal Committee would have had to remove recommendation 1.2 entirely and CSII treatment would require an

unsuccessful trial of MDI for all age groups. On balance, the committee considered that for those who did not have a trial of MDI as children, it was reasonable to recommend that they undertook the trial during the progression to adulthood.

Yours sincerely

Professor Andrew Stevens

Chair of the Appraisal Committee