Appendix G - professional organisation statement template

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Single Technology Appraisal (STA)

Empagliflozin combination therapy for treating type 2 diabetes [ID641]

Thank you for agreeing to give us a statement on your organisation's view of the technology and the way it should be used in the NHS.

Healthcare professionals can provide a unique perspective on the technology within the context of current clinical practice which is not typically available from the published literature.

To help you in making your statement, we have provided a template. The questions are there as prompts to guide you. It is not essential that you answer all of them.

Please do not exceed the 8-page limit.

About you

Your name: [redacted] **registrar submitting comments on behalf of:**

Name of your organisation: ABCD (Association of British Clinical Diabetologists) and RCP (Royal College of Physicians)

Are you (tick all that apply):

- a specialist in the treatment of people with the condition for which NICE is considering this technology?
- a specialist in the clinical evidence base that is to support the technology (e.g. involved in clinical trials for the technology)?
- an employee of a healthcare professional organisation that represents clinicians treating the condition for which NICE is considering the technology? If so, what is your position in the organisation where appropriate (e.g. policy officer, trustee, member etc)?
- other? (please specify)

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What is the expected place of the technology in current practice?

How is the condition currently treated in the NHS?

Type 2 diabetes treated with range of up to 10 therapeutic options , using guidelines that recognise individualised approach to treatment selection

Is there significant geographical variation in current practice?
Yes. National Diabetes audit and QoF returns show considerable variation in process measures , treatments used and outcomes

Are there differences of opinion between professionals as to what current practice should be?

New NICE T2 guidance will help. As care is individualised there should always be room for some variation in care.

What are the current alternatives (if any) to the technology, and what are their respective advantages and disadvantages?
This is 3rd in calls of SDGLT2 inhibitors but there are some variations in clinical utlity. Empagliflozin has been shown to be of effect in modest renal disease CKD3b

Are there any subgroups of patients with the condition who have a different prognosis from the typical patient?
Those with renal disease or multiple features of metabolic syndrome

Are there differences in the capacity of different subgroups to benefit from or to be put at risk by the technology?
Renal status will affect response

In what setting should/could the technology be used – for example, primary or secondary care, specialist clinics?
All settings – 2nd-3rd line in primary care and alongside insulin in secondary care

Would there be any requirements for additional professional input (for example, community care, specialist nursing, other healthcare professionals)?
No

If the technology is already available, is there variation in how it is being used in the NHS?
Gradual introduction of this new class into DM care in primary care setting

Is it always used within its licensed indications? If not, under what circumstances does this occur?
It may be considered for obese type 1 diabetes patients

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Please tell us about any relevant **clinical guidelines** and comment on the appropriateness of the methodology used in developing the guideline and the specific evidence that underpinned the various recommendations.
Vital that this class is incorporated into ongoing Type 2 DM NICE guidance

The advantages and disadvantages of the technology

NICE is particularly interested in your views on how the technology, when it becomes available, will compare with current alternatives used in the UK. Will the technology be easier or more difficult to use, and are there any practical implications (for example, concomitant treatments, other additional clinical requirements, patient acceptability/ease of use or the need for additional tests) surrounding its future use?
As with other drugs in class it is important to assess for genitourinary infections and avoid in elderly with CKD and/or recurrent UTIs

If appropriate, please give your view on the nature of any rules, informal or formal, for starting and stopping the use of the technology; this might include any requirements for additional testing to identify appropriate subgroups for treatment or to assess response and the potential for discontinuation.
All new classes should be used for 6 month trial and withdrawn if not showing sustained clinical benefit

If you are familiar with the evidence base for the technology, please comment on whether the use of the technology under clinical trial conditions reflects that observed in clinical practice. Do the circumstances in which the trials were conducted reflect current UK practice, and if not, how could the results be extrapolated to a UK setting? What, in your view, are the most important outcomes, and were they measured in the trials? If surrogate measures of outcome were used, do they adequately predict long-term outcomes?
HbA1c, weight, BP ,and renal function are key measures . The clinical study groups are similar to those seen in UK practice

What is the relative significance of any side effects or adverse reactions? In what ways do these affect the management of the condition and the patient's quality of life?
As with others in SGLT2I class, early potential for genitourinary infections in women more than men , often self-limiting and modest in nature

Are there any adverse effects that were not apparent in clinical trials but have come to light subsequently during routine clinical practice?

None our experts are aware of.

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Any additional sources of evidence

Can you provide information about any relevant evidence that might not be found by a technology-focused systematic review of the available trial evidence? This could be information on recent and informal unpublished evidence, or information from registries and other nationally coordinated clinical audits. Any such information must include sufficient detail to allow a judgement to be made as to the quality of the evidence and to allow potential sources of bias to be determined.

Implementation issues

The NHS is required by the Department of Health and the Welsh Assembly Government to provide funding and resources for medicines and treatments that have been recommended by NICE technology appraisal guidance. This provision has to be made within 3 months from the date of publication of the guidance.

If the technology is unlikely to be available in sufficient quantity, or the staff and facilities to fulfil the general nature of the guidance cannot be put in place within 3 months, NICE may advise the Department of Health and the Welsh Assembly Government to vary this direction.

Please note that NICE cannot suggest such a variation on the basis of budgetary constraints alone.

How would possible NICE guidance on this technology affect the delivery of care for patients with this condition? Would NHS staff need extra education and training? Would any additional resources be required (for example, facilities or equipment)?
No

Equality
NICE is committed to promoting equality of opportunity, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others. Please let us know if you think that this appraisal:

- could exclude from full consideration any people protected by the equality legislation who fall within the patient population for which [the treatment(s)] is/are/will be licensed;

- could lead to recommendations that have a different impact on people protected by the equality legislation than on the wider population, e.g. by making it more difficult in practice for a specific group to access the technology;
- could lead to recommendations that have any adverse impact on people with a particular disability or disabilities.

- No issues

Please tell us what evidence should be obtained to enable the Committee to identify and consider such impacts.