Appendix G - professional organisation statement template

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Single Technology Appraisal (STA)

Vedolizumab for treating moderately to severely active Crohn's disease after prior therapy [ID690]

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 canprovideauniqueperspectiveon thetechnologywithinthecontextofcurrentclinicalpracticewhichisnottypicallyavailablefro mthe publishedliterature.

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]
Name of your organisation: UK Clinical Pharmacy Association (UKCPA)

Are you (tick all that apply):

X 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? Is there significant geographical variation in current practice? Are there differences of opinion between professionals as to what current practice should be? What are the current alternatives (if any) to the technology, and what are their respective advantages and disadvantages?

Currently most units will follow ECCO/BSG guidelines for Inflammatory Bowel Disease and step treatment up from steroids (two episode /year) to thiopurines and then to biologics +/- thiopurines in accordance with NICE recommendations. However the duration depends on the strictness of the CCG and on local stopping rules/review rules and interpretation of NICE TA.
Advantage: adalimumab is cheaper for secondary care as it can go through homecare and therefore does not attract VAT. Homecare for Infliximab can noe be commissiones. Therapeutic drug monitoring is now possible informing threatment decisions.
Disadvantages: The anti-TNFs have a high risk of infection particularly in the elderly. Loss of response LOR is relatively high. Antibody formation is a risk or reason for LOR.

Are there any subgroups of patients with the condition who have a different prognosis from the typical patient? Are there differences in the capacity of different subgroups to benefit from or to be put at risk by the technology?
Currently patients aged >50 are of high risk if infection when biologics are used in CD longterm and therefore a biologics with less risk of infection in this older CD patient group would be of advantage if usage for maintenance in CD is recommended.
It is not clear if the typical patient having failed thiopurines who would be put on biologics in the UK responds differently to biologics than the treatment naïve patient. The trials do not consistently differentiate between these patient groups. Stratification is in its infancy in this disease area. Therefore it will be difficult to extrapolate the data of the trials to the UK population as the numbers are small and cannot guarantee adequate numbers in subgroups to be statistically significant. (unable to access supplementary Appendix)
It also seems that the course of the disease for the over 50 is different and therefore response for older patients needs to be analysed as a subgroup to identify if they response equally.

In what setting should/could the technology be used – for example, primary or secondary care, specialist clinics? Would there be any requirements for additional professional input (for example, community care, specialist nursing, other healthcare professionals)?
This is initially a secondary care administered infusion and therefore capacity would have to be found in most institutions for the provision of this technology if it would be mainly used after biologics failure. If it replaces biologics and is first line after thiopurines some capacity would be in the system for infusions in the hospital setting but probably not enough if it replaces adalimumab patients.

Homecare provision could be envisaged but parameters of good governance and patient safety would have to be established such as when to move to home care in view of safety etc.

If the technology is already available, is there variation in how it is being used in the NHS? Is it always used within its licensed indications? If not, under what circumstances does this occur?

NA

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.

No specific guideline for vedolizumab I know of.

ECCO 0DC guidelines
BSG IBD guidelines
UK IBD standards

These are the guidelines IBD services will follow and will be audited on through the UK IBD audit.
Would need to be incorprated into the IBD biologics audit.

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?

It will be easy to use the technology as the NHS is currently providing biologics as infusion in the hospital setting to a varied degree at most units.

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.

Currently patients would get selected if they failed conventional treatment and anti-TNFs . However this may change if treatment naïve patients would be eligible for this technology.

Stopping rules are only just in development for anti-TNFs (STORI data for IFX) and need to be evaluated.
http://www.cicra.org/what%E2%80%99s-the-stori-when-to-stop-infliximab

NICE would have to propose review dates and criteria.
Stratification of patients has not progressed enough to predict patient groups that would profit more than others from biologics.

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?

NICE 187: defines population eligible for biologics. '*This clinical definition normally, but not exclusively, corresponds to a Crohn's Disease Activity Index (CDAI) score of 300 or more, or a Harvey-Bradshaw score of 8 to 9 or above.*'

Issue around definition of sever acute (particular to UK) and severely active not being interchangeable. Trials were based on CDAI which is not routinely used for UK patients. From the data at 6 weeks this technology would not be suitable for sever acute disease so patient population needs clearly defining and this would have impact on service provision if different to current anti-TNF population.

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

Lower infection risk is of high importance.

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.

Unable to provide sources of additional data

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)?

Possibly more infusion space would need to be created as it may replace adalimuab or if mainly used as second line after anti-TNF ;failure as these patients creating an additional patient group for infusion.

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.

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

None ientified