Appendix G - professional organisation statement template

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Single Technology Appraisal (STA)

Vedolizumab for treating moderately to severely active ulcerative colitis [ID691]

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]

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 there is no option for the condition to be treated with biologics for maintenance despite the evidence that they work. There is significant geographical difference due to the different approach by CCGs on monitoring biologics expenditure used in IBD; some patients have access to biologics with CCGS not auditing usage strictly and CCGs monitoring according to NICE guidelines may enforce NICE guidance without considerations even for IFRs .
It is very clear that clinical practitioners are of the opinion that biologics are of great value in maontence of UC and would improve the management of UC considerably from the patient perspective.
Currently more toxic options such as methotrexate and thioguanin are available but their use is not well documented in UC with only a few case series currently published.

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 UC patient group would be of advantage if usage for maintenance in UC 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. 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.

ECCO UC 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.

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?

Current clinical practice does not involve the Mayo score as the NHS has not got the capacity for the number of colonoscopies and patient acceptability of assessment via colonoscopy is very low.

The trial includes the range from Mayo score 2-12 (highest possible) which includes our acute sever UC which are excluded in this review. This poses the question if the technology is as effectrive in lower may score pt as in high Mayo scorers. Therefore the population is not equivalent to the porposed UK population.

However the technology corresponds to current anti-TNF response rate in UC and has the advantage of lower infection risk and different mode of action making it attractive as second line treatment for anti-TNF failures and for patients at high risk of infections.

Long term outcome or remission at 1 year does not usually predict deep remission well. Further studies need to be conducted to predict future course of disease whilst on maintenance and after stopping.

There is a question if patients should continue with thiopurines whilst on this technology to prevent antibody formation or due to higher efficacy of dual therapy?

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

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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)?

There would need to be sufficient infusion clinic space be available to administer the technology. Currently this patient group only receives 3 infusion each so additional infusions spaces for a considerable number of patients would have to be found.

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.

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Please tell us what evidence should be obtained to enable the Committee to identify and consider such impacts. No discrimination identified