NHS organisation statement template

Thank you for agreeing to give us your views on the technology and the way it should be used in the NHS.

Primary Care Trusts (PCTs) provide a unique perspective on the technology, which is not typically available from the published literature. NICE believes it is important to involve NHS organisations that are responsible for commissioning and delivering care in the NHS in the process of making decisions about how technologies should be used in the NHS.

To help you give your views, we have provided a template. The questions are there as prompts to guide you. You do not have to answer every question. Short, focused answers, giving a PCT perspective on the issues you think the committee needs to consider, are what we need.

About you

Your name: [redacted]

NHS North Yorkshire & York PCT

Please indicate your position in the organisation:

A pharmacist whose remit includes the commissioning of medicines (within tariff and PbR excluded) in general and the development of pathways and policies.

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

NYYPCT and the 14 surrounding PCTs have a commissioning agreement with Yorkshire & Humber Specialist Commissioning Group to provide clinical expert opinion from the expert clinical panel which informs the local clinical consensus approach for a regional consistent policy.

The current treatment of multiple sclerosis (MS) includes the use of disease modifying therapies (specifically beta interferon, glatiramer acetate and natalizumab with specified starting/stopping criteria).

It has been identified that there are some differences in opinion in terms of beta interferon (for 1st or 2nd line use) and the use of natalizumab in the clinical pathway.

The current perceived advantage of fingolimod is that it is an oral therapy, whilst recognising that patients may prefer oral therapy to injectable treatment options, we have to acknowledge that the safety and efficacy of existing treatment options is largely known and established.

There is a question of where this drug fits in the clinical pathway. Whilst we can see a desire to use this as a 1st line treatment for new patients, we also recognise it may be used as a 2nd line agent after B interferon.

Additionally, there are two further groups of patients who may be considered for treatment. Firstly a patient who has exhausted existing therapies (B interferon, glatiramer, 2 years of natalizumab) and secondly, patients deemed to achieve some clinical response but that effect is suboptimal thus fingolimod may be used in addition to the existing injectable therapy.

To what extent and in which population(s) is the technology being used in your local health economy?

At present the technology is not being used.

Potential impact on the NHS if NICE recommends the technology

What impact would the guidance have on the delivery of care for patients with this condition?

In comparison to natalizumab for example, oral administration would be associated with a cost saving as a hospital day case tariff would not be required.

In comparison to B interferon, providing the patient/carer was self injecting, there are no savings identified. However, there would be some potential NHS resource savings if a district nurse was for example having visit the patient to administer the drug. At present it is worth noting that B interferon is supplied by a home care provider therefore is VAT exempt.

There are no immediate obvious additional resource implications identified for oral fingolimod as yet unless specific monitoring is in place which would generate significant additional uptake of resources from secondary/tertiary care for example.

In what setting should/could the technology be used – for example, primary or secondary care, specialist clinics? Would there be any requirements for additional resources (for example, staff, support services, facilities or equipment)?

MS is a specialist condition, and it would be expected that fingolimod would be at the very least initiated within the specialist clinic on the basis of specialist selection of appropriate patients would be required, it is new to clinical practice and unfamiliar necessitating a period of accumulation of experience, firstly (and most rapidly) by consultants in addition to drug and disease monitoring. We are not at present certain of all the drug monitoring requirements of this treatment however, we do note from the TRANSFORMS and FREEDOM clinical trials the adverse effects include dose dependent bradycardia, atrioventricular block, skin cancer and macular oedema and feel that the prevalence of adverse effects may dictate its place in the clinical pathway particularly if there are subsequent drug/service costs associated with managing the adverse effects as a result of fingolimod treatment.

Can you estimate the likely budget impact? If this is not possible, please comment on what factors should be considered (for example, costs, and epidemiological and clinical assumptions).

The comparative budget impact for NHS NYYPCT (on basis of estimated drug costs of fingolimod being between that of B interferon and natalizumab) are:

Fingolimod: £460,000
B interferon: £380,000
Natalizumab: £540,000 plus ancillaries and day case tariff per month

Based on a prevalence of 5/100,000 population

On the basis of the estimated costs, to use fingolimod 1st line for 40 patients rather than B interferon would equate to an additional cost of £80,000.

Would implementing this technology have resource implications for other services (for example, the trade-off between using funds to buy more diabetes nurses versus more insulin pumps, or the loss of funds to other programmes)?

Until the place of fingolimod is clarified in the MS treatment pathway, it is unclear whether its introduction would be offset by the reduction in costs of other treatments.

Would there be any need for education and training of NHS staff?

At present the staff training would be dependent on an understanding of the drug monitoring that is associated with the use of fingolimod.

Other Issues

Please include here any other issues you would like the Appraisal Committee to consider when appraising this technology.

At present whilst we recognize that the introduction of an oral therapy as an option for treatment of MS patients is perceived as attractive, the safety and adverse effect profile have to be considered and may influence its place in therapy. We are aware of the EMEA negative opinion at present regarding the other oral therapy, cladrabine.

It is important to ensure sufficiently robust audit and monitoring (initiation/discontinuation criteria) is in place.

The PCT is looking forward to seeing data that will enable us to understand how NICE will conduct its assessment taking in to account that B interferon, a comparator stated in the final scope in itself has not been established to be cost effective for MS.

Furthermore, we ask if fingolimod will be licensed for rapidly evolving severe relapsing-remitting MS? If not, we wish to ask whether comparison with natalizumab is appropriate?