HSCB Service Notification for the managed entry of new medicines and technologies

Health and Social Care Board

1	**Treatment & Condition** *(Title)* Infliximab, adalimumab and golimumab for treating moderately to severely active ulcerative colitis after the failure of conventional therapy (including a review of TA140 and TA262)
2	**Associated appraisal body** *(NICE/SMC/Other)* **& Summary of ruling** *(to include indication, restrictions, other relevant information)* NICE Technology Appraisal Guidance 329 (February 2015) Infliximab, adalimumab and golimumab are recommended, within their marketing authorisations, as options for treating moderately to severely active ulcerative colitis in adults whose disease has responded inadequately to conventional therapy including corticosteroids and mercaptopurine or azathioprine, or who cannot tolerate, or have medical contraindications for, such therapies. Golimumab is recommended only if the company provides the 100 mg dose of golimumab at the same cost as the 50 mg dose, as agreed in the patient access scheme. The choice of treatment between infliximab, adalimumab or golimumab should be made on an individual basis after discussion between the responsible clinician and the patient about the advantages and disadvantages of the treatments available. This should take into consideration therapeutic need and whether or not the patient is likely to adhere to treatment. If more than 1 treatment is suitable, the least expensive should be chosen (taking into account administration costs, dosage and price per dose). Infliximab is recommended, within its marketing authorisation, as an option for treating severely active ulcerative colitis in children and young people aged 6–17 years whose disease has responded inadequately to conventional therapy including corticosteroids and mercaptopurine or azathioprine, or who cannot tolerate, or have medical contraindications for, such therapies. Infliximab, adalimumab or golimumab should be given as a planned course of treatment until treatment fails (including the need for surgery) or until 12 months after starting treatment, whichever is shorter. Clinicians should then discuss the risks and benefits of continued treatment with the patient, and their parent or carer if appropriate: • Continue treatment only if there is clear evidence of response as determined by clinical symptoms, biological markers and investigation, including endoscopy if necessary. People who continue treatment should be reassessed at least every 12 months to determine whether ongoing treatment is still clinically appropriate. • Consider a trial withdrawal from treatment for all patients who are in stable clinical remission. People whose disease relapses after treatment is stopped should have the option to start treatment again.

3 **Number of people in Northern Ireland expected to take up service/therapy** *(including new cases per year)*

The costing template for NICE TA329 indicates that around 22 adults and 6 children (6-17 years) per 100,000 population are eligible for treatment. This would equate to around 308 adults and 24 children in NI.

The choice of treatment between infliximab, adalimumab and golimumab should be made on an individual basis after discussion between the responsible clinician and the patient. If more than one treatment is suitable, the least expensive should be chosen. Consideration should also be given to the use of biosimilars in relation to the implementation of this NICE technical appraisal.

Local clinicians have indicated the anticipated number of patients likely to access this treatment in NI once these therapies are formally commissioned is consistent with the NICE projections i.e. approx. 332 patients. Clinicians have also indicated that approximately 50% of patients will require ongoing maintenance therapy with the other 50% ceasing treatment within the first year.

4 **Patient Access Scheme availability**

Golimumab is recommended only if the company provides the 100 mg dose of golimumab at the same cost as the 50 mg dose, as agreed in the patient access scheme.

5 **Costs** *(before PAS if applicable)*

5.1 **Drug cost per patient per annum (for new and prevalent cases)**

The indicative drugs costs for adults and children are set out in the table below.

	Route	**Induction 8 weeks (£)**	**Maintenance 26 weeks (£)**
Adults			
Infliximab – proprietary	IV infusion	5,035	5,455
Infliximab – biosimilar	IV infusion	4,532	4,910
Adalimumab	Subcutaneous	2,817	5,306
Golimumab	Subcutaneous	3,052	4,959
Children			
Infliximab – proprietary	IV infusion	2,500	2,700
Infliximab – biosimilar	IV infusion	2,300	2,500

Costs may vary because of negotiated procurement discounts. Clinicians should consider stopping treatment in adults who do not benefit within the first 14 weeks or patients aged 6-17 years within 8 weeks

5.2 **Infrastructure costs per patient per annum**

The infrastructure costs associated with implementing this technical appraisal will be dependent on the mix of therapies utilised. All patients commencing biological therapies need input from IBD specialist nurses and an increase in these posts will be required. The HSC Board will work with Trusts to identify how the requirements compare to current infrastructure needs.

5.3	**Current in year costs** These therapies have been available in Northern Ireland from December 2014 on a cost per case basis. To date there have been approximately 10 requests per month approved by the HSC Board. A total of 78 cases have been approved between December 2014 and July 2015. It is anticipated that a similar number of requests per month will be received in the second and third quarters of 2015/16 but that the number of requests per month thereafter will increase to the projected future activity of around 25 per month in the last quarter once the therapies are formally commissioned. It is therefore projected that around 200 patients will have commenced on treatment by the end of 2015/16. Based on the information from clinicians which indicates that approximately 50% of patients will require ongoing maintenance therapy with the other 50% ceasing treatment within the first year, the costs in 2015/16 will be approximately £1m.
5.4	**Recurrent overall costs per annum** *(including additional costs)* The recurrent costs of implementing this TA for 200 patients on maintenance therapy will be approximately £2.4m The recurrent costs will be included in the HSC Board financial planning assumptions for predicted growth in this area from 2016/17.
5.5	**Opportunities for cost savings and how these will be secured** Implementation of NICE TA329 will lead to additional costs because of increased use of these therapies. The NICE guidance for TA329 indicates that there may be savings from delaying or avoiding surgery in some patients, and reduced hospital admissions because of improved disease management. The NICE guidance recommends that due to variation in clinical practice across regions in the NHS, that regions assess savings locally. The Board will consider the most appropriate approach to assessing savings in conjunction with the regional IBD interest group.
6	**Expected implementation period** These therapies are currently available in Northern Ireland on a cost per case basis. It is expected that the therapies will be formally commissioned during the third quarter of 2015/16. The introduction will be subject to confirmation of the level of funding available and submission of IPTs by Trusts for the drug costs and any infrastructure requirements.
7	**Commissioning arrangements** These therapies will be formally commissioned by the HSCB/PHA via the Specialist Services Commissioning Team initially on a cost-per-case (CPC) basis. Investment Proposal Templates will be completed by each Trust and the final profile of resources and revised monitoring arrangements agreed.

8	**Monitoring arrangements** HSCB currently receives monthly monitoring information in relation to the usage of biologic drugs in inflammatory bowel disease. The monitoring pro forma will be adapted to capture information in respect of these regimens and this group of patients. This monitoring report is submitted to the Specialist Services Commissioning Team for formal review and comment by the Team.
9	**DHSSPS Legislative/Policy Caveats** This advice does not override or replace the individual responsibility of health professionals to make appropriate decisions in the circumstances of their individual patients, in consultation with the patient and/or guardian or carer. This would, for example, include situations where individual patients have other conditions or complications that need to be taken into account in determining whether the NICE guidance is fully appropriate in their case.