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

1	**Treatment & Condition** *(Title)* Vedolizumab for treating moderately to severely active Crohn's disease after prior therapy
2	**Associated appraisal body** *(NICE/SMC/Other)* **& Summary of ruling** *(to include indication, restrictions, other relevant information)* NICE technology appraisal guidance 352 (August 2015) Vedolizumab is recommended as an option for treating moderately to severely active Crohn's disease only if: • a tumour necrosis factor-alpha inhibitor has failed (that is, the disease has responded inadequately or has lost response to treatment) or • a tumour necrosis factor-alpha inhibitor cannot be tolerated or is contraindicated. Vedolizumab is recommended only if the company provides it with the discount agreed in the patient access scheme. Vedolizumab should be given as a planned course of treatment until it stops working or surgery is needed, or until 12 months after the start of treatment, whichever is shorter. At 12 months, people should be reassessed to determine whether treatment should continue. Treatment should only continue if there is clear evidence of ongoing clinical benefit. For people in complete remission at 12 months, consider stopping vedolizumab, resuming treatment if there is a relapse. People who continue vedolizumab should be reassessed at least every 12 months to decide whether continued treatment is justified.
3	**Number of people in Northern Ireland expected to take up service/therapy** *(including new cases per year)* Implementation of this guidance offers an additional treatment option for treating moderately to severely active Crohn's disease. Infliximab and adalimumab are already licensed and NICE-approved for the management of this condition. The costing template that accompanies TA 352, indicates that in Northern Ireland the prevalent population of people eligible for treatment with vedolizumab is 246 and the incident population is 13.
4	**Patient Access Scheme availability** The company that makes vedolizumab has agreed a patient access scheme with the Department of Health. The level of the discount is commercial in confidence.

5	**Costs** *(before PAS if applicable)*
5.1	**Drug cost per patient per annum (for new and prevalent cases)** The recommended dosage of vedolizumab for treating Crohn's disease is 300 mg at 0, 2 and 6 weeks, then every 8 weeks thereafter. It is administered by intravenous infusion. The list price of vedolizumab is £2,050 per 300 mg vial. Therefore the cost per patient per year (before any PAS discount) is: • Year 1 = £16,400 • Subsequent years = £13,325
5.2	**Infrastructure costs per patient per annum** It is recognised from the NICE guidance that there may be some infrastructure requirements associated with the introduction of this therapy. The HSC Board will work with clinicians to identify how the requirements compare to current infrastructure needs.
5.3	**Current in year costs** Vedolizumab is an additional treatment option alongside current standard treatment for Crohn's disease. It is projected that around 20 patients may benefit from this treatment in 2015/16 at a cost of £164k before the PAS discount is applied.
5.4	**Recurrent overall costs per annum** *(including additional costs)* The recurrent costs of implementing this TA will be included in the HSC Board financial planning assumptions for predicted growth in this area in 2016/17.
5.5	**Opportunities for cost savings and how these will be secured** It is not anticipated that there will be significant cost savings associated with the introduction of this treatment. The HSC Board will work with Trusts to ensure that opportunities to achieve any savings are maximised.
6	**Expected implementation period** This therapy is currently available in Northern Ireland on a cost per case basis. It is expected that this therapy will be formally commissioned during the first quarter of 2016/17. The introduction will be subject to confirmation of the level of funding available and submission of an IPT by Trusts for the overall drug cost requirements for treating patients with Crohn's disease.
7	**Commissioning arrangements** This drug will be formally commissioned by the HSCB/PHA via the Specialist Services Commissioning Team initially on a cost-per-case (CPC) basis. The treatment will be commissioned through the existing Investment Proposal Templates and subsequent negotiation process as part of the overall

	commissioning arrangements for patients with Crohn's disease.
8	**Monitoring arrangements** HSC Board currently receives monthly monitoring information in relation to the usage of biologic drugs for inflammatory bowel disease. The monitoring pro forma will be adapted to capture information in respect of this regimen 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** *(NICE guidance only)* 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.