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

1.	**Treatment & Condition** Ustekinumab for moderately to severely active Crohn's disease after previous treatment.
2.	**Associated appraisal body *&* Summary of ruling** NICE Technology Appraisal guidance TA456 (July 2017) Ustekinumab is recommended, within its marketing authorisation, as an option for treating moderately to severely active Crohn's disease, that is, for adults who have had an inadequate response with, lost response to, or were intolerant to either conventional therapy or a TNF-alpha inhibitor or have medical contraindications to such therapies. The choice of treatment between ustekinumab or another biological therapy should be made on an individual basis after discussion between the patient and their clinician about the advantages and disadvantages of the treatments available. If more than 1 treatment is suitable, the least expensive should be chosen (taking into account administration costs, dosage and price per dose). Ustekinumab should be given until treatment failure (including the need for surgery) or until 12 months after the start of treatment, whichever is shorter. People should then have their disease reassessed in accordance with NICE's recommendations stated in TA187 to see whether treatment should continue.
3.	**Number of people in Northern Ireland expected to take up service/therapy** 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 NICE resource impact statement indicates that the guidance is not expected to have an impact on resources. This is because the technology is an option alongside current standard treatment options that are similarly priced and practice is not expected to change substantially.
4.	**Patient Access Scheme Availability** Not applicable
5.	**Costs** *(before PAS if applicable)*
5.1	**Drug cost per patient per annum (for new and prevalent cases)** Ustekinumab is given as intravenous infusion at induction and as subcutaneous injection at maintenance: • 1 intravenous induction treatment (dose depends on body weight and is approximately 6mg/kg).

	• Maintenance subcutaneous treatment at week 8 (90mg), then every 12 weeks. The list price for ustekinumab is £2,147 per 130-mg vial concentrate for solution for infusion and per 90-mg vial solution for injection Assuming an average person's body weight of 84kg: • Intravenous induction dose = 6 x 84 = 504mg (4 vials) = £8,588 • Maintenance treatment = 90mg = £2,147 every 12 weeks Therefore: • Year 1 costs = £17,176 per person • Year 2 and subsequent years = £8,588 per person
5.2	**Infrastructure costs Per annum** It is anticipated that infrastructure requirements will be minimal. Infrastructure requirements for the delivery of all biologics are reviewed annually as part of the routine commissioning arrangements for supporting growth in the provision of these therapies.
6.	**Expected implementation period** There is no impediment to implementation of this guidance.
7.	**Commissioning arrangements** This regime will be formally commissioned by the HSCB/PHA via the Specialist Services Commissioning Team.
8.	**Monitoring arrangements** The HSC Board has robust arrangements in place for the monthly monitoring of all biologic therapies (activity/cost and waiting times) and this regime will be included within the routinely provided return. All monitoring returns for biologics are reviewed by the specialist services commissioning team monthly.
9.	**DoH (NI) 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.