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

Health and Social Care Board

1.	**Treatment & Condition** Ustekinumab for moderately to severely active Ulcerative Colitis
2.	**Associated appraisal body *&* Summary of ruling** NICE Technology Appraisal guidance TA633 (July 2020) Ustekinumab is recommended, within its marketing authorisation, as an option for treating moderately to severely active Ulcerative Colitis in adults when conventional therapy or a biological agent cannot be tolerated, or the disease has responded inadequately or lost response to treatment 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 not suitable, **and** • the company provides ustekinumab at the same price or lower that that agreed with the Commercial Medicines Unit.
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 Ulcerative Colitis. 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** (Yes/**No**) - Not applicable The company (Janssen-Cilag Ltd) has agreed a nationally available price reduction for ustekinumab with the Commercial Medicine Unit. The prices agreed through the framework are commercial in confidence.
5.	**Infrastructure Requirements** 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 immediate implementation for new patients.
7.	**Commissioning arrangements** This drug will be formally commissioned by HSCB/PHA via the Specialist Services Commissioning Team.
8.	**Monitoring arrangements** The HSC Board has robust arrangements in place for the quarterly 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 quarterly.
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.