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

1.	**Treatment & Condition** Guselkumab for treating moderate to severe plaque psoriasis.
2.	**Associated appraisal body *&* Summary of ruling** NICE Technology Appraisal guidance TA521 (June 2018) Guselkumab (Tremfya®) is recommended as an option for treating plaque psoriasis in adults, only if: • the disease is severe, as defined by a total Psoriasis Area and Severity Index (PASI) of 10 or more and a Dermatology Life Quality Index (DLQI) of more than 10 and • the disease has not responded to other systemic therapies, including ciclosporin, methotrexate and PUVA (psoralen and long-wave ultraviolet A radiation), or these options are contraindicated or not tolerated and • the company provides the drug according to the commercial arrangement. Stop guselkumab treatment at 16 weeks if the psoriasis has not responded adequately. An adequate response is defined as: • a 75% reduction in the PASI score (PASI 75) from when treatment started or • a 50% reduction in the PASI score (PASI 50) and a 5-point reduction in DLQI from when treatment started.
3.	**Number of people in Northern Ireland expected to take up service/therapy** Implementation of this guidance offers an additional treatment option for treating severe plaque psoriasis. The guidance is not expected to have an impact on resources. This is because the technology is an option alongside current standard treatment options.
4.	**Patient Access Scheme Availability** (**Yes**/No) The company (Janssen) has a commercial arrangement in place. This makes guselkumab available to the NHS with a discount. The size of the discount is commercial in confidence.
5.	**Infrastructure Requirements** Any additional infrastructure costs associated with the introduction of this medicine for this indication will be dealt with as part of the routine commissioning process.
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 initially on a cost per case basis.
8.	**Monitoring arrangements** The HSC Board has robust arrangements in place for the monthly monitoring of all biologic therapies (patient numbers and waiting times), and this regime will be included within the routinely provided return from HSC Trusts. All monitoring returns for biologics are reviewed by the Specialist Services Commissioning Team.
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 applicable in their case.