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

1	**Treatment & Condition** *(Title)* Omalizumab for previously treated chronic spontaneous urticaria.
2	**Associated appraisal body** *(NICE/SMC/Other)* ***&*** **Summary of ruling** *(to include indication, restrictions, other relevant information)* NICE technology appraisal guidance 339 (June 2015) Omalizumab is recommended as an option as add-on therapy for treating severe chronic spontaneous urticaria in adults and young people aged 12 years and over only if: • the severity of the condition is assessed objectively, for example, using a weekly urticaria activity score of 28 or more • the person's condition has not responded to standard treatment with H1-antihistamines and leukotriene receptor antagonists • omalizumab is stopped at or before the fourth dose if the condition has not responded • omalizumab is stopped at the end of a course of treatment (6 doses) if the condition has responded, to establish whether the condition has gone into spontaneous remission, and is restarted only if the condition relapses • omalizumab is administered under the management of a secondary care specialist in dermatology, immunology or allergy • the company provides omalizumab with the discount agreed in the patient access scheme.
3	**Number of people in Northern Ireland expected to take up service/therapy** *(including new cases per year)* Based on a pro rata calculation from the Costing Statement that accompanies TA339, there would be 129 people eligible for this treatment. However, local clinical advice indicates that the uptake of this treatment regime may be higher than that projected by NICE. The HSC Board will therefore monitor usage of this regime and adjust funding accordingly.
4	**Patient Access Scheme availability** The company has agreed a patient access scheme. This scheme would provide a simple discount to the list price of omalizumab across all indications, with the discount applied at the point of purchase or invoice. 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)** Omalizumab is available as a 150 mg solution for subcutaneous injection in a pre-filled syringe, and the recommended dose is 300 mg (as 2 injections) once every 4

	weeks. In the summary of product characteristics, prescribers are advised to periodically reassess patients for the need for continued treatment. It also notes that clinical trial experience of long-term treatment beyond 6 months in this indication is limited. Omalizumab costs £256.15 for a 150 mg prefilled syringe (excluding VAT); A single dose of 300 mg costs £512.30 and the cost for a 24-week course of treatment is £3073.80 per patient (excluding VAT).
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 HSCB/PHA do not anticipate that this will be a significant resource and will work with clinicians to identify how the requirements compare to current infrastructure needs. HSCB/PHA will monitor the use of this treatment in order to assess its impact on infrastructure.
5.3	**Current in year costs** In year costs are estimated to be £330k before the Patient Access Scheme is applied.
5.4	**Recurrent overall costs per annum** *(including additional costs)* Based on a pro rata calculation from the Costing Statement that accompanies TA339, the estimated cost of implementing TA339 is £670k for the population of Northern Ireland. This cost is before taking into account the discount available in the patient access scheme. The HSCB/PHA will closely monitor uptake of this regime and expenditure in this regards in the context of the overall expenditure on the treatment of people with chronic spontaneous urticaria.
5.5	**Opportunities for cost savings and how these will be secured** It is unlikely that the implementation of TA339 will result in any cost-savings.
6	**Expected implementation period** There is no impediment to immediate implementation for new patients.
7	**Commissioning arrangements** At present, this drug is commissioned on a cost per case basis. This was on the basis of the recommendation by NICE in their Final Appraisal Determination (March 2015). HSCB will now move to routine commissioning of this drug.
8	**Monitoring arrangements** Trusts will be required to provide to Specialist Services Commissioning Team on a quarterly basis with details of patients started on treatment to include: 1. Confirmation that each patient that have been given the drug complies with the NICE requirement for this treatment. 2. The number of patients that have been given the drug and the cost of the drug

	3. The number of patients that have stopped using this drug at or before the fourth dose if the condition has not responded 4. The number of patients in which the drug is stopped at the end of a course of treatment (6 doses) to establish the patient response whether the condition has gone into spontaneous remission 5. The number of patients who are restarted due to relapse of this condition The first return will be due in January 2016 for the quarter ending 31 December 2015.
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.