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

Health and Social Care Board

1.	**Treatment & Condition** Ravulizumab for treating atypical haemolytic uraemic syndrome
2.	**Associated appraisal body *&* Summary of ruling** NICE Technology Appraisal guidance TA710 (June 2021) Ravulizumab (Ultomiris®)is recommended, within its marketing authorisation, as an option for treating atypical haemolytic uraemic syndrome (aHUS) in people weighing 10kg or more: • who have not had a complement inhibitor before or • whose disease has responded to at least 3 months of eculizumab treatment It is recommended only if the company provides ravulizumab according to the commercial arrangement.
3.	**Number of people in Northern Ireland expected to take up service/therapy** By extrapolation from the Resource Impact Statement provided by NICE, it is estimated that 8 patients per year in Northern Ireland will be eligible for treatment with ravulizumab for this indication
4.	**Patient Access Scheme Availability** (**Yes**/No) The company (Alexion Pharmaceuticals) has a commercial arrangement (simple discount patient access scheme). This makes ravulizumab 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 regimen will be formally commissioned by the HSCB/PHA via the Specialist Services Commissioning Team initially on a cost per case basis initially. Thereafter, numbers of patients who received or are receiving treatment will be reviewed and consideration will be given to moving to recurrent funding to support this regimen.

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. 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.