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

1.	**Treatment & Condition** Cladribine tablets (Mavenclad®) for treating relapsing–remitting multiple sclerosis
2.	**Associated appraisal body *&* Summary of ruling** NICE Technology Appraisal guidance TA493 (December 2017) Cladribine tablets (Mavenclad®) are recommended as an option for treating highly active multiple sclerosis in adults, only if the person has: • rapidly evolving severe relapsing–remitting multiple sclerosis, that is, at least two relapses in the previous year and at least one T1 gadolinium-enhancing lesion at baseline MRI or • relapsing–remitting multiple sclerosis that has responded inadequately to treatment with disease-modifying therapy, defined as one relapse in the previous year and MRI evidence of disease activity
3.	**Number of people in Northern Ireland expected to take up service/therapy** According to the Resource Impact Template that accompanies TA493, it is expected that by year 5, **13 people** in Northern Ireland will take up treatment with cladribine. The NICE resource impact template predicts a steady state with 5 patients being treated per annum by year 3.
4.	**Patient Access Scheme Availability** **(**Yes**/<u>No</u>)** Not applicable
5.	**Costs** *(before PAS if applicable)*
5.1	**Drug cost per patient per annum (for new and prevalent cases)** Cladribine tablets (Mavenclad®) are 'indicated for the treatment of adult patients with highly active relapsing multiple sclerosis as defined by clinical or imaging features'. In the summary of product characteristics the recommended cumulative dose is 3.5mg/kg body weight over 2 years, taken as one treatment course of 1.75mg/kg per year. Each treatment course consists of 2 treatment weeks, one at the beginning of the first month and one at the beginning of the second month of the respective treatment year. Each treatment week consists of 4 or 5 days on which a patient takes 10mg or 20mg (1 or 2 tablets) as a single daily dose, depending on body weight. Following completion of the 2 treatment courses, no further cladribine treatment is required in years 3 and 4. The list price of cladribine is £2,047.24 per 10mg tablet.

	The table below indicates the dose and number of tablets needed for each body weight range: **Dose of cladribine per treatment week by patient weight in each treatment year** Weight range: Dose in mg (number of 10mg tablets) per treatment week kg: Treatment week 1: Treatment week 2 40 to <50: 40 mg (4 tablets): 40 mg (4 tablets) 50 to <60: 50 mg (5 tablets): 50 mg (5 tablets) 60 to <70: 60 mg (6 tablets): 60 mg (6 tablets) 70 to <80: 70 mg (7 tablets): 70 mg (7 tablets) 80 to <90: 80 mg (8 tablets): 70 mg (7 tablets) 90 to <100: 90 mg (9 tablets): 80 mg (8 tablets) 100 to <110: 100 mg (10 tablets): 90 mg (9 tablets) 110 and above: 100 mg (10 tablets): 100 mg (10 tablets) Thus the cost per patient per annum is in the range £16,377.92 to £40,944.80 per annum (depending on patient's body weight). Each patient will require 2 years treatment so the total cost of treatment per patient for 2 years treatment will range from £32,755.84 to £81,889.60
5.2	**Infrastructure costs Per annum** It is anticipated that infrastructure requirements will be minimal. Infrastructure requirements for the delivery of all Disease Modifying Therapies (DMTs) for MS are reviewed annually as part of 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 on a cost-per-case (CPC) basis.
8.	**Monitoring arrangements** The HSC Board has robust arrangements in place for the monthly monitoring of all DMTs (patient numbers, costs and waiting times). This regime will be included within the monitoring information. Monitoring returns are reviewed by the Specialist Services Commissioning Team each month.
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.