

1.	<p>Treatment & Condition</p> <p>Cladribine for treating relapsing–remitting multiple sclerosis.</p>
2.	<p>Associated appraisal body & Summary of ruling</p> <p>NICE Technology Appraisal guidance (TA616) December 2019 [Review of TA493]</p> <p>Cladribine (Mavenclad[®]) is recommended as an option for treating highly active multiple sclerosis in adults, only if the person has:</p> <ul style="list-style-type: none"> • rapidly evolving severe relapsing–remitting multiple sclerosis, that is with at least: <ul style="list-style-type: none"> ➢ 2 relapses in the previous year and ➢ 1 T1 gadolinium-enhancing lesion at baseline MRI or a significant increase in T2-lesion load compared with a previous MRI, or • relapsing–remitting multiple sclerosis that has responded inadequately to treatment with disease-modifying therapy, defined as 1 relapse in the previous year and MRI evidence of disease activity.
3.	<p>Number of people in Northern Ireland expected to take up service/therapy</p> <p>The Resource Impact Template that accompanies TA616 indicates that the implementation of this guidance is not expected to have a significant impact on resources or projected patient numbers. This therapy is an additional treatment option for patients with this condition.</p> <p>Cladribine is less costly and needs less frequent dosing and monitoring than some of the other treatment options. However, any savings as a result of implementing the updated recommendations are not expected to be significant at a national level.</p>
4.	<p>Patient Access Scheme Availability</p> <p>(Yes/<u>No</u>) - Not applicable</p>
5.	<p>Infrastructure Requirements</p> <p>It is anticipated that infrastructure requirements will be minimal.</p> <p>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.</p>
6.	<p>Expected implementation period</p> <p>There is no impediment to immediate implementation for new patients.</p>

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 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. The Rural Needs Act (NI) 2016 has been considered and this guidance, which is purely of a technical nature, is not regarded as falling within the scope of the Act.