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# Cladribine for treating relapsing–remitting multiple sclerosis – NICE guidance update

The Accelerated Access Collaborative (AAC) is a unique partnership bringing together leaders from across the healthcare landscape. This includes government, NHS, industry and patient representatives. The AAC aims to drive the uptake and adoption of innovation within the health and care system by identifying and supporting the best new innovations that will be most promising for patients.

The AAC is supporting the rapid uptake of 7 high-potential technologies with full evidence bases that are already in the system. These products will enable patients to access new treatments faster and improve patients' lives, but are not currently available to everyone who could benefit. MAVENCLAD® (cladribine tablets) is one of these products.

Locally, AAC support and implementation for the 'rapid uptake products' will be delivered through the Academic Health Science Networks and Regional Medicines Optimisation Committees.

***NICE recommendation wording and eligibility update***

In December 2017, NICE published technology appraisal guidance on cladribine tablets for treating relapsing-remitting multiple sclerosis [TA493]. TA493 recommended cladribine tablets 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 2 relapses in the previous year* ***and at least 1 T1 gadolinium-enhancing lesion at baseline 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.*

The AAC raised concerns that the requirement for gadolinium-enhancing MRI before treatment is a barrier to accessing cladribine tablets and uptake has been slow. The Association of British Neurologists also contacted NICE to reiterate this point. Historically, safety concerns with gadolinium have been raised and although the specific agents of concern have been withdrawn from the market, there is still a perception that gadolinium is unsafe.

Because of this, a review of TA493 has been done earlier than the scheduled review date, in which it was agreed that TA493 should be updated and reissued without going through a full appraisal process.

To be completely confident that this was appropriate, NICE asked all relevant consultees and commentators to inform them of any evidence that would help them decide the best way to update this guidance. Following the proposal to update the guidance and a consultation review in July 2019, NICE recently updated the recommendation wording to:

- *rapidly evolving severe relapsing–remitting multiple sclerosis, that is, with at least:*

    - *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.*

Prescribers should be aware that the NHS England Blueteq forms for cladribine tablets have been updated at commissioned centres to reflect the NICE guidance changes.

***ENDS***