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Real-World Use of Cladribine Tablets (Completion Rates and Treatment Persistence) in Patients With Multiple Sclerosis in England: The CLARENCE Study

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CONCLUSIONS

Among patients with sufficient follow-up, those treated with cladribine tablets showed:

- **High rates of treatment completion and persistence**
- **Low switching rate of 4%**
- **Stable EDSS scores between Years 1 and 2**

The CLARENCE study highlights the early use of cladribine tablets in the DMT sequencing pathway (84% of patients were either treatment naïve or had only received one prior DMT)

INTRODUCTION

- Cladribine tablets have been available in England for the treatment of highly active relapsing multiple sclerosis (MS) since 2017, following placebo-controlled randomised clinical trials (RCTs)[1-3]
- Data from routine clinical practice can provide valuable insights into the patterns of use and effectiveness of cladribine tablets in the wider population, outside of the tightly-controlled RCT setting
- As a compulsory requirement of National Health Service (NHS) reimbursement, all disease-modifying therapies (DMTs) prescribed for MS within NHS England must be registered via the Blueteq® high-cost drug platform[4]

OBJECTIVE

To evaluate the real-world use of cladribine tablets in England, using data collected by the Blueteq® platform, as part of the CLARENCE study

METHODS

- NHS England collect data on use of cladribine tablets via the Blueteq® platform, and provide the associated anonymised patient-level data to the study sponsor on a quarterly basis
- Longitudinal data were collated for patients prescribed cladribine tablets (3.5 mg/kg cumulative dose over 2 years) between November 2017 and September 2021
- To be included in the study, patients must have:
  - ≥1 completed Blueteq® form, and
  - ≥1 invoice record
- At treatment initiation, treatment history (including prior DMT use) and baseline Expanded Disability Status Scale (EDSS) scores were recorded
- Over the length of the study, the following outcomes were evaluated:
  - **Treatment completion** (full course of cladribine tablets received)
  - **Treatment persistence** (patients who did not switch treatment and/or discontinue treatment before receiving the full course of cladribine tablets)
  - **Treatment switch rate** (patients who switched treatment from cladribine tablets to another DMT at any point after their first dose)
  - Change in **EDSS score**
- Stable EDSS score was defined as no change or a decrease (improvement) in score
- Data were analysed descriptively

RESULTS

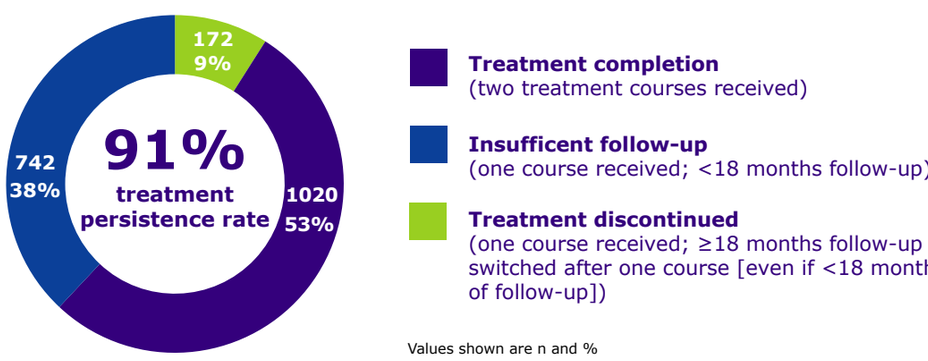
Table 1. Patient Characteristics at Treatment Initiation

Characteristic	Total
Number of patients	1934
Median EDSS score (range)	2.5 (0–8.5)
Treatment naïve, n (%)*	691 (36)
Treatment experienced, n (%)*†	1239 (64)
One prior DMT only	920 (48)
Two prior DMTs	228 (12)
Three prior DMTs	73 (4)
≥ Four prior DMTs	18 (1)

*Treatment history was missing for 4 patients; †69% were treated with a platform therapy only (beta-interferon, glatiramer acetate, dimethyl fumarate, or teriflunomide)
DMT, disease-modifying therapy; **EDSS**, Expanded Disability Status Scale

- Among those patients with treatment history details before initiation of cladribine tablets (N=1930), 84% were either treatment naïve (36%) or had received only one prior DMT (48%; **Table 1**)

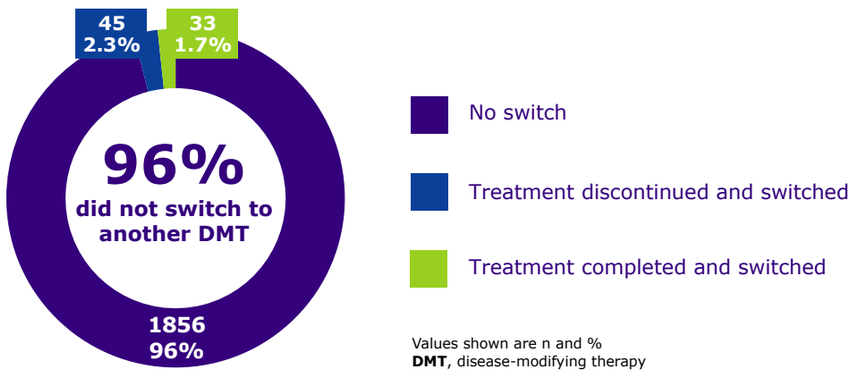
Figure 1. Treatment Completion and Persistence (Nov 2017 – Sept 2021; N=1934)



Values shown are n and %

- Treatment discontinuation was more often observed in patients with severe disability (14% with EDSS score ≥5 between Year 1 and 2 of treatment versus ≤9% each in lower categories; see **Supplementary Figure 1a**)
- Treatment completion (52–53%) and discontinuation (8–9%) rates were similar between treatment-naïve and DMT-experienced patients (see **Supplementary Figure 1b**)
- Treatment completion rates were higher among patients who received cladribine tablets as first- or second-line therapy (87% and 86% completed; 13% and 14% discontinued) versus as a third-line therapy (81% completed; 19% discontinued)

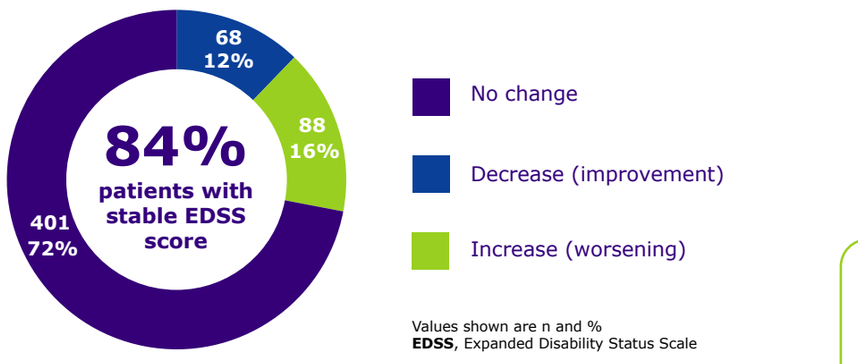
Figure 2. Treatment Switch Rate (Nov 2017 – Sept 2021; N=1934)



Values shown are n and %
DMT, disease-modifying therapy

- Most patients who switched did not receive the full 2-year course of cladribine tablets (n=45, 2.3%)
- 33 patients (1.7%) were known to have switched after completing the 2nd-year course of treatment, primarily in Years 3 and 4
- Switching occurred most frequently in DMT-experienced (n=58, 3.0%) versus treatment-naïve (n=20, 1.0%) patients
- In all, 509 patients were assumed to be in Year 3 and 4 of treatment based on the date of their 2nd-year course and having not switched to another DMT

Figure 3. Change in EDSS Score Between Years 1 and 2 of Treatment With Cladribine Tablets (N=557)



Values shown are n and %
EDSS, Expanded Disability Status Scale

- The sample size reflects the number of patients (557/1020) who had received two treatment courses and had EDSS data available
- No differences were observed between treatment-naïve and DMT-experienced patients with respect to the EDSS change categories (see **Supplementary Figure 2**)

SCAN HERE FOR ADDITIONAL CONTENT

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