A Budget Impact Analysis of Cladribine in England and Wales for Patients with Highly Active Relapsing-Remitting Multiple Sclerosis (HA-RRMS)

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CONCLUSIONS

- **Due to the unique dosing regimen and low administration and monitoring requirements for cladribine, increasing uptake of cladribine is estimated to result in budget savings to the NHS, both in terms of drug acquisition costs and healthcare resource use compared to current usage of established and newly approved therapies in HA-RRMS**
- **Based on a developed budget impact model, increasing the uptake of cladribine by 5% may provide a cost saving of up to £5.7m to the NHS in England and Wales over a 4-year period**
- **This budget impact is also accompanied by an estimated 10,862 fewer hours of treatment administration time in hospitals and 4,581 fewer infusions over the same time period**

INTRODUCTION

- Cladribine, a high-efficacy disease-modifying therapy (DMT), has been available in England and Wales since 2017 for patients with HA-RRMS, following a positive NICE recommendation[1]
- Cladribine is an oral treatment with a unique dosing regimen of 3.5 mg/kg cumulative dose over 2 years, administered as 1 treatment course of 1.75 mg/kg per year (1 treatment course is comprised of 2 weeks of treatment), with no further treatment required in years 3 and 4[2]
- Due to the availability of multiple MS treatment options, the aim of this budget impact model was to explore the potential budget saving that cladribine could provide to the NHS based on its dosing schedule and method of administration

OBJECTIVE

- To evaluate the potential economic impact to the NHS of increasing the uptake of cladribine compared to the current usage of cladribine alongside other approved MS therapies in England and Wales

METHODS

- A budget impact model with an England and Wales NHS perspective was developed to compare two scenarios: (1) current market share of available therapies, including current usage of cladribine and (2) a future scenario with increased uptake of cladribine. The model assumed a 4-year time horizon
- The data sources and assumptions used for each input are summarised in **Table 1**

Table 1. Inputs and data sources used in the budget impact analysis

Input	Data source
Eligible population	
Population of England and Wales	• Office for National Statistics, 2022[3]
Percentage of population assumed to be adults	• Office for National Statistics, 2022[3]
Prevalence of MS	• Mackenzie *et al.*, 2014[4]
Proportion of MS patients with RRMS	• National Multiple Sclerosis Society[5]
Proportion of RRMS patients taking a DMT	• MS Society, 2019[6]
Proportion of treated RRMS patients with HA disease	• Merck – data on file 2023
Costs and resource use	
Drug acquisition costs	• BNF[7] and eMIT[8]
Drug dosing schedule	• Summary of product characteristics[9]
Administration and monitoring costs	• NHS reference costs 21/22[10] • PSSRU Unit Costs of Health and Social Care 2021[11] • Previous NICE submissions[12]
Administration and monitoring frequencies	• Summary of product characteristics[9]
Other	
Current and future market shares	• Figures adapted from IQVIA Hospital Pharmacy Audit (March 2023)[13]

Eligible population

- The eligible population was estimated using the total population of England & Wales and applying published evidence to estimate the number of adults with HA-RRMS currently receiving a DMT

Inclusion of costs

- Costs included drug acquisition costs, administration costs and monitoring costs, all based on published sources
- DMT costs were calculated using NHS list prices and dosing schedules from SmPCs[9]. As cladribine dosing is dependent on weight an assumed body weight of 70-<80 kg was used
- The costs associated with the administration and monitoring of treatments were based on published sources and the frequency of healthcare resource use specified in the SmPCs[9]

Inclusion of resource use

- Administration time was calculated using the time in a hospital setting that is associated with pre-medication, delivery of infusions or patient observation, as specified in SmPCs[9]

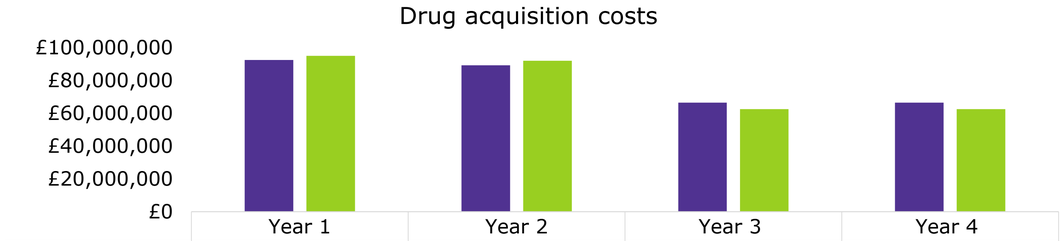
Market shares

- The treatments included in the model were cladribine, alemtuzumab, fingolimod, natalizumab (infusion), ocrelizumab and ofatumumab
- The current market share scenario was based on a representative distribution of DMTs based on figures from a hospital pharmacy audit. The future scenario was based on a 5% uptake in cladribine usage, taken proportionally from other treatments

RESULTS

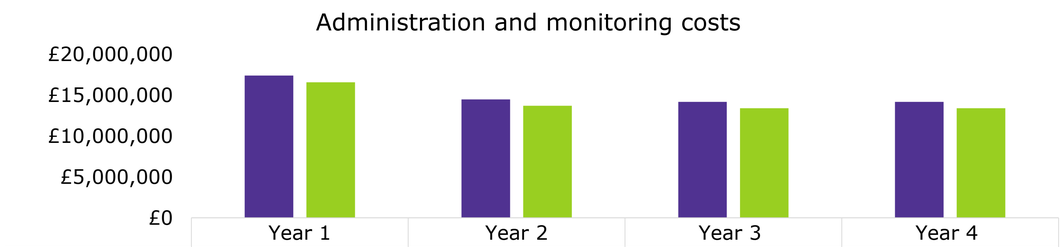
- 4,724 patients were estimated to currently be receiving a DMT for the treatment of HA-RRMS in England and Wales
- The model indicated that increasing the uptake of cladribine by 5% could save the NHS a total of £5.7m over a 4-year period, excluding the impact of any commercial discounts (**Figures 1–2**)
- This reflects total spending of £374.9m (£314.8m on drug costs and £60.2m on administration and monitoring) in the current scenario and £369.2m (£312.2m on drug costs and £57.0m on administration and monitoring) after increased cladribine uptake
- Of the total cost savings, £2.6m is attributed to lower drug acquisition costs and £3.1m is attributed to reduced administration and monitoring costs (**Figures 1–2**)
- This same increase in cladribine uptake is also estimated to reduce the time associated with the administration of treatments in hospital by 10,862 hours over a 4-year period, and the administration of 4,581 fewer infusions **(Figures 3-4)**
- The budget impact results will be different when accounting for confidential discounts for cladribine and other treatments

Figure 1. Drug acquisition costs for current and increased cladribine scenarios



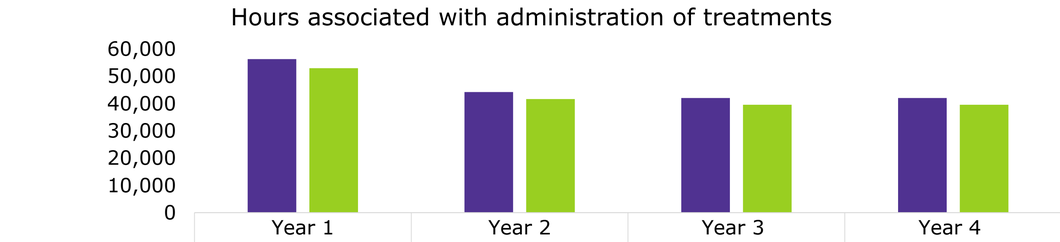
	Year 1	Year 2	Year 3	Year 4
Current scenario	£92,540,304	£89,292,920	£66,469,591	£66,469,591
Cladribine +5%	£95,063,526	£92,007,337	£62,556,074	£62,556,074

Figure 2. Administration and monitoring costs for current and increased cladribine scenarios



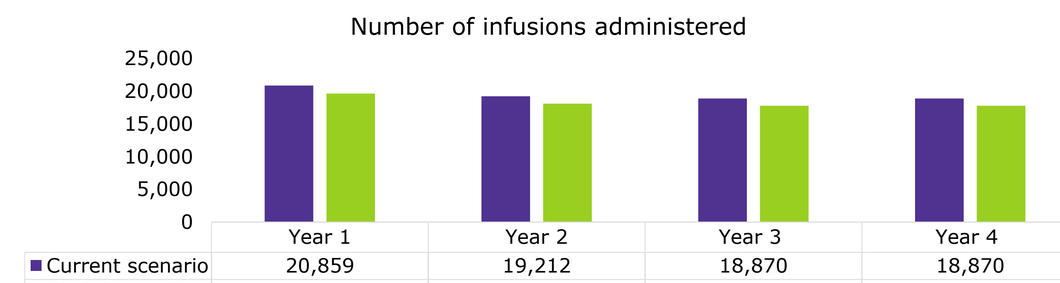
	Year 1	Year 2	Year 3	Year 4
Current scenario	£17,379,075	£14,464,944	£14,163,418	£14,163,418
Cladribine +5%	£16,554,217	£13,683,464	£13,392,494	£13,392,494

Figure 3. Hours associated with administration of treatments for current and increased cladribine scenarios



	Year 1	Year 2	Year 3	Year 4
Current scenario	56,263	44,221	41,998	41,998
Cladribine +5%	52,951	41,617	39,525	39,525

Figure 4. Number of infusions administered for current and increased cladribine scenarios



	Year 1	Year 2	Year 3	Year 4
Current scenario	20,859	19,212	18,870	18,870
Cladribine +5%	19,631	18,081	17,759	17,759

Abbreviations: BNF: British National Formulary; **DMT**: Disease-modifying therapy; **eMIT**: electronic Market Information Tool; **HA**: Highly active; **HA-RRMS**: Highly active relapsing-remitting multiple sclerosis; **MS**: Multiple Sclerosis, **NHS**: National Health Service; **NICE**: National Institute for Health and Care Excellence; **PSSRU**: Personal Social Services Research Unit; **RRMS**: Relapsing-remitting multiple sclerosis; **SmPC**: Summary of Product Characteristic

References: 1. NICE TA616, https://www.nice.org.uk/guidance/ta616, accessed October 2023; 2. Cladribine SmPC, https://www.medicines.org.uk/emc/product/8435/smpc#gref, accessed October 2023; 3. Office for National Statistics population estimates: mid-2021. https://www.ons.gov.uk/peoplepopulationandcommunity/populationandmigration/populationestimates/bulletins/annualmidyearpopulationestimates/mid2021, accessed October 2023; 4. Mackenzie et al. Journal of Neurology, Neurosurgery and Psychiatry. 2014; 85:76-84; 5. National Multiple Sclerosis Society 2023. https://www.nationalmssociety.org/What-is-MS/Types-of-MS, accessed October 2023; 6. MS Society 2019. https://www.mssociety.org.uk/sites/default/files/2020-08/MMMN3-nations-data-tables.pdf, accessed October 2023; 7. British National Formulary (BNF) 2023. https://bnf.nice.org.uk/, accessed October 2023; 8. Drugs and pharmaceutical electronic market information tool (eMIT). https://www.gov.uk/government/publications/drugs-and-pharmaceutical-electronic-market-information-emit, accessed October 2023; 9. Electronic medicines compendium 2023. https://www.medicines.org.uk/emc, accessed October 2023; 10. NHS Reference Costs 2021/22. https://www.england.nhs.uk/costing-in-the-nhs/national-cost-collection/, accessed October 2023; 11. Personal Social Services Research Unit. Unit Costs of Health and Social Care 2021. https://www.pssru.ac.uk/project-pages/unit-costs/unit-costs-of-health-and-social-care-2021/, accessed October 2023; 12. NICE 2023, https://www.nice.org.uk/, accessed October 2023; 13. IQVIA, Hospital Pharmacy Audit March 2023

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