

# A plain language summary on assessing the long-term effectiveness of cladribine tablets in people living with relapsing multiple sclerosis: The CLASSIC-MS study

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## Summary

### What is this summary about?

Previous studies have shown that people living with multiple sclerosis (MS) treated with cladribine tablets have fewer relapses (where new symptoms occur or existing symptoms get worse for 24 hours or more) and delayed disability progression (slowing down of the disease getting worse).

The CLASSIC-MS study looked at the long-term effectiveness of treatment with cladribine tablets in people living with MS who had taken part in the original CLARITY and CLARITY Extension clinical studies.






### What were the results?

Results showed that people treated with cladribine tablets maintained their mobility (the ability to move freely) for longer and experienced other positive effects long after their treatment ended, including being less likely to need further treatment for their MS.

### What do the results mean?

The results obtained from CLASSIC-MS show that the benefits of taking cladribine tablets carry on even when patients stop taking the treatment.

How to say (double click sound icon to play sound)...

- **Cladribine:** CLAD-ree-BEEN 
- **Multiple sclerosis:** MUHL-tuh-pl-sklr-OW-suhs 
- **Myelin:** Mai-UH-lin 
- **Placebo:** pluh-SEE-boh 
- **Relapse:** RE-lapse 

## Where can I find the original article on which this summary is based?

The original article is called 'Long-term follow-up of patients with relapsing multiple sclerosis from the CLARITY/CLARITY Extension cohort of CLASSIC-MS: An ambispective study'. You can read the article for free here: [https://journals.sagepub.com/doi/full/10.1177/13524585231161494?rfr\\_dat=cr\\_pub++0pubmed&url\\_ver=Z39.88-2003&rfr\\_id=ori%3Arid%3Acrossref.org](https://journals.sagepub.com/doi/full/10.1177/13524585231161494?rfr_dat=cr_pub++0pubmed&url_ver=Z39.88-2003&rfr_id=ori%3Arid%3Acrossref.org)

## Who sponsored this study?

Financial support for this summary was provided by Merck (CrossRef Funder ID: 10.13039/100009945).

## Who should read this article?

The authors of the original publication developed this summary to help people living with multiple sclerosis, their caregivers, healthcare professionals, and patient advocates to understand the results of this study.

## The original studies

**CLARITY:** The study looked at whether cladribine tablets work well for people with relapsing-remitting multiple sclerosis, including its side effects and tolerability (the degree to which a drug's side effects can be put up with by a patient). It was carried out between April 2005 and November 2008.

**CLARITY Extension:** This extension study further tested the side effects and tolerability of cladribine tablets in people who have previously completed treatment within CLARITY. It was carried out between February 2008 and December 2011.

## What is multiple sclerosis?

Multiple sclerosis (also known as MS) is a potentially disabling disease where the body's own immune cells (the body's own defence cells) attack the **central nervous system** (CNS). The reasons why this happens are not yet understood.

**Central nervous system:** The central nervous system (CNS) is made up of the brain and spinal cord. The CNS controls most functions of the body through nerves.

**Cognition:** Cognition refers to 'thinking' processes such as attention, learning, memory, understanding, planning, and making decisions. About half of people with MS experience changes in their cognitive abilities. Sometimes people with MS describe the experience as 'brain fog', when they may be struggling to organise their thoughts.

Immune cells damage the CNS by attacking the nerves and the fatty covering (known as myelin) that protects the nerves. This means it is more difficult for nerve signals to travel through the body in someone with MS, resulting in a range of possible symptoms.

People living with MS may experience problems with movement, fatigue (lack of energy), eyesight, or **cognition** (thinking, learning, and planning). These are just some of the examples of the possible symptoms of MS.



Movement



Fatigue



Eyesight



Cognition

There is currently no cure for MS. However, disease-modifying therapies (treatments that can change how your MS develops over time) have been proven to help ease symptoms and delay the course of the disease.

There are different types of MS. The most common type is called relapsing-remitting MS. It affects around 85% (almost 9 out of 10) of people first diagnosed with the illness. People living with relapsing-remitting MS have relapses (where new symptoms occur or existing symptoms get worse for 24 hours or more), followed by a period of full or partial recovery (feeling better).

## What are cladribine tablets?

Cladribine tablets (Mavenclad®) are an oral medicine (given by mouth) for treating relapsing types of MS.

The treatment works by reducing the numbers of certain immune cells, called B and T **lymphocytes** (white blood cells).

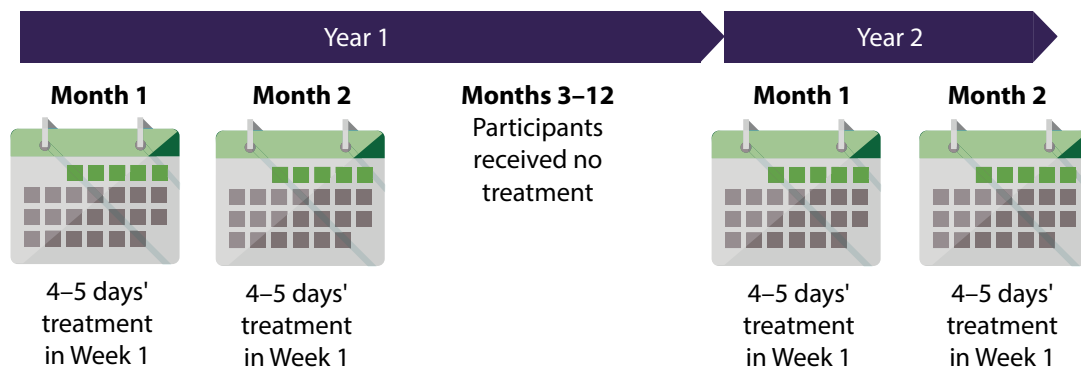
These lymphocytes are thought to be the main immune cells involved in MS, and so MS treatments often target them.

Cladribine tablets are given for a short amount of time followed by a long break. To explain in more detail, patients receive 8–10 days of treatment, then they have a break of 12 months. After the 12 months have passed, patients receive another treatment course of 8–10 days.

**Lymphocytes:** Lymphocytes are types of white blood cells that are part of the immune system. Lymphocytes include B cells, T cells, and natural killer cells. B and T cells work together to fight infections.

Studies on cladribine tablets have shown that the treatment works to lower the number of relapses in people living with MS and slows the worsening of their illness.

### Cladribine tablets are administered as two courses, based on the patient's weight, separated by 1 year



**Maximum of 20 days of treatment**

## Why was the CLASSIC-MS study carried out?

The original CLARITY and CLARITY Extension clinical studies showed that cladribine tablets lowered the number of relapses that people living with MS have. The studies also showed that treatment helped to lower the risk of people's disabilities getting worse.

People took part in CLARITY and CLARITY Extension several years ago. The same people then took part in the CLASSIC-MS study, and so researchers had the chance to find out how well treatment with cladribine tablets had worked after the original 2-year treatment course.

- On average, people took part in the CLASSIC-MS study around 11 years after their last dose of treatment received during the CLARITY or CLARITY Extension studies

## How was the CLASSIC-MS study carried out and who took part?

A total of 435 people were included in CLASSIC-MS from the original CLARITY and CLARITY Extension studies.

- They were an average age of 53 years and were mainly women (68% or almost 7 out of 10)
- 91% (just over 9 out of 10) had received cladribine tablets in CLARITY or CLARITY Extension, with 160 people having received the prescribed dose of 3.5 mg/kg over 2 years. The other 234 people received different doses of cladribine tablets during the studies

**Expanded Disability Status Score (or EDSS):** This is a way of measuring disability in people living with MS that considers aspects such as vision, coordination, and mobility. The score is widely used in clinical studies and ranges from 0 to 10; a higher score represents a higher level of disability.

The score is often summarised as the median, which is the middle number when the values are sorted from smallest to largest.

Concerning their level of disability, people had a median **Expanded Disability Status Score (EDSS)** of 3.5 at the start of CLASSIC-MS; it was 2.5 at the start of either CLARITY or CLARITY Extension.

## What did the researchers measure in CLASSIC-MS?

### Long-term mobility

- This was defined as no wheelchair use in the 3 months before a person's first visit in CLASSIC-MS, and not bedridden at any time since their last dose of treatment in CLARITY or CLARITY Extension (meaning that the person had an EDSS less than 7)



### Long-term disability status

- This concerned people with no use of a walking aid (such as a cane or frame) at any time since their last dose of treatment in CLARITY or CLARITY Extension (meaning the person had an EDSS less than 6)



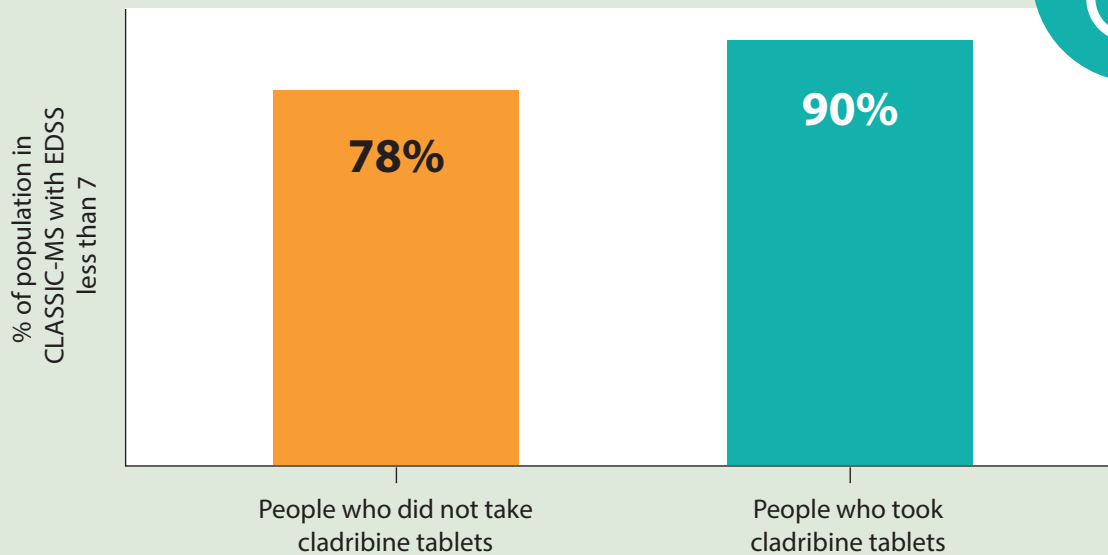
### Real-world treatment patterns and outcomes, since taking part in CLARITY or CLARITY Extension

- Whether people used any further disease-modifying medication for their MS
- The number of relapses that people experienced
- The employment status of people living with MS who enrolled in CLASSIC-MS

## What were the results from the study?

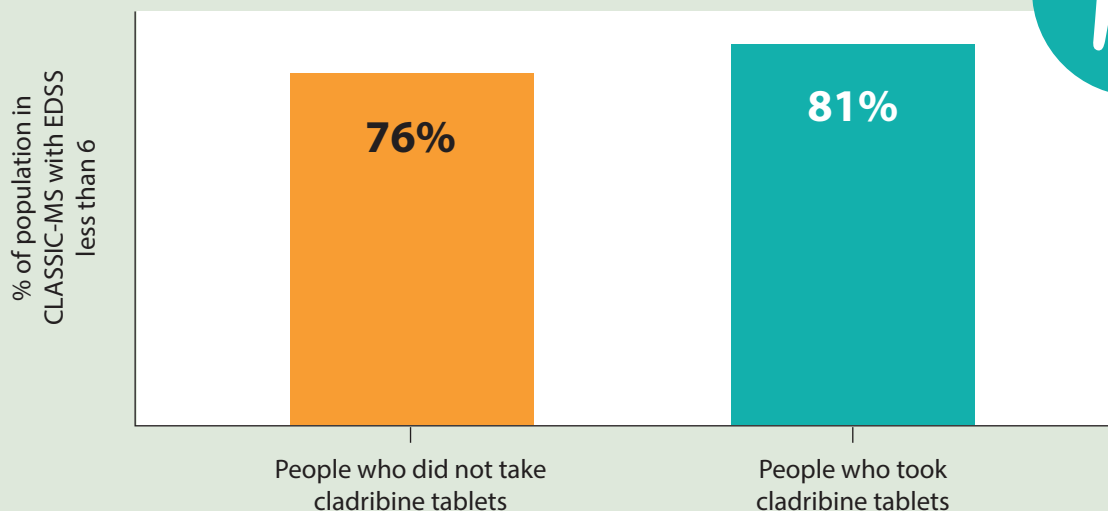
### Long term mobility

- Most people were not using a wheelchair in the 3 months before they took part in CLASSIC-MS and were not bedridden at any time since their last dose of treatment received during the original studies. This included 90% (9 out of 10) of the people who took cladribine tablets in CLARITY or CLARITY Extension and 78% (almost 8 out of 10) of people who did not
- Considering the people who took the prescribed dose of cladribine tablets (3.5 mg/kg over 2 years), this figure was 88% (almost 9 out of 10)



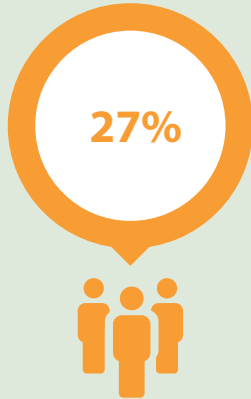
### Long-term disability status

- Most people taking part in CLASSIC-MS did not use a walking aid at any time since their last dose of treatment received during the original studies. This included 81% (just over 8 out of 10) of the people who took cladribine tablets in CLARITY or CLARITY Extension and 76% (almost 8 out of 10) of those who did not
- Considering the people who took the prescribed dose of cladribine tablets (3.5 mg/kg over 2 years), this figure was 79% (almost 8 out of 10)



### Treatment patterns and outcomes

- Around half of people taking part in CLASSIC-MS did not use any further treatment for their MS since their last dose of treatment received during the original studies. This included 56% (almost 6 out of 10) of the people who took cladribine tablets in CLARITY or CLARITY Extension and 27% (almost 3 out of 10) of those who did not
  - For people who received the prescribed dose of cladribine tablets (3.5 mg/kg over 2 years), 58% (almost 6 out of 10) did not use any further treatment for their MS



People who had not taken cladribine tablets

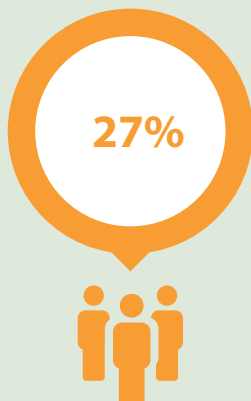


Did not use further medication



People who took cladribine tablets

- In the total study population, 46% (almost 5 out of 10) were relapse-free at the time of the CLASSIC-MS study. This included 48% (almost 5 out of 10) of the people who took cladribine tablets in CLARITY or CLARITY Extension and 27% (almost 3 out of 10) of those who did not
  - For people who received the prescribed dose of cladribine tablets (3.5 mg/kg over 2 years), 47% (almost 5 out of 10) were relapse-free



People who had not taken cladribine tablets



Were relapse free



People who took cladribine tablets

- Finally, the investigators asked people if they were employed in some way at the start of CLASSIC-MS. This included 51% (just over 5 out of 10) of the people who took cladribine tablets in CLARITY or CLARITY Extension and 28% (almost 3 out of 10) of those who did not
  - In the group of people who received the prescribed dose of cladribine tablets (3.5 mg/kg over 2 years), 54% (just over 5 out of 10) were employed in some capacity



People who had not taken cladribine tablets



Remained in employment



People who took cladribine tablets

## What do the results of this study mean?

The findings show that people treated with cladribine tablets had a lower risk of their disability getting worse compared with people who did not take the treatment. People taking cladribine tablets were also less likely to need further treatment for their MS.

The results from CLASSIC-MS show that the benefits of cladribine tablets carry on even when patients stop taking the treatment.

## Where can readers find more information on this study?

This is a summary of an article called “Long-term follow-up of patients with relapsing multiple sclerosis from the CLARITY/CLARITY Extension cohort of CLASSIC-MS: An ambispective study”, originally published in *Multiple Sclerosis Journal*. You can read the full article here: <https://journals.sagepub.com/doi/10.1177/13524585231161494>

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## Educational resources

Read more about multiple sclerosis, including symptoms and criteria for diagnosis, treatment options, and general support for those living with multiple sclerosis, at these websites:

- National Multiple Sclerosis Society available at: <https://www.nationalmssociety.org>
- Multiple Sclerosis Trust available at: <https://mstrust.org.uk/>

### Financial & competing interests disclosure

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