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Clinical Commissioning Policy:

# Prolonged-released (PR) fampridine as a treatment of adults with Multiple Sclerosis and associated walking impairment [2341]

## Summary

PR fampridine is recommended to be available as a routine commissioning treatment option for adults with MS and associated walking impairment (as defined by EDSS score of 4-7) within the criteria set out in this document.

The policy is restricted to adults[1] in line with the marketing authorisation.

## Committee discussion

Clinical Panel agreed with the policy and recommended this proceeds as a routine commissioning policy. Please Clinical Panel reports for full details of Clinical Panel's discussion.

The Clinical Priorities Advisory Group committee papers can be accessed here: Clinical commissioning policy: Prolonged-released (PR) fampridine as a treatment of adults with multiple sclerosis and associated walking impairment

## What we have decided

NHS England has carefully reviewed the evidence to treat walking impairment in multiple sclerosis (MS) with PR fampridine. We have concluded that there is enough evidence to make the treatment available at this time.

The evidence review which informs this commissioning position can be accessed here: Clinical commissioning policy: Prolonged-released (PR) fampridine as a treatment of adults with multiple sclerosis and associated walking impairment

## Links and updates to other policies

Not applicable.

# Plain language summary

## About Multiple Sclerosis

MS is a chronic neurological disease that is often initially diagnosed in young adults but will affect a patient for the rest of their life. Patients experience episodes of inflammation in the brain or spinal cord, which damages the nerves in these areas. The damage to these nerves means patients can experience a variety of symptoms in different parts of the body,

[1] Fampridine may be used in post-pubescent children via NHS England's Policy 170001/P Commissioning Medicines for Children in Specialised Services (commissioning medicines children).

such as weakness, pins and needles or a loss of sensation, loss of vision, or difficulty in balance and co-ordination. Fatigue and issues with bowels and bladder can also be symptoms of MS. Some people have episodes called relapses, where symptoms are severe for a period of time and then improve again but because of the nerve damage during the relapse they often won't return to their previous level of function, leading to disability. Other patients may experience progressive nerve damage without relapses, where they experience progressively worse function over a period of time.

Progression of MS causing more nerve damage leads to an increased level of disability, meaning most patients will experience difficulty in mobilising or carrying out their normal daily activities. About half of people with MS need a walking aid, and a quarter are wheelchair users after 15 years of the illness (Albrecht et al., 2018).

### About current treatment

There is no cure for MS, but Disease Modifying Therapies (DMTs) are available which can reduce the number of relapses a patient has and slows or reduces the rate of disability. However, treatment options for patients with walking impairment as a result of their MS are limited. Current standard treatment is supportive, and includes exercises and physiotherapy, walking aids, orthotic devices to support feet and treatments to help manage of muscle stiffness or rigidity (known as spasticity).

### About fampridine

Fampridine is a medicine which aims to improve walking in adults with MS. It is a tablet medication that works by helping impulses travel down damaged nerves.  Fampridine is the first licensed treatment in the UK for people with MS who have a walking impairment. Its marketing authorisation is for adult patients with multiple sclerosis with walking disability, defined as having an EDSS score of 4 to 7 (SmPC). Four is defined as ambulatory without rest for >500 meters and 7 is defined as unable to walk 5 meters even with aid, essentially restricted to wheelchair for around 12 hours a day.

## Epidemiology and needs assessment

The intervention is for people with MS associated walking impairment, with an EDSS score from 4 to 7.

It is unknown exactly how many patients would be eligible for fampridine and how many would remain on it. In England it is estimated that there are about 220 people with MS per 100,000 population with around 5,800 new diagnoses each year (MS Society). It is thought that an EDSS score of 4-7 is seen in 57% of MS patients which equates to 125 per 100,000 and of these not all will have walking impairment as the cause of the EDSS score. Walking impairment is thought to be present in two-thirds of this group, which is 83 per 100,000. Not all of these will be eligible for treatment, such as those with history of renal failure or epilepsy.

In trials, about 43% of people were deemed timed walk responders, so after a few weeks trial, treatment in non-responders is stopped. Therefore, it is estimated 36 patients per 100,000 population in England could remain on treatment. However, in the last 12 months 160 patients in Wales have continued on fampridine beyond four weeks, which would equate to around 3,250 patients in England. Considering service provision in England may have greater capacity to review patients in the first year, an estimate of 5000 eligible

patients would access the treatment in the first year. The intervention will be for people with MS associated walking impairment, with an EDSS score from 4 to 7.

## Inclusion criteria

- Patients with a diagnosis of MS (any subtype)

  **AND**

- MS associated walking impairment as defined by EDSS score of 4-7.

## Exclusion criteria

Patients who meet ANY of the contraindications to fampridine as outlined in the summary of product characteristics (SmPC). are not eligible for treatment with fampridine under this policy.

## Starting criteria

The decision to initiate treatment should be made after clinical review by a physician with significant experience in the management of MS.

Initial prescription should be limited up to four weeks of therapy as clinical benefits should generally be identified within two to four weeks after starting PR fampridine.

Assessment of walking ability should be taken prior to commencing treatment. Ideally, this should be comprised of both an objective measure such as the timed 25 -foot walk (T25FW), and a patient-reported measure such as the Twelve Item Multiple Sclerosis Walking Scale (MSWS-12).

Given the mechanism of treatment and progressive nature of the disease, patients who fulfil the inclusion criteria can be restarted on fampridine even if they have previously been deemed a ‘non-responder’ to treatment.

## Stopping criteria

Treatment with fampridine should be withdrawn and ceased immediately in the case of a severe allergic reaction.

Determining treatment responders:

- After two to four weeks of treatment with fampridine, therapy should be ceased in the following situations:
  - If no improvement is seen in the T25FW or MSWS-12 from baseline scores. An improvement of around 20% from baseline is expected to be seen in either of the T25FW or MSWS-12.
  - If no benefit is reported by patients.

Once established on treatment:

- If a decline in walking ability is observed, physicians or specialist practitioners (supported by the MDT including a named Consultant) should consider a two to four

week interruption to treatment in order to reassess the benefits of fampridine (see above).

- The re-evaluation should include withdrawal of fampridine and then performing an assessment of walking ability in line with the Summary of Product Characteristic (SmPC).
- Fampridine can then be re-commenced and walking ability assessed after two to four weeks of treatment (see above).
- Fampridine should be stopped if no improvement is seen.

## Dosing

The recommended dose is one 10 mg tablet, twice daily, taken 12 hours apart (one tablet in the morning and one tablet in the evening).

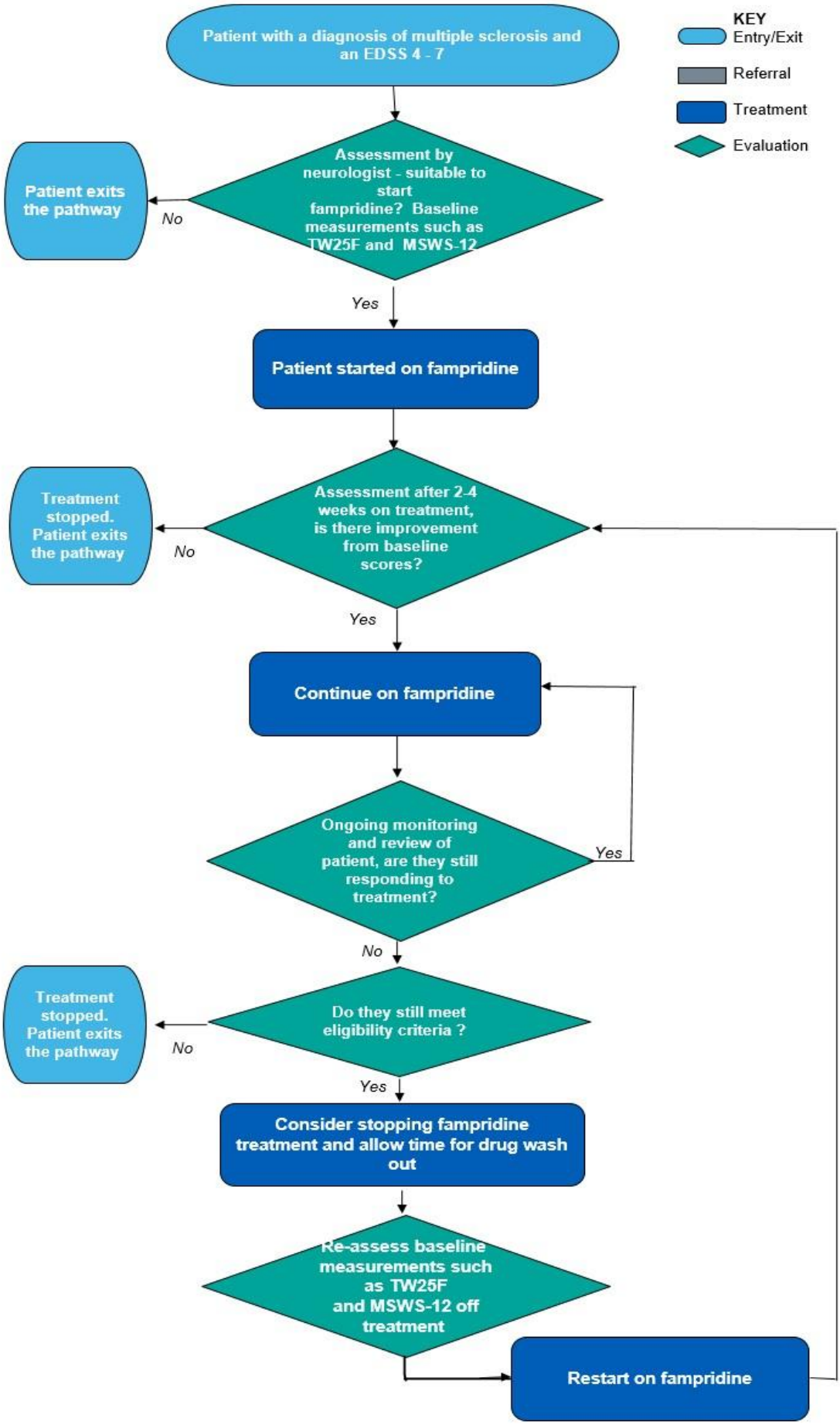
## Monitoring

Patients should be assessed prior to commencing PR fampridine and then assessed after two to four weeks on treatment.

If deemed to have 'responded', patients should have a further follow-up within 3-6 months of starting treatment to ensure they are still responding. Once established on treatment, patients should be reviewed every 6-12 months.

At all these points, objective assessments such as the T25FW or MSWS-12 should be carried out to ensure that the patient is still receiving walking benefit. Clinicians or specialist practitioner (supported by the MDT including a named Consultant) should assess each patient on an individual basis, taking into account their disease progression, previous trends in assessments, reported benefit and overall clinical picture when assessing ongoing walking benefit.

## Patient pathway



## Governance arrangements

This policy should be used in conjunction with the following Service Specialised Specification for Neurosciences Specialised Neurology (adults) D04/S/a.

The use of PR fampridine as set out in this Policy is within its licensed indication. Provider organisations must register all patients using prior approval software and ensure monitoring arrangements are in place to demonstrate compliance against the criteria as outlined.

## Mechanism for funding

PR fampridine within the criteria set out in this document will be commissioned and funded by NHS England under existing arrangements for the provision of specialised services. PR fampridine is categorised as a high-cost drug to be reimbursed under the cost and volume process.

## Audit requirements

Provider organisations must register all patients using prior approval software and ensure audit arrangements are in place to demonstrate compliance against the criteria as outlined in this policy.

## Policy review date

This document will be reviewed when information is received which indicates that the policy requires revision. If a review is needed due to a new evidence base then a new Preliminary Policy Proposal needs to be submitted by contacting england.CET@nhs.net.

Our policies provide access on the basis that the prices of therapies will be at or below the prices and commercial terms submitted for consideration at the time evaluated. NHS England reserves the right to review policies where the supplier of an intervention is no longer willing to supply the treatment to the NHS at or below this price and to review policies where the supplier is unable or unwilling to match price reductions in alternative therapies.

## Equality statement

Promoting equality and addressing health inequalities are at the heart of NHS England's values. Throughout the development of the policies and processes cited in this document, we have:

- Given due regard to the need to eliminate discrimination, harassment and victimisation, to advance equality of opportunity, and to foster good relations between people who share a relevant protected characteristic (as cited under the Equality Act 2010) and those who do not share it; and
- Given regard to the need to reduce inequalities between patients in access to, and outcomes from healthcare services and to ensure services are provided in an integrated way where this might reduce health inequalities.

# Definitions

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| Expanded Disability Status Scale (EDSS): | A method of measuring disability in multiple sclerosis, where a higher number refers to more severe disability. A score between 4 and 7 indicates some impairment to walking. |

# References

Albrecht, P., Bjørnå, I. K., Brassat, D., Farrell, R., Feys, P., Hobart, J., Hupperts, R., Linnebank, M., Magdič, J., Oreja-Guevara, C., Pozzilli, C., Salgado, A. V., & Ziemssen, T. (2018). Prolonged-release fampridine in multiple sclerosis: clinical data and real-world experience. Report of an expert meeting. Therapeutic advances in neurological disorders, 11, 1756286418803248. https://doi.org/10.1177/1756286418803248.

MS Society *MS in the UK*. [online] MS Society. Available at: www.mssociety.org.uk/what-we-do/our-work/our-evidence/ms-in-the-uk [Accessed 18 Jun. 2024].