Engagement Report

Topic details

Title of policy or policy statement:	Prolonged-released (PR) fampridine as a treatment of adults with Multiple Sclerosis and associated walking impairment (as defined by Expanded Disability Status Score 4-7) [2341]
Programme of Care:	Trauma
Clinical Reference Group:	Neurology
URN:	2341

1. Summary

This report summarises the feedback NHS England received from engagement during the development of this policy proposition, and how this feedback has been considered.

2. Background

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, 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).

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).

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 in the UK to treat patients with MS who have a walking disability. This is defined as having an EDSS score of 4 to 7. 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.

Engagement

Following stakeholder testing feedback, the Programme of Care considered that the proposition offers a clear and positive impact on patient treatment, by potentially making a new treatment available which widens the range of treatment options without disrupting current care or limiting patient choice, and therefore further public consultation was not required. This decision has been assured by the Patient Public Voice Advisory Group.

NHS England has a duty under Section 13Q of the NHS Act 2006 (as amended) to 'make arrangements' to involve the public in commissioning. Full guidance is available in the Statement of Arrangements and Guidance on Patient and Public Participation in Commissioning. In addition, NHS England has a legal duty to promote equality under the Equality Act (2010) and reduce health inequalities under the Health and Social Care Act (2012).

The policy proposition underwent a four-week stakeholder testing between the 25th October 2024 to 21st November 2024 (due to some having difficulties accessing documents in the initial two- week period) with registered stakeholders from the following Clinical Reference Groups:

- Neurology

Respondents were asked the following consultation questions:

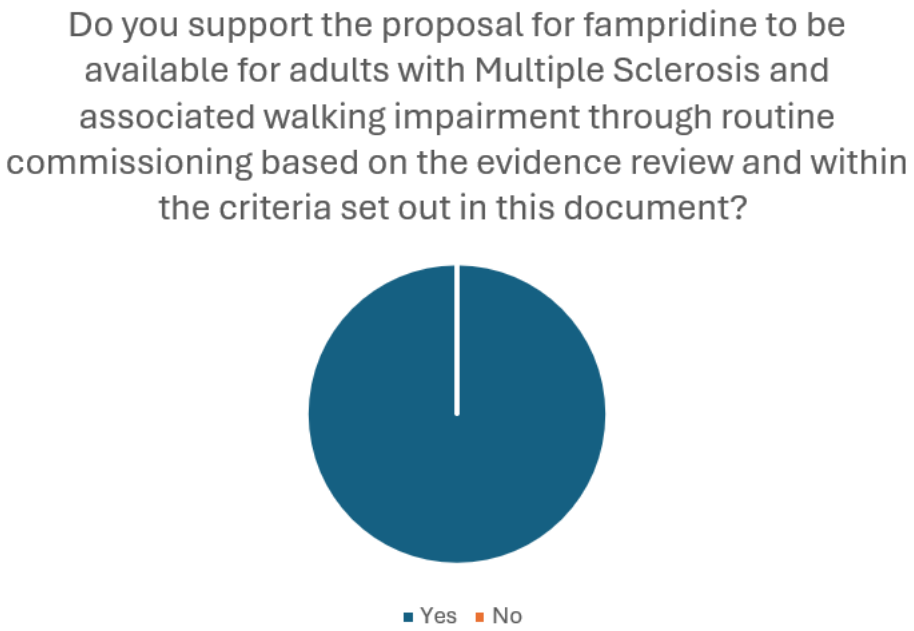
- Do you support the proposal for fampridine to be available for adults with Multiple Sclerosis and associated walking impairment through routine commissioning based on the evidence review and within the criteria set out in this document?
- Do you believe that there is any additional information that we should have considered in the evidence review? If so, please give brief details.
- Do you believe that there are any potential positive and/or negative impacts on patient care as a result of making this treatment option available?
- Do you have any further comments on the proposal? If Yes, please describe below, in no more than 500 words, any further comments on the proposed changes to the document as part of this initial 'sense check'.
- Do you support the Equality and Health Inequalities Impact Assessment (EHIA)?
- Does the Patient Impact Assessment (PIA) present a true reflection of the patient and carers lived experience of this condition?
- Do you have any potential conflict of interest relating to this document or service area?

3. Engagement Results

Number stakeholders responded: 9

- 6 clinicians
- 3 patient organisations

All respondents were supportive of the policy proposal.



4. How has feedback been considered?

Responses to engagement have been reviewed by the Policy Working Group (PWG) and the Neurology Clinical Reference Group (CRG).

The following themes were raised during engagement:

Keys themes in feedback	NHS England Response
Impact Assessment	
The majority of respondents supported the PIA. One stated they 'somewhat' supported but did not elaborate.	No further action taken.
One respondent had issues accessing the document links.	The portal was re-opened for an additional 48 hours for those who had difficulties accessing documents.
Potential impact on equality and health inequalities	
All respondents supported the EHIA	No further action taken.
Changes/addition to policy	
One respondent stated that the use of 'physician' was limited and	The policy proposition was edited to include 'physician or specialist

recommended it be broadened to include wider specialist practitioners.	practitioner (supported by the MDT including a named Consultant)' following initiation and initial follow-up by the MS specialist Physician.
Another respondent recommended that the policy allow for primary care prescribing once drug was established.	As outlined in the policy proposition and a prerequisite of the prior approval forms, patients who are initiated on fampridine following their initial trial period and 6-month follow-up must be reviewed every 6- to 12-months. The assessment requires specialist understanding of the disease, assessments and overview previous trends. It is therefore the understanding of the PWG that this must be carried out in a secondary care setting All costs associated with funding will be covered in the commissioning plan.
One respondent queried about the funding of additional administrative and clinical work for MS services.	The policy proposition is currently in the process of financial modelling which aids in rationalising the cost of treatment. Though the proposed policy document does not directly provide guidance on this matter, proposed funding will be discussed within the Commissioning plan and Financial Impact Assessment.

The responses should answer all the themes reported in section 4 and cover the outcome of reviews of any additional evidence highlighted during engagement

5. Has anything been changed in the policy proposition as a result of the stakeholder testing and consultation?

The following change(s) based on the engagement responses has (have) been made to the policy proposition:

Document	Changes
Policy Proposition	The policy proposition was edited to include 'physician or specialist practitioner (supported by the MDT)' following initiation and initial follow-up by the MS specialist Physician.

6. Are there any remaining concerns outstanding following the consultation that have not been resolved in the final policy proposition?

No.