NICE National Institute for Health and Care Excellence

Putting NICE guidance into practice

Resource impact report:
Siponimod for treating secondary progressive multiple sclerosis (TA656)

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Summary

NICE has recommended siponimod, within its marketing authorisation, for treating secondary progressive multiple sclerosis (SPMS) with evidence of active disease (that is, relapses or imaging features of inflammatory activity) in adults, only if the company provides siponimod according to the commercial arrangement.

Secondary progressive disease would usually only be diagnosed in people with an Expanded Disability Status Scale (EDSS) score of 6.0 or greater. Most people identified as having SPMS are EDSS 7.0 and above. Based on the NHS England Treatment Algorithm for Multiple Sclerosis Disease-modifying Therapies these people are not eligible for treatment with disease-modifying therapies. Therefore, only people with an EDSS score of 6.0 to less than 7.0 are considered.

We estimate that:

- 11,000 people with SPMS with an EDSS score of 6.0 to less than 7.0 are eligible for treatment with siponimod.
- 4,400 people with SPMS with evidence of active disease will be receiving treatment with siponimod by year 2024/2025 onwards once uptake has reached 40% as shown in table 1.

Table 1 Estimated number of people in England receiving siponimod

	2020/21	2021/22	2022/23	2023/24	2024/25
Population receiving siponimod each year	1,100	2,200	3,300	3,850	4,400

This report is supported by a local resource impact template because the list price of siponimod has a discount that is commercial in confidence. The discounted price of siponimod can be put into the template and other variables may be amended.

This technology is commissioned by NHS England. Providers are NHS hospital trusts.

1 Siponimod

1.1 NICE has recommended siponimod, within its marketing authorisation, for treating secondary progressive multiple sclerosis with evidence of active disease (that is, relapses or imaging features of inflammatory activity) in adults, only if the company provides siponimod according to the commercial arrangement.

1.2 Secondary progressive disease would usually only be diagnosed in people with an EDSS of 6.0 or greater. Most people identified as having SPMS are EDSS 7.0 and above. Based on the NHS England Treatment Algorithm for Multiple Sclerosis Disease-modifying Therapies these people are not eligible for treatment with disease-modifying therapies. Therefore, only people with an EDSS score of 6.0 to less than 7.0 are considered

1.3 Interferon beta-1b (Extavia) is the only disease-modifying treatment available for people with active SPMS. However, few people take it (Technology appraisal guidance TA527). Effective treatment options for SPMS are therefore very limited.

1.4 Disease-modifying treatments for relapsing–remitting multiple sclerosis are no longer indicated once someone is diagnosed with SPMS, so treatment usually stops.

2 Resource impact of the guidance

2.1 We estimate that:

- 11,000 people with SPMS with an EDSS score of 6.0 to less than 7.0 are eligible for treatment with siponimod.
- 4,400 people will receive siponimod from year 2024/25 onwards once uptake has reached 40% as shown in table 2.

2.2 The current treatment and future uptake figure assumptions are based on the company submission and clinical expert opinion and are shown in the resource impact template. Table 2 shows the

number of people in England who are estimated to have siponimod by financial year.

Table 2 Estimated number of people receiving siponimod using NICE assumptions

	2020/21	2021/22	2022/23	2023/24	2024/25
Population receiving siponimod each year	1,100	2,200	3,300	3,850	4,400

2.3 This report is supported by a local resource impact template. Siponimod has an agreed patient access scheme which makes it available with a commercial-in-confidence discount to the list price. The discounted price of siponimod can be put into the template and other variables may be amended. For enquiries about the patient access scheme contact: commercial.team@novartis.com.

Savings and benefits

2.4 Siponimod demonstrates efficacy in slowing disability progression in people with SPMS. Therefore, use of siponimod may lower the NHS costs associated with SPMS.

2.5 Experts suggest that historically, there has been reluctance to diagnose patients with SPMS because there is only 1 licensed treatment which people may already have taken. Therefore, use of siponimod may result in earlier diagnosis of adults with SPMS.

3 Implications for commissioners

This technology is commissioned by NHS England. Providers are NHS hospital trusts.

3.1 Siponimod falls within the programme budgeting category PBC07X, Neurological.

4 How we estimated the resource impact

The population

4.1 Based on a UK prevalence of SPMS of around 0.06%, there are around 25,400 adults with SPMS in England.

4.2 Table 3 shows the number of adults with SPMS who are eligible for treatment with siponimod.

Table 3 Number of people eligible for treatment in England

Population	Proportion of previous row (%)	Number of people
Adult population		44,022,560
Prevalence of secondary progressive multiple sclerosis (SPMS)[1]	0.06	25,450
People with SPMS with an Expanded Disability Status Scale (EDSS) score of 6.0 to less than 7.0[2]	43.4	11,040
Total number of people eligible for treatment with siponimod[3]	99.6	11,000
Total number of people with active SPMS estimated to be receiving siponimod by year 2024/25[3]	40	4,400

[1] Estimated prevalence of SPMS in the USA and Europe: results from a systematic literature search (P2.380)
Vivek Khurana, Harsh Sharma, Jennie Medin Neurology Apr 2018, 90 (15 Supplement) P2.380.
[2] NHS England.
[3] Clinical expert opinion and discussions with NHS England.

Assumptions

4.3 The resource impact template assumes that:

- Interferon beta-1b and best supportive care are the comparators. Interferon beta-1b is currently the only disease-modifying treatment for people with active SPMS. However, the template includes the option for organisations to model other disease modifying therapies at a local level.

- Actual number of people with SPMS with active disease (that is, relapses or imaging features of inflammatory activity) would be determined through uptake data.
- Treatment with interferon beta-1b is only for a year. Clinical experts suggest that many people have difficulty tolerating the treatment because it can cause side effects such as flu-like symptoms. Therefore, people are not expected to receive interferon beta1-b treatment beyond 1 year.
- The cost of interferon beta-1b includes drug administration and monitoring costs of £590 in the first year of treatment and £260 in second year. However, the model assumes there will be no second-year treatment with interferon beta 1-b.
- The cost of best supportive care is to be considered at a local level.
- Treatment with siponimod includes drug administration and monitoring costs of £756 and £247 in year 1 and year 2, respectively. However, the model uses a weighted average annual cost of £398 over the 5-year treatment horizon. Full details of the costs are provided in the resource impact template.
- Treatment with siponimod continues up to 5 years. No treatment discontinuation has been factored into the model. However, some level of discontinuation is anticipated in practice, but this is a simplifying assumption for the purpose of the model whereby discontinuation has been implicitly considered in the overall uptake assumptions.
- The incident population is not considered in the model. This is because the prevalent population of people with an EDSS score of 6.0 to less than 7.0 will already have been considered. It is anticipated that any changes resulting from people transitioning in and out of the eligible EDSS score and whose disease is active/non-active will be of an equivalent number.

Other factors

4.4 The clinical experts, patient experts, company and ERG all indicated that there is a period of transition in which people with relapsing–remitting multiple sclerosis (RRMS) may be suspected of having secondary progressive disease but are not formally diagnosed.

4.5 Clinical experts highlighted that, because of capacity issues in MS services, uptake is anticipated to be slow among people on RRMS disease modifying therapy. Therefore, it is expected that there would be a phased approach to switching existing patients with SPMS to siponimod.

4.6 Clinical experts highlighted that more people would have an MRI scan as part of their diagnosis to identify if they are eligible for siponimod. They also explained that people already diagnosed with secondary progressive disease would have to have MRI scans and visit a neurologist to assess if siponimod is a suitable treatment option.

4.7 The committee was aware that this additional activity could have a substantial resource impact for the NHS. Therefore, any additional costs should be considered at a local level.

4.8 Also, earlier diagnosis may mean more people than estimated in the model may end up having siponimod. The model should be reviewed in line with changes in local SPMS diagnosis procedures.

About this resource impact report

This resource impact report accompanies the NICE guidance on siponimod for treating secondary progressive multiple sclerosis and should be read with it.