



NHS Shropshire and NHS Telford and Wrekin Clinical Commissioning Groups Commissioning Policy: Sativex® Oromucosal Spray for spasticity in multiple sclerosis

Policy statement:

NHS Shropshire and NHS Telford and Wrekin Clinical Commissioning Groups have considered the evidence relating for the prescribing of Sativex® for patients with MS.

Sativex® has not been considered suitable for routine prescribing due to limitations in existing clinical trial data and lack of evidence that it represents value for money in terms of use of NHS resources.

The funding of Sativex® will only be considered in exceptional circumstances through the Individual Funding Request Route.

Background

Sativex® is licensed as an add-on treatment for symptom improvement in patients with moderate to severe spasticity due to MS who have not responded adequately to other anti-spasticity medication and who demonstrate a clinically significant improvement in spasticity related symptoms during an initial trial of therapy.

Summary of the evidence

NICE Clinical Guideline 186 Management of multiple sclerosis in primary and secondary care (October 2014) states the following: *Do not offer Sativex® to treat spasticity in people with MS because it is not a cost effective treatment.*¹

NICE Clinical Guideline 144 Cannabis-based medicinal products (November 2019) has indicated that a trail of THC:CBD could be offered, however they also conclude that evidence is lacking²

'The committee noted that despite THC: CBD spray being found to be clinically effective at reducing spasticity, no studies found any significant differences in health-related quality of life (HRQoL) measures whether using the EQ-5D, SF-36 or VAS 0-100 instruments. Additionally, differences in point estimates between the two arms of all trials collecting HRQoL measures were very small. They considered that this might be because HRQoL measures have some level of insensitivity to changes in spasticity NRS and are therefore not capturing the benefits of the treatment appropriately. Another contributory factor could be condition severity in the population in the trials, as patients with advanced MS typically have many other important symptoms that can influence their HRQoL and reducing spasticity might not change their self-reported scores by much. The economic model estimated a fairly large difference in HRQoL between responders and non-responders of 0.15, which may therefore have been an overestimate. This difference was 0.09 in data that Lu et al report was observed in the Novotna trial, but using a lower response cut-off, which might also explain the discrepancy.'

It still remains that there is no robust long term efficacy data.

Adverse events such as dizziness, fatigue, somnolence, vertigo and disorientation were reported commonly during clinical trials.

No studies that directly compare Sativex® with other treatments for spasticity have been identified and so there is a lack of evidence suggesting Sativex® could be used in place of currently recommended treatments.

A health technology commissioning group developed a ‘decision-analytic model’ to estimate the cost-effectiveness of Sativex.² The authors concluded that the use of Sativex for treatment of spasticity associated with MS was not cost-effective.

It should also be noted that a number of other CCGs have also stated that they will not support the prescribing of Sativex® in primary or secondary care.

This policy is based on the best available information at the time of writing.

References

1 Multiple sclerosis in adults: management Published October 2014. <https://www.nice.org.uk/guidance/cg186>

2 Peninsular Health Technology Commissioning Group, 2011. Sativex for treatment of spasticity in multiple sclerosis [online]. Accessed April 2014
[http://www.medicinesresources.nhs.uk/upload/documents/Evidence/Drug%20Specific%20Reviews/Sativex_treatment_of_MS.p
df](http://www.medicinesresources.nhs.uk/upload/documents/Evidence/Drug%20Specific%20Reviews/Sativex_treatment_of_MS.pdf)

3 Cannabis-based medicinal products. Published November 2019.
<https://www.nice.org.uk/guidance/ng144/chapter/Recommendations#spasticity>