

Policy Recommendation: Delta-9-tetrahydrocannabinol/cannabidiol (Sativex) for symptom improvement in adult patients with moderate to severe spasticity due to multiple sclerosis

Date of Issue: April 2020

The Priorities Committee supports the restricted use of Sativex in line with NICE Clinical Guideline number 144 (November 2019), and in accordance with the following recommendations;

Trial of Treatment

Consider a trial of THC:CBD spray to treat **moderate to severe** spasticity in adults with multiple sclerosis only if the following criteria are met:

- All other pharmacological treatments for moderate to severe spasticity are not effective and the company provides THC:CBD spray according to its pay-for-responders scheme.
- Treatment with THC:CBD spray must be **initiated and supervised** by a physician with specialist expertise in treating spasticity due to multiple sclerosis, in line with its marketing authorisation.
- **Specialist Review.** After a 4-week trial, continue THC:CBD spray only if the person has had at least a 20% reduction in spasticity-related symptoms on a 0 to 10 patient-reported numeric rating scale.

Supply

Prescribing should be initiated by the specialist and continued for 3 months, after which time the patient should be reviewed. If the individual's response remains in line with the criteria above, consideration of transfer to GP prescribing may be appropriate in accordance with a locally approved shared care agreement (once available).

Specialist symptom review is recommended after the first 6 months, and then periodically as normally required.

Diversion and Misuse

From the Summary of Product Characteristics, patients who have a history of substance abuse may be more prone to abuse Sativex (see section 5.1).

In a study designed to identify its abuse potential, Sativex at a dose of 4 sprays taken at one time did not differ significantly from placebo. Higher doses of Sativex of 8 to 16 sprays taken at one time did show abuse potential comparable to equivalent doses of dronabinol, a synthetic THC.

Euphoria is listed as a common side effect, so diversion and misuse is a potential problem that requires careful monitoring.

Monitoring Uptake and Impact

Use of the Blueteq tool is recommended for at least the first 12 months of treatment, in order to monitor uptake and appropriate use, with timely patient review.

Existing NHS and Private Patients

In line with other policy statements, patients currently accessing Sativex via private or NHS prescription would need to be eligible for NHS treatment, and therefore are subject to the same criteria and processes outlined above.

Notes:

Whilst the panel recognised the considered expert advice of NICE in their recommendation the panel also had a duty to prioritise spending of a finite resource locally and made a decision which it felt gave the most equitable and effective use of investment.