

# Putting NICE guidance into practice

# Resource impact report: Cannabis-based medicinal products (NG144)

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### Summary

This report focuses on the recommendation from NICE's guideline on <u>cannabis-based medicinal products</u> that we think will have the greatest resource impact nationally (for England), and will need the most additional resources to implement. It is:

 Offer a 4-week trial of THC:CBD spray to treat moderate to severe spasticity in adults with multiple sclerosis. After the 4-week trial, continue THC:CBD spray if the person has had at least a 20% reduction in spasticity-related symptoms on a 0 to 10 patient-reported numeric rating scale (recommendation 1.3.1).

The estimated annual cost of implementing this guideline for the population of England based on the resource impact assumptions is shown in table 1.

Table 1 Estimated annual cost of implementing the guideline

	Current practice Baseline	2019/20	2020/21	2021/22	2022/23	2023/24
Implementation rate	22%	30%	75%	90%	90%	90%
Number of adults treated	800	981	2,453	3,271	3,271	3,271
Annual cost	2.6	3.1	7.4	10.3	10.6	10.6
Annual saving	0	0.0	-0.2	-0.3	-0.3	-0.3
Resource impact £m	0	3.1	7.2	10.0	10.3	10.3
Baseline cost £m	0	-2.6	-2.6	-2.6	-2.6	-2.6
Incremental resource impact £m	0	0.5	4.6	7.4	7.7	7.7

Implementing the guideline may result in the following costs and savings:

- Increased drug costs using THC:CBD spray to treat moderate to severe spasticity in adults with multiple sclerosis compared to standard care alone.
- Savings from reduced resource use of spasticity management compared to standard care alone.

#### 1 Introduction

- 1.1 The guideline offers best practice advice on <u>cannabis-based</u> medicinal products.
- 1.2 This report discusses the resource impact of implementing our guideline on cannabis-based medicinal products in England. It aims to help organisations plan for the financial implications of implementing this NICE guideline.
- 1.3 A resource impact template accompanies this report to help with assessing the resource impact at a local level in England, Wales or Northern Ireland. We encourage organisations to evaluate their own practices against the recommendations in the NICE guideline and assess costs and savings locally by amending blue cells in the template.
- 1.4 Services for the prescribing of cannabis-based medicinal products are commissioned by NHS England and clinical commissioning groups. Providers are NHS hospital trusts and primary care services.

## 2 Background

- 2.1 As of October 2019 Sativex is the only delta-9-tetrahydrocannibinol and cannabidiol (THC:CBD) spray licensed for use in the UK by the Medicines and Healthcare products Regulatory Agency (MHRA) as a treatment for spasticity in multiple sclerosis.
- 2.2 Spasticity is a specific form of increased muscle tone (hypertonia) associated with a number of neurological disorders. The prevalence of adults reporting spasticity-related symptoms in people with multiple sclerosis is 60%. The impact of spasticity and co-existing disorders on the individual varies. Common problems include motor developmental delay (in children), pain from muscle spasms, impaired motor function affecting the person's ability to

Resource impact report: Cannabis-based medicinal products (November 2019) 3 of 9

participate in society, and difficulties with daily care due to the onset of secondary complications of spasticity.

# 3 Recommendations with potential resource impact

One recommendation is likely to lead to a significant resource impact:

3.1 Offer THC:CBD spray to treat moderate to severe spasticity in adults with multiple sclerosis.

The guideline recommends:

Offer a 4-week trial of THC:CBD spray to treat moderate to severe spasticity in adults with multiple sclerosis, if:

- other pharmacological treatments for spasticity are not effective (see the recommendations on spasticity in NICE's guideline on multiple sclerosis)
- the company provides THC:CBD spray according to its pay-forresponders scheme<sup>1</sup>

After the 4-week trial, continue THC:CBD spray if the person has had at least a 20% reduction in spasticity-related symptoms on a 0 to 10 patient-reported numeric rating scale (**recommendation** 1.3.1).

#### **Background**

3.1.1 Prescriptions of cannabis-based medicinal products to treat moderate to severe spasticity in adults with multiple sclerosis are currently rare. Treatment with THC:CBD spray should be initiated

Resource impact report: Cannabis-based medicinal products (November 2019) 4 of 9

<sup>&</sup>lt;sup>1</sup> According to the terms of the pay-for-responders scheme, the company will fund the first 3 x10-ml vials of THC:CBD spray if there is an agreement for continued funding for people who experience at least a 20% reduction in spasticity-related symptoms on a 0 to–10 patient-reported numeric rating scale after 4 weeks of treatment.

and supervised by a physician with specialist expertise in treating multiple sclerosis, in line with its marketing authorisation.

#### **Population**

3.1.2 The annual prevalence of adults in England with multiple sclerosis (MS) is around 90,500 (MS society, MS in the UK, 2018). Table 2 shows the details of the prevalent population with MS who are estimated to be eligible for treatment with THC:CBD spray.

Table 2 Number of people eligible for treatment in England

Population	Proportion of previous row (%)	Number of people
Total adult population		43,752,473
Prevalence of multiple sclerosis (MS) <sup>1</sup>	0.21	90,500
Proportion of adults reporting spasticity-related symptoms <sup>2</sup>	60	54,300
Proportion of adults reporting spasticity-related symptoms rated as moderate or severe <sup>3</sup>	44.5	24,200
Proportion of adults eligible for treatment with THC:CBD spray, due to other pharmacological treatments for spasticity not being effective <sup>4</sup>	20	4,800
Proportion of people who experience at least a 20% reduction in spasticity-related symptoms on a 0 to 10 patient-reported numeric rating scale after 4 weeks of treatment <sup>5</sup>	75.2	3,600
Total number of people eligible for treatment with THC:CBD spray		3,600

<sup>&</sup>lt;sup>1</sup> MS society.MS in the UK 2018.

Note: numbers rounded to nearest 100 from row 2 onwards.

#### **Resource impact**

3.1.3 The estimated resource impact of current and future prescribing of THC:CBD spray is set out in table 3.

Resource impact report: Cannabis-based medicinal products (November 2019) 5 of 9

<sup>2</sup> Royal College of Physicians: Spasticity in adults, April 2018.

<sup>&</sup>lt;sup>3</sup> <u>Dr Farrell. Optimisation of pharmacological management of multiple sclerosis</u> related spasticity, October 2019.

<sup>&</sup>lt;sup>4</sup> Expert clinical opinion.

<sup>&</sup>lt;sup>5</sup> Etges 2016, dataset indicating that 22% of the eligible population of UK receive Sativex.

Table 3 The estimated current and future resource impact of prescribing for THC:CBD spray (Sativex) to treat moderate to severe spasticity in adults with multiple sclerosis

Variables	Number of people treated	Number of packs paid for (3 vials per pack)	Annual cost £000	Annual saving £000	Resource impact £000	Baseline cost £000	Incremental resource impact £000
Current practice (baseline)	800	7,200	2,590	0	0	0	0
Year 1 of treatment	981	8,292	3,114	-22	3,091	-2,590	501
Year 2 of treatment	2,453	17,661	7,418	-203	7,215	-2,590	4,624
Year 3 of treatment	3,271	26,985	10,303	-304	9,999	-2,590	7,408
Year 4 of treatment	3,271	29,439	10,597	-304	10,293	-2,590	7,703
Year 5 of treatment	3,271	29,439	10,597	-304	10,293	-2,590	7,703

#### **Assumptions made**

- 3.1.4 The mean dose per day is based on the committee agreement that it is appropriate to use the mean dose data from Messina et al.
  2017 and from the randomised control trials in the economic evidence.
- 3.1.5 The number of doses per vial is assumed to be 90, taken from the SPC for Sativex and each pack contains 3 vials. The <u>BNF</u> quoted figure of 270 doses is in line with the pack size.
- 3.1.6 The number of vials per person used in year 1 is assumed to be 27, based on 90 doses per vial and the mean doses per day. The first 3 vials are provided under the pay-for-responders scheme, for all people starting treatment.
- 3.1.7 The number of vials used per person in year 2 is assumed to be 27, based on 90 doses per vial and the mean doses per day.

Resource impact report: Cannabis-based medicinal products (November 2019) 6 of 9

- 3.1.8 The resource impact calculation includes the costs for Sativex because this is the TBC:CBD spray that is currently licensed for use in the UK.
- 3.1.9 No cost is included for people who do not respond to treatment because the initial trial period is under the pay-for-responders scheme.
- 3.1.10 The eligible population will remain the same, due to increases in the prevalent population matching the number of people discontinuing treatment, each year.
- 3.1.11 The savings were taken from a published UK study (Stevenson et al. 2015), as shown in the <a href="evidence review">evidence review</a> [C] for spasticity, which reported spasticity management costs by NRS categories.

# 3.2 Other recommendations with potential resource impact

3.2.1 The following recommendation was also highlighted as having potential resource implications:

Consider nabilione as an add-on treatment for adults (18 years and over) with chemotherapy-induced nausea and vomiting which persists with optimised conventional antiemetics (recommendation 1.1.1).

3.2.2 However, nabilone is already used by a small number of people in this population and expert clinical opinion suggests that the level of prescribing will not change significantly as a result of the guideline.

## 4 Implications for commissioners

4.1 Currently, prescribing and monitoring cannabis-based medicinal products takes place in tertiary care. The recommendations focus on shared care after the initial prescription with the involvement of other healthcare professionals such as non-medical prescribers Resource impact report: Cannabis-based medicinal products (November 2019)

and GPs. This will allow a more holistic approach to care. Moving away from tertiary care may be cost saving for the NHS.

4.2 Prescribing of cannabis-based medicinal products falls under programme budgeting category 23E (other, multiple conditions).

## About this resource impact report

This resource impact report accompanies the NICE guideline on <u>cannabis-based medicinal products</u> and should be read in conjunction with it. See <u>terms and conditions</u> on the NICE website.

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