



# Approved but denied

Access to Sativex to treat MS  
related spasticity in England

**#ApprovedButDenied**

## About MS

MS is a neurological condition that affects more than 130,000 people in the UK. It's unpredictable and different for everyone. It's often painful, exhausting and can cause problems with how people walk, move, see, think and feel.

## About the MS Society

We're the MS Society. We're here by your side through the highs, lows and everything in between. Together we fund world-leading research. We provide information and services so everyone can live well with MS. We make our voices heard and campaign for everyone's rights. And we support one another so no one has to feel alone. Together we are a community. And together we will stop MS.

## Contents

<b>1.</b>	Executive summary	4
<b>2.</b>	About Sativex and spasticity	8
<b>3.</b>	The wider issue of medical cannabis	10
<b>4.</b>	Access to Sativex in the UK	13
<b>5.</b>	Prescribing in England	16
<b>6.</b>	The barriers to accessing Sativex	20
<b>7.</b>	How to overcome the barriers - recommendations for action	24
<b>8.</b>	Conclusion	25
<b>9.</b>	Appendix 1: Scottish and Welsh prescribing data	26
<b>10.</b>	References	28



# 1. Executive summary

**Getting the treatment you need shouldn't be a game of chance. But new findings in this report show too often that is the case for people with MS trying to access Sativex.**

MS is relentless, painful and exhausting. It can make it harder to do everyday things like walk, talk, eat and think. Symptoms can fluctuate, making life unpredictable. They can include loss of balance, speech problems, fatigue, pain, bladder and bowel problems, and vision problems.

One of the most challenging symptoms to deal with can be muscle spasms or stiffness, known as spasticity. Spasticity affects up to 80% of people with MS at some time<sup>1</sup> and can be a very challenging symptom, especially if it's not managed well. It has a big impact on the lives of people with MS and their friends, families and carers. There is a high cost associated with treating spasticity for health and social care systems, as well as wider society<sup>2</sup>. That's why any treatment that works and is cost-effective for MS-spasticity needs to be made available to everyone who could benefit.

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**“I am so used to the constant spasms and pain I can't imagine what it would be like without them. But I want to get that feeling if it is possible”**

– **Paul**, 50, living with secondary progressive MS

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There are a number of treatments and therapies for spasticity that have been available on the NHS for some time<sup>3</sup>. But they are not effective or appropriate for everyone with MS who experiences this symptom. MS is the only condition which has a licensed,

cannabis-derived treatment for spasticity, called Sativex. However, for a long time, eligible people with MS have been struggling to access this treatment on the NHS.

For over 10 years Sativex has been licensed – allowed to be used – in the UK for treating moderate to severe spasticity in MS, when other medicines haven't worked<sup>4,5</sup>. Sativex is licensed as an “add on” treatment, which means it can be taken alongside a patient's existing anti-spasticity medication.

In November 2019, nine years after it obtained a licence, the National Institute for Health and Care Excellence (NICE) recommended that Sativex be made available on the NHS in England, for people with MS with moderate to severe spasticity for whom other treatments have not worked<sup>6</sup>.

But despite NICE approving the treatment, eligible people with MS are being denied the option to try it. Many are finding that despite the treatment being approved, they are being denied access in their area – including Anne, Chris and Paul, who share their experiences in this report.

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**“It feels like someone somewhere has something against me and won't let me try this treatment that could change my life for the better”**

– **Anne**, 40, living with relapsing-remitting MS.

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Access to Sativex differs across each nation of the UK, which we explore in the section “Access to Sativex in the UK”. In England, Sativex funding decisions are

the responsibility of individual health bodies called Clinical Commissioning Groups (CCGs). It should be noted that, subject to the passing of appropriate legislation, relevant commissioning functions of CCGs are set to be replaced by Integrated Care Systems on the NHS in England by April 2022. At the moment, Sativex is funded in 49 out of 106 CCGs- that's just 46%. NICE estimated that around 4,800 people in England are eligible for a four-week Sativex trial and continuing treatment if Sativex is effective for them<sup>7</sup>. But our analysis of available NHS data on prescriptions suggests only around 630 people were accessing Sativex on the NHS in England in May 2021, the last available monthly prescribing figures at the time of writing. This means that thousands of people with MS could be missing out on a treatment that's safe, effective and could greatly improve their quality of life.

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### **Only 46% of health bodies in England fund Sativex**

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Sativex was approved in England only shortly before the COVID-19 pandemic hit. This will undoubtedly have impacted uptake of the treatment by CCGs, as quite understandably

the focus of the NHS was on the pandemic and saving lives. We all understand the pandemic has meant some care has had to wait. But that's undeniably had a huge impact on people with long term conditions like MS. As the NHS builds back, people with MS simply deserve equal access to effective treatment no matter where they live. The postcode lottery will continue unless all CCGs in England make Sativex available.

We don't underestimate the barriers to achieving this for people with MS – Sativex prescription is very likely affected by challenges related both to perception and practice. Some people are uncomfortable because it is a cannabis-based medicine, others seem to view it as less effective despite the published evidence underpinning its use. Some areas may lack the clear pathway required to make Sativex available.

However, as with many areas of NHS practice – those at the forefront show what is possible for everyone. In the best-performing areas, shared care agreements and agreed pathways provide a clear basis for Sativex to be prescribed – and the potential benefits are understood such that clinicians have the confidence and ability to prescribe it. There is also an important role for national bodies like NHS England and the Regional Medicines Optimisation Committees in producing resources such as a template shared care agreement to make it easier for others to follow these examples.

### **Actions for CCGs and prescribers:**

- ▶ Review the evidence and put Sativex on your formulary – Sativex is safe, recommended by NICE and good value for money.
- ▶ Develop a shared care prescribing agreement for its use, so that care can be shared with GPs.
- ▶ Ensure a spasticity pathway and spasticity service are in place, involving a multidisciplinary team.

### **Actions for NHS England:**

- ▶ Write to CCGs highlighting the clinical and cost effectiveness evidence regarding Sativex.
- ▶ Improve data collection on prescribing of Sativex
- ▶ Instruct the Regional Medicines Optimisation Committees (RMOCs) to develop national shared care agreement guidelines for Sativex.
- ▶ Ensure local NHS services have an adequate number and mixture of professionals with expertise to treat patients with spasticity

### **Actions for UK Government:**

- ▶ Ensure that until routine access to Sativex is achieved on the NHS across the UK for eligible patients, people do not face prosecution for using cannabis to treat their MS symptoms.
- ▶ Develop a cross-government plan on medical cannabis that seeks to encourage further research, prioritise patient access, and improve education and support for professionals.

### **Actions for Sativex's manufacturer, GW:**

- ▶ Submit an application to the Scottish Medicines Consortium for the approval of Sativex for its licensed indication, to ensure equitable access to Sativex across the UK
- ▶ Ensure CCGs are aware of the “Pay for Responder” scheme in which the cost of the first three vials of Sativex to the NHS is refunded

Sativex is not a “wonder drug” – it doesn’t work for everyone with spasticity. But when it does work, the impact can be life changing. People with MS – like Neil and Sheila, who share their stories in this report – tell us their spasms and related pain have disappeared, meaning they and their families are able to live their lives, not just exist.

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**“After starting on the Sativex I had the first good night’s sleep in 10 years”**

– **Neil**, 61, living with secondary progressive MS

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Sativex isn’t just life-changing – according to NICE’s analysis, it’s also cost effective. The first three vials are free from the pharmaceutical company who manufacture it and it will be clear if people can benefit in this trial period. CCGs who choose to fund Sativex would only be paying for a treatment that definitely works.

**People with MS are right to ask – how can a treatment be approved but also denied?**

We want everyone with MS in the UK who meets the criteria to be able to access Sativex, no matter where they live. We hope this report provides commissioners and prescribers with the evidence and information they need to make Sativex available in their area.



**Neil, 61, lives with secondary progressive MS and uses Sativex**

“My neurologist wrote to me saying they were planning

a Sativex protocol [treatment plan] so come in for an appointment. I did and I was given the 28-day trial pack of Sativex. It worked, so I have carried on.

Before I started on Sativex all my symptoms were getting worse. I had spasms and muscle cramping every night. It was a case of when I would wake up not if. I hadn’t had a full night’s sleep in 10 years, and neither had my wife.

It was incredibly painful with my body trying to do things it really couldn’t do

as a result of the spasms. I would often cramp into a foetal position.

After starting on the Sativex I had the first good night’s sleep in 10 years. I didn’t suffer with MS fatigue, but I hadn’t realised how much I was running on fumes due to a lack of sleep until I had some sleep. I didn’t realise how tough it was until it stopped.

I usually take four doses a day. I can tell if I only have three. But I have a spray of Sativex and it gets rid of the spasms within 10 minutes.”

## 2. About Sativex and spasticity

### What is Sativex?

Sativex (brand name), or Nabiximols, is a cannabis-based medicine. It is a form of “medical cannabis”, a term which can be used to refer to both the cannabis plant itself and medicines that contain some of the component compounds found in cannabis. Sativex contains two chemicals- called cannabinoids- that have been extracted from the cannabis plant. They are in an equal mix of tetrahydrocannabinol (THC) and cannabidiol (CBD). As it is derived from cannabis, the Home Office classifies Sativex as a “Schedule 4” controlled drug. This means that Sativex can be prescribed by healthcare professionals and legally possessed by anyone who has a prescription<sup>8</sup>.

Sativex is a spray you use in your mouth. People with MS start off taking one dose (a single spray) each day, then slowly add more doses until they get the best relief possible from their symptoms. NICE recommend not to exceed more than 12 doses of Sativex a day.

The side effects of Sativex can include feeling sick or sleepy, dizziness, tiredness, a dry mouth, or fatigue. Side effects tend to fade after a few weeks and can often be reduced by taking fewer doses. Whilst some symptoms characteristic of a “cannabis high” are reported, this is not very common. For further information see our evidence pack<sup>9</sup>.

### What is spasticity?

Spasticity is a disabling symptom of MS that will affect up to 80% of people with MS at some point in their lives<sup>1</sup>. Spasticity symptoms can range from mild to severe. On the mild end, people can experience a feeling of stiffness in a limb which causes mild problems with walking, for example. But on the severe end,

people can suffer from tightened muscles in their whole body. This can impair their ability to move independently and to care for themselves without help. It can also lead to other complications, including muscle shortening, pain and disturbances with sleep<sup>2, 6, 10</sup>. Spasticity can greatly affect people’s quality of life and is also linked to high costs for the people affected, health and social care systems and society<sup>2</sup>. That’s why it’s important to treat and manage it early and as best as possible.

**Dr Eli Silber,**  
consultant  
neurologist,  
King’s College  
Hospital, London



“As disability progresses in MS, there is often a greater need for symptom management treatment including treatment of spasticity. There have been few new recent treatments for spasticity, and Sativex is a proven, tried and tested treatment, helpful in management of spasticity in a significant number of people living with MS. Yet often patients cannot access it.

The current limitations on funding for Sativex discourages doctors from prescribing it, leaving them unable to act in the best interest of their patients. This may be partly due the ongoing stigma about cannabis-based products. There is significant unmet need amongst people who have not responded to or cannot tolerate other drugs for spasticity. Sativex is not a panacea, and yet in some patients, it can make a huge difference to quality of life.”



## The costs of spasticity and the need for treatment

On top of the impact spasticity has on a person's quality of life, it's also very costly for our health and social care systems, and wider society<sup>2,9</sup>. It's difficult to estimate exact costs associated with spasticity, because how spasticity is managed varies between individuals. Also, few cost estimates take into account the affect that MS spasticity has on people's ability to work and on the lives of unpaid carers.

There are already a number of different drugs and therapies for spasticity, including physiotherapy, baclofen, tizanidine, and gabapentin, or benzodiazepines such as diazepam and clonazepam. However, about one third of people continue to have problems after receiving the first drugs they are offered and need a combination of medicines to treat their spasticity<sup>11,12</sup>.

A study in 2014 showed that 41% of doctors of patients with MS spasticity and 36% of patients with MS spasticity aren't satisfied with the effectiveness of the spasticity drugs<sup>12</sup>. In addition, some of the treatments that are commonly prescribed (such as benzodiazepines) cause side effects that many can't tolerate, including memory problems, depression and withdrawal syndrome if people suddenly stop taking them<sup>13</sup>.

People who don't respond well to those treatments or can't tolerate the side effects have limited options. At that stage, people often have to consider treatments that are very invasive, such as having a baclofen pump surgically implanted. This procedure requires a trial that includes a lumbar puncture and the implantation is carried out under general anaesthesia, which means it's not an option for everyone.

Sativex is much less invasive than some existing treatments and offers an additional treatment option to people dealing with life-changing spasticity.

### Sativex and MS related pain

Many people with MS want to access Sativex in the hope of treating their MS-related pain. While some people with MS tell us their spasticity-related pain has improved after using Sativex, we accept that the evidence for Sativex in treating MS-related pain alone has not been considered sufficient for Sativex to gain a licence, or NICE recommendation.

### Dr Rachel Farrell, consultant neurologist, National Hospital for Neurology and Neurosurgery, Queen's Square.

"It is important to be aware that Sativex is not licensed for neuropathic pain and NICE have not recommended it for the management of pain. Some people with spasticity will experience pain related to the muscle activity, cramps and spasms and this improves when spasticity is better treated. Sativex is not indicated for treatment of a neuropathic pain syndrome independent of spasticity and in our clinics we disappoint people when we advise them that we are unable to prescribe this in the absence of significant spasticity. The hands-on assessment of a person with spasticity is key to ensure that spasticity is the problem"

### 3. The wider issue of medical cannabis

Sativex fits into a wider issue, that of medical cannabis. Medical cannabis can be defined as cannabis, or cannabis extracts, prescribed by medical professionals for their patients. These are often referred to as cannabis-based medicinal products (CBMPs). Many forms are available, including oils, tinctures, capsules and dry plant. Sativex remains the only licensed form of medical cannabis for MS.

In 2016, the MS Society revisited its stance on the use of unlicensed cannabis-based medicinal products and medical cannabis to reflect the latest evidence<sup>14</sup>. This was after hearing from many people with MS who felt they gained benefits from the use of forms of medical cannabis for a variety of MS symptoms, including spasticity and pain, after reviewing the evidence, and consulting with our medical advisors. In an anonymised survey we conducted in 2014, 22% of people with MS told us that they had tried illegal forms of cannabis to treat their MS symptoms<sup>15</sup>. We maintain it is unacceptable that so many people feel the only option to treat their MS symptoms is to obtain cannabis illegally. We called on the government to address this issue.

In November 2018, the Government made it legal for specialist doctors to prescribe cannabis-based medicinal products in the UK<sup>16</sup>. They stated that cannabis for medicinal use should be moved out of Schedule 1 to Schedule 2 in the Misuse of Drugs Regulations<sup>17</sup>. Sativex, as a licensed medicine classified as Schedule 4, was not directly affected by this change in the law.

It's important to remember that it remains illegal to buy cannabis on the street, even if you wish to use it to treat medical symptoms. Rather, the change in the law allowed doctors to prescribe cannabis-based medicines

when they believe that their patients could benefit. Some products containing CBD are sold directly to people online or in shops as "food supplements"; such products are legal if they have sufficiently low levels of THC. However, there is no quality control for these products or guarantee they could have any medical benefit<sup>17</sup>.

Following the change in the law, the Department of Health asked NICE to develop guidance on the prescribing of medical cannabis, or CBMPs. NICE looked at both unlicensed forms of medical cannabis like CBD oil, as well as licenced forms like Sativex<sup>6</sup>. The resulting NICE guideline only recommended Sativex for use in MS and did not recommend any unlicensed forms of medical cannabis.

NICE said that although doctors should take their guidance into account, the choice to prescribe medical cannabis is ultimately the choice of individual specialist doctors. Since the change in the law, almost no prescriptions have been issued on the NHS for unlicensed forms of medical cannabis<sup>18</sup>. Some people are using private clinics to access medical cannabis prescriptions, often at a high cost<sup>19</sup>. Doctors can be unwilling to prescribe unlicensed forms of medical cannabis which are not recommended by NICE, as they feel the evidence base for these products is lacking. We continue to support access to other forms of medical cannabis for people with MS. Some people with MS still feel forced to break the law to source illegal forms of cannabis to treat their symptoms – not only spasticity but also pain. This is unjust, as well as dangerous; smoking cannabis with tobacco in particular can speed up the progression of someone's MS<sup>20</sup>.

We want to see further research into the safety, quality and efficacy of both unlicensed and licenced forms of medical cannabis. The Advisory Council on the Misuse of Drugs made this recommendation to the National Institute for Health Research (NIHR) in their November 2020 report<sup>21</sup>.

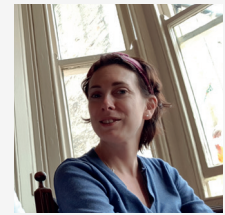
But most importantly, until routine access to medical cannabis is achieved on the NHS across the UK, people should not face prosecution for using cannabis to treat their MS symptoms.

### Why focus on access to Sativex?

This year, we have chosen to focus our campaigning efforts around medical cannabis on access to Sativex. In response to parliamentary questions on medical cannabis, the government has repeatedly stated that Sativex has “been made available for prescribing on the NHS, where clinically appropriate”<sup>22, 23</sup>. The evidence we present in this report challenges that statement – Sativex is routinely **un**available to NHS patients for whom it would be clinically appropriate. As a result of conversations with our campaigns community, we know that many people are spending as much as £500 a month to access Sativex privately in order to manage their symptoms.

We believe it is unacceptable that even when a cannabis-based medical product is licenced, underpinned by positive NICE guidance, and by published evidence of effectiveness, people with MS still face a postcode lottery in trying to access that treatment. We believe this is evidence of resistance to the use of forms of medical cannabis.

**Anne, 40, lives with relapsing-remitting MS. Anne has tried to access Sativex locally, but has been told it is not available in her area.**



“My legs are constantly stiff and I often can’t sleep because of the pain. I sometimes really struggle as I want to get up because it hurts, but I also don’t want to get up because it hurts so much. I can’t do anything to reduce the pain.

I know that Sativex is available and is changing people’s lives. It is so hard to hear that other people are getting it (I am really pleased for them) as it is something I know could help me but I can’t even try it.”

It feels like someone somewhere has something against me and won’t let me try this treatment that could change my life for the better.

It is such a rotten situation.”

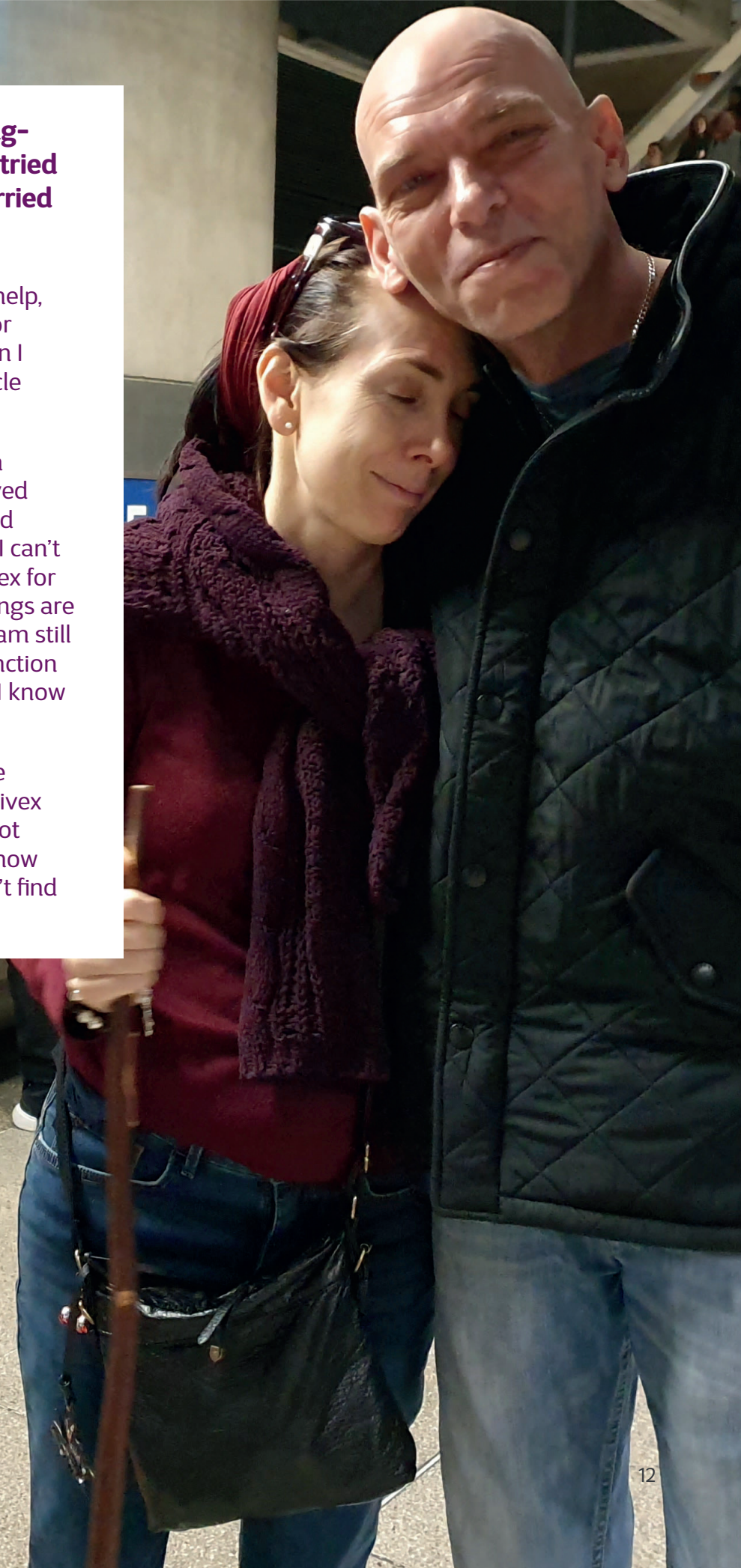


**Chris, 52, lives with relapsing-remitting MS, who has also tried to access Sativex and is married to Anne.**

“I’ve tried every medication to help, but they’ve either not worked, or given me bad side effects. When I used Baclofen to treat the muscle spasms it made me vomit.

It is so frustrating that there is a treatment available and approved by NICE that I know can help and completely change my life, but I can’t get it. I’ve been asking for Sativex for ten years. My MS team says things are moving, but they never have. I am still in pain, can’t sleep and can’t function but still can’t get Sativex which I know would help.

If only the people who make the decisions about prescribing Sativex could wake up each morning, not having slept much and feeling how my wife and I feel. They wouldn’t find it so easy to say no then.”





## 4. Access to Sativex in the UK

Access to Sativex differs in each of the four countries of the UK. Public healthcare in the UK is made up of four separate systems – NHS England, NHS Wales, NHS Scotland, and the Health and Social Care (HSC) system in Northern Ireland. For a drug to be funded and made routinely available in each healthcare system it needs to be reviewed by the organisations that make decisions on whether a drug benefits patients, and whether it is value for money.

In 2010, Sativex became the first cannabis-based drug to be granted a licence by the UK's regulatory body, the Medicines and Healthcare products Regulatory Agency (MHRA)<sup>4</sup>. A licence gives permission for a medicine to be used to treat certain conditions or symptoms. The granting of a licence means that the MHRA has reviewed the clinical trial evidence for the use of a treatment, and decided that that treatment is acceptably safe and effective for the proposed indication. Sativex was licenced as an “add-on” treatment for MS patients with moderate

to severe spasticity, when other treatments have not worked, and when these patients show a significant response to an initial trial of this treatment<sup>6</sup>. This means Sativex can be used in addition to the other medicines a person may be on to treat their MS spasticity.

Doctors can, if they wish, prescribe Sativex for other conditions not covered by the drug's licence. This is known as “off-label” prescribing. In some cases, Sativex may be prescribed for conditions such as chronic pain, or cancer related pain. It is not clear how often this is happening.

However, the granting of a licence is only the first stage in eligible patients gaining access to a treatment on the NHS. While doctors may be willing to prescribe a licenced medicine to eligible patients on the NHS without clinical guidelines underpinning their decision, it is more difficult for them to obtain funding for that medicine on the NHS. Doctors may prescribe licenced medicines privately to their patients. We don't know how often private prescribing is happening with Sativex.

## Access policy in England

In November 2019, following the change in the law around cannabis, NICE published a guideline on cannabis-based medicinal products. This recommended the use of Sativex for spasticity in MS for patients with moderate to severe spasticity who haven't responded well to other treatments. The guideline stated that such patients should continue to receive Sativex if their symptoms reduce by at least 20% following an initial 4-week trial, and if the company who make Sativex pay for the first three vials of the product<sup>6</sup>. NICE recommended decisions to fund Sativex prescriptions were the responsibility of individual health bodies (CCGs). Unlike a NICE "Technology Appraisal", a NICE guideline does not confer a legal obligation on CCGs to fund the treatment.

Importantly, the guideline stated that prescribing of Sativex should be started by an MS specialist doctor, but that subsequent prescriptions of Sativex may be issued by a non-specialist, such as a GP. The guideline recommended that GPs and specialist doctors develop "Shared Care" arrangements. By sharing responsibility for prescribing Sativex, shared care arrangements can free up specialists' time, reducing costs for the NHS and making it easier for them to treat and care for more patients with MS. Shared care can also be more convenient for patients, as being able to see a GP for medication reviews and prescriptions rather than a specialist can allow access to treatment closer to home. While care can be shared without a formal agreement in place, having the process agreed makes it easier to do.

## Access policy in Wales

In 2014, Wales became the first country in the UK to grant routine access to Sativex on the NHS when the All Wales Medicines Strategy Group approved it for its licenced indication for treatment of moderate to severe spasticity in MS patients who have not responded to other treatments<sup>24</sup>. The AWMSG made this decision independently of NICE, who had, in 2014<sup>25</sup>, initially rejected Sativex as too costly for the benefit it gave. Individual health boards in Wales can still make their own decisions about whether to fund Sativex. Please see Appendix 1 for data on prescribing.

## Access policy in Scotland

The company who make Sativex have not yet submitted an application to the Scottish Medicines Consortium for the approval of Sativex for routine use in Scotland, but they intend to do so in 2021. Individual doctors may, in some cases, still be willing to prescribe Sativex without SMC approval. Please see Appendix 1 for data on prescribing.

## Access policy in Northern Ireland

In Northern Ireland, in April 2021, the Health and Social Care Board process for the Managed Entry of Medicines accepted Sativex for use as a treatment option for patients with moderate to severe spasticity who have not responded well enough to other treatments<sup>26</sup>. Specialist doctors have to submit requests for funding for individual patients to their local Health Board. It is too early for data to be available on prescribing, but the MS Society will continue to monitor the situation.

## Sheila, 71, lives with secondary progressive MS and is using Sativex.

I was diagnosed with SPMS in March 2013. From then my MS progressed gradually. I had difficulty with lifting my right foot and had some falls. So I started using a stick to walk and moved on to a four wheel walker.

In April 2019 my symptoms deteriorated. This was particularly my mobility so I found it hard to stand and my pain increased. They tried Gabapentin which did not do anything. Pregabalin helped with the nerve pain, but nothing helped with my mobility. By August 2019 I was experiencing spasms and went for an assessment. They steadily got worse meaning that I couldn't sleep in a bed, then couldn't sleep in a reclining chair. I ended up sleeping on my commode but that led to pressure sores. I was prescribed increased Baclofen and Clonazepam but they didn't help. They tried everything. I was waking up as many as seven times a night. Neither I nor my husband had much sleep for months.

On 20 November the MS nurse reduced the Baclofen and gave notice of an intention for me to try Sativex. I got the prescription on 6 December and took my first spray. Within four days I had a full night's sleep – still on the commode.

I progressed to sleeping in the reclining chair and then in a hospital bed. And all the pain I had was gone.

At a review in January 2020 I was encouraged to continue using two sprays a day, which was enough and to keep taking my (other) meds. No changes were needed as things were working so well. After Sativex I can exercise my arms and legs with no problems. There hasn't been any deterioration of my MS symptoms. I no longer get any spasms. After Sativex I can move my limbs without fear that it will set off painful spasms. I can do more as there isn't the fear that it will set spasms off. And I had such a lot of pain with the spasms.

Sativex has made life possible for me and my husband again. Before we weren't functioning, we were barely existing. We weren't sleeping, but that has all changed. Sativex has been life changing.

We are hoping to move so we can be closer to our son, but the availability of Sativex will affect that decision. I have asked but can't be assured that I would still get Sativex, so we can't move.

## 5. Prescribing in England

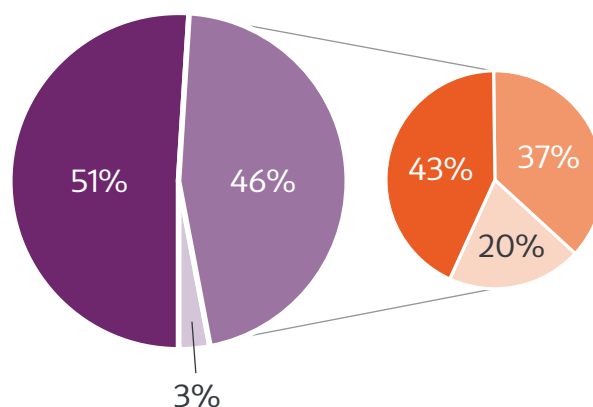
### Key points

- ▶ Sativex is only available in 46% of CCGs, representing a postcode lottery in access.
- ▶ In May 2021, of the approximately 4,800 people who NICE estimated could benefit in England, approximately 13% were accessing Sativex.
- ▶ The overall number of prescriptions for Sativex in England has risen little following the November 2019 NICE guideline.
- ▶ While secondary care (hospital) prescribing levels have risen somewhat since the NICE guideline was issued in November 2019, primary care (GP) prescribing levels have risen only a small amount since this time, highlighting the urgent need for shared care agreements to be developed in more CCGs.

### Which CCGs fund Sativex?

In May 2021 we accessed information published on CCG and formulary websites about which drugs CCGs had chosen to put on their formularies. A formulary is the list of drugs a CCG is willing to fund so that their patients can access them. We found that just 49 of 106 CCGs are funding Sativex (figure 1). Of the 49 CCGs who have chosen to fund Sativex, only 21 had listed it as suitable for shared care, while 18 labelled Sativex as unsuitable for shared care, stating that only specialist doctors should prescribe this medicine, despite NICE’s recommendation on shared care arrangements for Sativex<sup>6</sup>.

**Figure 1:** Sativex inclusion on CCG drug formulary lists. The left-hand pie chart indicates whether or not Sativex was included on a CCG’s formulary drug list, and the right-hand pie chart indicates the proportion of CCGs which have labelled Sativex as suitable or unsuitable for shared care. In both charts, “unknown” indicates that information was not available on CCG and formulary websites about the status of Sativex in an individual CCG



- Sativex not on formulary | 54 = 51%
- Sativex on formulary | 49 = 46%
- Unknown | 3 = 3%
- No shared care agreement | 21 = 43%
- Shared care agreement | 18 = 37%
- Unknown | 10 = 20%



## How many people are accessing Sativex?

We analysed available NHS data on prescriptions for Sativex, to see whether more people have been able to access it since NICE's positive recommendation.

We looked at data on GP prescriptions given out by high street ("community") pharmacies, as well as prescriptions made by hospital doctors which were given out in hospital or community pharmacies<sup>27,28</sup>.

Our analysis suggests that in essence, little has changed. Prescribing in England appears to be significantly below NICE's recommended levels and has risen only a little since the NICE guideline. While secondary care (hospital) prescribing has increased somewhat, primary care (GP) prescribing levels have risen only a small amount since November 2019.

Table 1 shows the total number of standard size 270 spray dose packs of Sativex<sup>29</sup> issued each month by the NHS in England, at three separate timepoints, before and after the NICE guideline. Please note the number of prescriptions is not the same as the number of patients. Also, it is not possible to determine which of these prescriptions are recurring and which are new.

**Table 1:** Total number of 270 spray packs of Dronabinol 2.7mg/dose/Cannabidiol 2.5mg/dose oromucosal spray (Sativex) issued each month on the NHS in England, at three separate timepoints.

Month	Number of 270 spray packs of Sativex issued per month by the NHS in England		
	Before NICE guideline NG144	After NICE guideline NG144	Most recent available figures
	Nov-19	Nov-20	May-21
Primary care community pharmacy	130	134	148
Secondary care hospital pharmacy	173	249	263
Secondary care community pharmacy	61	60	62
<b>Total</b>	364	443	473

The data shows that a relatively high proportion of Sativex prescribing happens in primary care in England, given that few CCGs have shared care arrangements in place. It is not possible to determine how many prescriptions of Sativex were for MS-related spasticity, however it is likely that at least some NHS prescriptions for Sativex are “off-label” for conditions other than MS.

Available NHS data does not report the number of people using Sativex each month, it only reports the number of doses (or sprays) of Sativex used. People use different numbers of daily doses and the best, or average number of doses used per day has not been clearly determined. It is therefore not possible to determine the exact number of patients using Sativex at any one time. However, an

estimation of the number of people using Sativex each month can be made using number of daily doses that NICE assumed people would use- 6.7 sprays per day<sup>30</sup>. This is shown in Table 2. NICE estimated that around 4,800 people in England are eligible for a four-week Sativex trial and continuing treatment if Sativex is effective for them. Yet, we estimate only 630 people in England were in receipt of a prescription in May 2021.

**Table 2:** Estimated number of individuals in receipt of a prescription of Dronabinol 2.7mg/dose/Cannabidiol 2.5mg/dose oromucosal spray (Sativex) issued on the NHS in England, at three separate monthly timepoints.

Month	Estimated number of NHS patients in England in receipt of a Sativex prescription per month		
	Before NICE guideline NG144	After NICE guideline NG144	Most recent available figures
	Nov-19	Nov-20	May-21
Primary care community pharmacy	144	149	197
Secondary care hospital pharmacy	231	332	351
Secondary care community pharmacy	81	80	82
<b>Total</b>	456	561	630

It should be noted that a proportion – NICE estimate 25% – of those accessing a Sativex prescription in any given month will not remain on the medication long term, as some people will not gain benefit from the medicine during their initial 4-week trial, or may find the side effects of the medicine outweigh the benefits for them. This means that of the 4,800 people who are eligible to try Sativex, NICE think that 3,600 will be able to benefit from it long-term.

Because it is not possible to know in advance who will benefit, the priority for the NHS must be ensuring access for all 4,800 people, as set out elsewhere in this report.

It is difficult to draw firm conclusions about prescribing levels in the other home nations of the UK, as prescribing data is not complete or more difficult to interpret, and secondary care hospital pharmacy data is not made publicly available. Please see Appendix 1.



### **Paul, 50, lives with secondary progressive MS and would like to try Sativex**

“I have been experiencing spasms for quite a while and

asked my GP about (Sativex) 12 years ago. My neurologist mentioned that a cannabis-based treatment was being developed that could help. I have asked about it every year since but have never been prescribed.

Since the spasms I haven't had a full night's sleep. I spend the first hour apologising to my wife for my jerking. Then if I do get to sleep I wake up needing to go to the toilet as a result of the spasms in my bladder. I never get up feeling I have had a good night's sleep. As a result of the spasms I am in pain constantly. I have got used to it, but I shouldn't have to get used to it. I do manage to push through to do things, but the pain is always there.

I have tried everything and nothing has worked. I have tried Baclofen, Tizanadine, Gabopentin, Pregabalin, Amotriptiline,

Motriptiline, Tramadol, patches, acupuncture, reflexology, massage therapy.

I know Sativex has been approved and could help, I just want the opportunity to try it. I know it might not work, but it might.

I am so used to the constant spasms and pain I can't imagine what it would be like without them. But I want to get that feeling if it is possible. My quality of life would be significantly improved, I might get a full night's sleep and not be constantly thinking about pain. I could do anything...

I have been in touch with someone on Facebook whose husband has PPMS [primary progressive MS]. He is in Blackpool and has been prescribed Sativex for spasms. Why can't I have the same? What is the difference between living in Blackpool and Bradford? There is no clear explanation, it is a postcode lottery.”

## 6. The barriers to accessing Sativex

We have seen that prescribing levels of Sativex in England have risen relatively little since NICE recommended Sativex for use on the NHS in England in November 2019. This represents huge disappointment to eligible people with MS, many of whom have waited years to access this treatment.

There is no doubt that the NHS has faced an unprecedented challenge since the beginning of the COVID-19 pandemic, with staff and services placed under huge demands. It is likely that this has been a factor in the lack of availability of Sativex to eligible patients, including making clinical assessments of spasticity more difficult. However, the evidence we have gathered suggests that the pandemic is not the only factor contributing to the slow response to NICE's recommendations.

In drawing up this report, we have had discussions with doctors, pharmacists, commissioners, and people living with MS. Based on the information we have gathered, we believe these are the major barriers to more people who could benefit from Sativex being able to access the treatment.

### 1. Perceived lack of clinical effectiveness

On their websites, some CCGs cite a lack of clinical effectiveness as the reason they will not fund Sativex.

The last two decades of research have shown that Sativex is an effective treatment for spasticity in MS which has potential to greatly improve the lives of some of the people who take it. Using Sativex, around 70% of people achieve at least 20% reduction in spasticity<sup>6, 9, 31, 32</sup> and around 36% to 40% achieve a reduction of 30% or higher<sup>33, 34</sup>.

Sativex also improves spasticity-related symptoms, like sleep quality or pain and improves people's ability to carry out daily living tasks<sup>32, 35, 36, 37</sup>. These effects stay over time and people don't develop a tolerance to Sativex<sup>38</sup>.

We would urge CCG formulary committees to fully review the clinical evidence covered by NICE in its assessment of the evidence base for Sativex in MS spasticity, and to also refer to the review of clinical effectiveness in our Sativex evidence pack<sup>9</sup>.

### 2. Perceived lack of cost effectiveness

Other CCGs cited cost effectiveness as the reason for their decision not to fund Sativex. Cost-effectiveness describes whether a treatment or intervention provides good value for money. If a treatment offers increased effectiveness against an illness or symptom at a reasonable cost, it is considered cost-effective. Again, we would urge CCG formulary committees to review the cost effectiveness model published as part of the NICE recommendation<sup>6</sup>, which concludes Sativex is a cost-effective treatment and also refer to our Sativex evidence pack<sup>9</sup>.

The company who make Sativex, GW, offer an NHS "Pay for Responder" scheme which means that the cost of the first three vials of Sativex to the NHS is refunded by GW. CCGs should factor into cost effectiveness calculations that they would only paying for a treatment that definitely works for those accessing it.

### 3. Stigma around cannabis-based products and concern about psychoactive effects

Prescribers and people with MS who wish to try Sativex may sometimes be concerned that Sativex, as a cannabis-based product containing THC, may produce a “high” in users similar to that seen with illegal street cannabis. While some symptoms characteristic of a “cannabis high” have been reported in clinical trials, our review of the evidence indicates this is not very common. In one clinical trial less than 4% of subjects on Sativex reported feeling euphoric<sup>33</sup>. Feelings of mild intoxication or euphoria while receiving Sativex treatment are likely to be uncommon and mild. Research has also found that in the small percentage of people who do experience intoxication, these effects decrease significantly with continuing use of Sativex<sup>39</sup>. For further information, please see our evidence pack<sup>9</sup>.

### 4. Limits on specialist doctors’ time and the administrative burden of putting shared care in place

Clinicians have told us that getting a shared care agreement in place takes significant time and effort, because professionals in different parts of the health system have to come together and agree a detailed procedure. Without shared care and a CCG agreeing to fund Sativex, specialist doctors can struggle practically to provide repeat prescriptions.

There is no nationally agreed shared care template. This would help make it easier for CCGs to start shared care, reducing the administrative burden on CCGs in the prescribing of Sativex and avoiding duplication of effort in the production of shared care arrangements.

The Regional Medicines Optimisation Committees (RMOCs) are NHS pharmacy groups that work to ensure that people get the right choice of medicines and that medicines deliver value<sup>42</sup>. We want to work with the RMOCs to develop national shared care guidelines for the prescription of Sativex.

Dr Rachel Farrell, a Consultant Neurologist at the National Hospital for Neurology and Neurosurgery, Queen Square, London, talks below about how the spasticity team at the National Hospital for Neurology and Neurosurgery were able to get shared care in place in her area. Those interested in establishing shared care and the evidence base for Sativex can also watch [this webinar](#) produced by the Neurology Academy in which Dr Farrell and Joela Mathews, Lead Neuroscience Pharmacist at Barts, London, explain in more detail how to establish shared care and its benefits<sup>40</sup>.

## **Dr Rachel Farrell, consultant neurologist, National Hospital for Neurology and Neurosurgery, Queen Square, London.**

“Spasticity is a troublesome symptom for many people with MS and requires multidisciplinary management to develop an individualised approach.

Although first line treatments for spasticity are effective and tolerated by many, some do not have sufficient relief of symptoms and require alternative strategies -which might include Sativex.

At NHNN (National Hospital for Neurology and Neurosurgery) Queen Square London we have been fortunate to be able to offer Sativex treatment to people who otherwise might require a more invasive treatment such as implantation of an intrathecal baclofen pump.

Sativex, like other medications, does not work for everybody, and must be used with a wider treatment model, which can offer advice about all aspects of managing spasticity and offer access to specialist services if required. In those patients we treat who have responded to Sativex many report a positive effect on stiffness, spasms or improved sleep. Those who stopped treatment with Sativex did so due to lack of efficacy, side effects or worsening spasticity.

NICE’s shared care recommendations have clearly set out the need for specialists with experience in managing MS spasticity – that is, for neurologists and rehabilitation medicine physicians to initiate treatment, monitor patients’ responses to treatment and adjust their dose, before handing the prescribing role to GPs in primary care. It is therefore essential that all CCGs work with MS specialists, pharmacists, GPs and other stakeholders to develop a local protocol to ensure access to this

medication for those who are eligible. For patient with MS spasticity this will reduce the need to attend a specialist centre purely for prescription of Sativex and will keep treatment closer to home in line with planned integrated care systems. It will also reduce the burden on specialist services by moving routine prescribing from the specialist centre once a person is stable on the treatment- enabling us to use our time to deliver care to more people with MS.

The NCL shared care guideline was published in November 2020 and it can serve as a template to be adapted in other areas. Our experience with Sativex and working closely with local stakeholders (particularly GPs) greatly assisted the process in Sativex being listed as “amber” (suitable for shared care) on the NCL formulary and the agreement to adopt a shared care protocol. However, it also meant that people from other CCGs who have not yet approved Sativex could not access the treatment, highlighting the inequality in the system, depending on postcode.

With regards to service development, MS centres will need to ensure that they have capacity to assess people with MS spasticity in person. Involvement of a neuro-physiotherapist can be useful in assessing spasticity and its impact on the individual.

The North Central London Joint Formulary Committee have published their [shared care guidance](#) online in the hope that this will enable CCGs in other parts of the country to make Sativex available<sup>41</sup>.”



## **5. Lack of an appropriate pathway and services for the treatment of spasticity**

Appropriate treatment of spasticity involves a multi-disciplinary team. Ideally, this team would include a neurologist or rehabilitation medicine specialist, an MS or spasticity specialist nurse, a physiotherapist and, if possible, an occupational therapist<sup>40</sup>. This multi-disciplinary team can work with a person with MS to help them self-manage, and to try drug treatments for spasticity, before considering whether Sativex should be tried.

Given that Sativex is only recommended for use in people with MS with moderate to severe spasticity for whom other treatments have not worked, CCGs may not be in a position to offer Sativex to patients unless

they have been through the appropriate spasticity treatment pathway. In parts of the country where there is limited or no access to the range of health care professionals needed, and no pathway in place, this will be a barrier to accessing spasticity treatment.

We understand that the pandemic has put unique pressures on NHS services, and that for some centres, setting up a new pathway or services may be challenging at this time. CCGs and local MS centres should also consider that shared care arrangements are not only intended for use with primary care services; they can be made between a CCG and one of NHS England's regional neuroscience centres. This would enable a person with MS to access Sativex from a hospital, but funded by their local CCG<sup>40</sup>.

## 7. How to overcome the barriers - recommendations for action

### For CCGs, prescribers and NHS Trusts

- ▶ Review the clinical and cost-effectiveness evidence and put Sativex on your formulary. Sativex is safe, recommended by NICE and good value for money. The first vials are free from the pharmaceutical company and it will be clear if people can benefit in this trial period. You would only be paying for treatment that definitely works.
- ▶ Develop a shared care prescribing agreement for the use of Sativex. [See the example published by North Central London Joint Formulary<sup>41</sup>](#). We can work with you to support this if required.
- ▶ Ensure a spasticity pathway and spasticity service are in place, involving a multidisciplinary team in the care and management of MS patients

### NHS England

- ▶ Write to CCGs highlighting the clinical and cost effectiveness evidence regarding Sativex.
- ▶ Improve data collection on prescribing of Sativex, so that it is possible to monitor access levels across the country and take action where they are far short of NICE's estimates.
- ▶ Instruct the Regional Medicines Optimisation Committees (RMOCs) to develop national shared care agreement guidelines for Sativex, working with clinical experts and the MS Society.

- ▶ Ensure local NHS services have an adequate number and mixture of professionals with expertise to treat patients with spasticity.

### UK Government

- ▶ Ensure that until routine access to Sativex is achieved on the NHS across the UK for eligible patients, people do not face prosecution for using cannabis to treat their MS symptoms.
- ▶ Develop a cross-government plan on medical cannabis that seeks to encourage further research, prioritise patient access, and improve education and support for professionals.

### Sativex's manufacturer, GW

- ▶ Submit an application to the Scottish Medicines Consortium for the approval of Sativex for its licenced indication, to ensure equitable access to Sativex across the UK.
- ▶ Ensure CCGs are aware of the "Pay for Responder" scheme in which the cost of the first three vials of Sativex to the NHS is refunded, and that they would only be paying for treatment that actually works.



## 8. Conclusion

We understand that Sativex doesn't work for everyone. But when it does, the results can be truly life changing. As Neil and Sheila have powerfully described, being able to sleep through the night for the first time in years, feeling "normal" again, and their spasms disappearing.

Others, like Anne, Chris and Paul, tell us of waiting over a decade in the hope of accessing a treatment that could potentially transform their quality of life, of their bafflement and frustration at the current unequal access to a medicine they know has a chance of helping them.

Sativex is effective, safe, and value for money. People with MS should not face a postcode lottery in trying to access the treatment they need, knowing it is approved but finding that they are denied it. It's been a long journey, but we won't give up until everyone who meets the criteria gets a chance to try Sativex if they wish to.



## 9. Appendix 1

### Prescribing data: Wales

We looked at Sativex prescribing data for GP and hospital prescriptions given out by community pharmacies on the NHS in Wales. This data is published by the NHS Wales Shared Services Partnership<sup>43</sup> (Tables 3-4). Secondary care hospital pharmacy data is not made publicly available by the NHS in Wales – for this reason, it is not possible to get a complete picture of prescribing figures for Sativex in Wales. In addition, community prescribing quantity data for November 2019 was not available. The last available monthly prescribing figures at the time of writing are shown in the right-hand column.

**Table 3:** Number of 270 spray packs of Dronabinol 2.7mg/dose/Cannabidiol 2.5mg/dose oromucosal spray (Sativex) issued each month by NHS Wales at community pharmacies only, at two separate timepoints.

	Number of 270 spray packs of Sativex issued per month by the NHS in Wales (community pharmacy prescribing only)	
Month	Nov-20	May-21
Primary care community pharmacy	54	45
Secondary care community pharmacy	34	46
<b>Total</b>	<b>88</b>	<b>91</b>

**Table 4:** Estimated number of individuals in receipt of a prescription of Dronabinol 2.7mg/dose/Cannabidiol 2.5mg/dose oromucosal spray (Sativex) issued each month by NHS Wales at community pharmacies only, at two separate timepoints.

	Estimated number of NHS Wales patients in receipt of a Sativex prescription (from community pharmacies only)	
Month	Nov-20	May-21
Primary care community pharmacy	72	60
Secondary care community pharmacy	46	61
<b>Total</b>	<b>118</b>	<b>121</b>

Despite the fact that NHS Wales prescribing data is incomplete, it can be seen that, relative to the number of people with MS in each nation<sup>44</sup>, prescribing levels of Sativex must be higher on the NHS in Wales than on the NHS in England. However, it is not possible to determine whether prescribing levels of Sativex in Wales are at the level recommended by the All Wales Strategy Group, because of the lack of published hospital prescribing data in Wales.

## Prescribing data: Scotland

In Scotland, the only publicly available prescribing data is a set published by Public Health Scotland which includes prescriptions issued by GPs and dispensed in community pharmacies, as well as prescriptions issued in hospitals and dispensed in community pharmacies<sup>45</sup>. As with Wales, hospital pharmacy prescribing data is not publicly available, so it is not possible to get a complete picture of Sativex prescribing figures in Scotland. The last available monthly prescribing figures at the time of writing are shown in the right-hand column of tables 5-6.

**Table 5:** Number of 270 spray packs of Dronabinol 2.7mg/dose/Cannabidiol 2.5mg/dose oromucosal spray (Sativex) issued each month on the NHS in Scotland, dispensed at community pharmacies, at three separate timepoints.

	Number of 270 spray packs of Sativex issued per month by the NHS in Scotland (community pharmacy prescribing only)		
Month	Nov-19	Nov-20	May-21
Primary care community pharmacy	79	100	92

**Table 6:** Estimated number of individuals in receipt of a prescription of Dronabinol 2.7mg/dose/ Cannabidiol 2.5mg/dose oromucosal spray (Sativex) issued on the NHS in Scotland and dispensed at community pharmacies only, at three separate timepoints.

	Estimated number of NHS Scotland patients in receipt of a Sativex prescription (from community pharmacies only)		
Month	Nov-19	Nov-20	May-21
Primary care community pharmacy	105	133	123

As only community pharmacy prescription data is made publicly available, it is difficult to draw any firm conclusions from available prescribing data in Scotland. Prescribing data published by Public Health Scotland is in a different form to that published by the NHS in other nations, therefore, we made inferences on figures published on cost to estimate monthly numbers of packs, and patients. However, the indication is that prescribing of Sativex may be higher than expected in Scotland, considering that Sativex has not yet been assessed by the SMC for its licenced indication.

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# We're the MS Society.

Our community is here for you through the highs, lows and everything in between. We understand what life's like with MS.

**Together, we are strong enough to stop MS.**

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## #ApprovedButDenied

▶ Let's Stop MS together



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