# The economics of prescribing cannabis for chronic pain

Assessing the viability of NHS prescribing









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# Partners









#### Ethypharm

The Cannabis Industry Council (CIC) is the leading membership organisation representing the entire UK cannabis industry. The CIC has over 100 members covering the supply chain and those working to improve the industry, including charities, clinical groups, and patient representatives. The CIC believes improving access to cannabis can enhance health, the environment and the economy. <u>cicouncil.org.uk</u>

Drug Science is a charity that works to provide an evidence base free from commercial or political influence, creating the foundation for sensible and effective drug laws, and equipping the public, media and policy makers with the knowledge and resources to enact positive change. <u>drugscience.org.uk</u>

Glass Pharms is a licensed cultivator of medical cannabis based in the UK. Based at a purpose-built 2.4-hectare facility that is powered and heated by food waste from anaerobic digestion, Glass Pharms provide a range of highly-standardised cannabis chemotypes for use in medicines. Using a patent-pending continuous manufacturing process, Glass Pharms provides freshly produced flower all year round. <u>glasspharms.com</u>

Rua Bioscience is a leading Aotearoa New Zealand-based biotechnology company specialising in the research, development, and commercialisation of natural products and medicinal cannabis products for health and wellness. As one of few Maori-born biotech businesses in Aotearoa, Rua Bioscience is the only New Zealand-based medicinal cannabis company with an explicit focus on delivering social impact. <u>ruabio.com</u>

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# **Executive Summary**

An early cost-effectiveness model was developed to estimate the impact of prescribing CBPMs alone and/or in addition to analgesics, physiotherapy and cognitive behavioural therapy for chronic pain in the UK for one year.

This working model predominantly uses data from Project Twenty21 (T21), a real-world evidence (RWE) study constituting the UK's largest medical registry on cannabis-based products for medicinal use in humans (CBPMs). 5% increased efficacy was conservatively assumed based on current RWE.

This model allows us to undertake an analysis of the predicted economic implications of prescribed CBPMs by the NHS. This considers patient numbers, prescribing costs, prescription fulfilment and associated costs, as well as potential savings on alternative treatments, and impact on costs associated with ill health, such as reduced capacity to work.

Where possible, robust data sources were used, including national databases, formal submissions to NICE (for unit costs), and relevant academic research. All other inputs were based upon informed assumptions.

## Key findings

The key findings from the economic model were as follows:

- CBPMs were found to be significantly more cost-effective, and as costs relating to the prescribing of these continue to fall, relative savings are predicted to increase.
- CBPMs are a cost-effective treatment, or adjunct treatment, for chronic pain, saving an estimated £332 per person per year.
- The overall saving to the NHS is £729 per person per year. If those with moderately/ severely disabling chronic pain (5.45 million) were beneficiaries, this would equate to a potential saving of £3.97 billion to the NHS each year.
- CBPMs also result in 27.51 fewer hours taken off work, in order to attend appointments or residential rehabilitations, saving £406.37 per year, when compared to analgesics, physiotherapy and CBT.
- Overall, this economic gain rises to £1,037 per person when external benefits (e.g. fewer hours taken off work) are considered. If those with moderately/ severely disabling chronic pain (5.45 million) were beneficiaries, this would equate to a potential boost of £5.65 billion to the economy each year.

It is also worth noting that additional benefits are also predicted, based on the findings on RWE to date, in addition to a reduction in pain levels. These include better quality and duration of sleep, increased appetite, improved mobility and higher quality of life scores. The use of CBPMs would also increase overall population health, both by increasing the health of those using it, and freeing up resources for people with other conditions.

These findings highlight the substantial cost saving that CBPMs may represent for the treatment of chronic pain patients, and the benefits for healthcare providers as a cost effective treatment for this often hard-to-treat population.

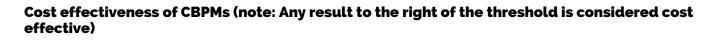
Given our results strongly indicate that CBPMs can be cost effective for the treatment of chronic pain, this indicates that the 2019 NICE assessment, based solely on randomised control trial (RCT) evidence, could be usefully expanded to help both patients and healthcare systems in need.

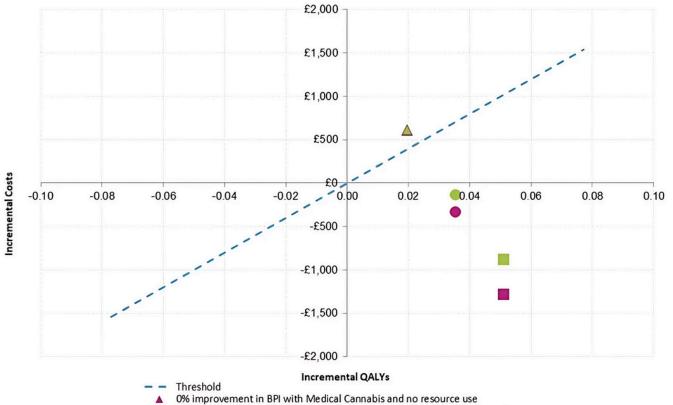
It is worth noting the main assumptions included in the economic model are as follows:

- The prevalence of chronic pain is 43.5%, which equates to 22,787,025 people.
- Between 10.4% 14.3% have moderately/severely disabling chronic pain, which equates to 5,447,932 people (at 10.4% lower level).
- The efficacy of the intervention was sourced from the T21 study data.
- It is assumed that the 'no pain' health state used no resources and the 'severe pain' health states used the most resources.

## Key findings

While this model was based on UK costs, populations, and typical NHS treatment patterns, it has been designed so it can be modified to be used in other healthcare systems and funding models around the world.





- O% improvement in BPI with Medical Cannabis and same resource use as base case
  - 5% improvement in BPI with Medical Cannabis and no resource use
- 5% improvement in BPI with Medical Cannabis and same resource use as base case
- 10% improvement in BPI with Medical Cannabis and no resource use
- 10% improvement in BPI with Medical Cannabis and same resource use as base case



# Introduction

Interest in the therapeutic benefits of medical cannabis has grown rapidly in the past 20 years, with an increasing number of territories globally legalising cannabis as a medicine [1].

In the UK, medical cannabis was legalised on November 1st 2018, leading many patients to believe that it would become widely available on the National Health Service (NHS).

However, over five years later, this has proved not to be the case. Currently, the NICE guidelines only recommends the prescription of three licenced cannabis-based medicines for the treatment of four conditions: Sativex for spasticity of adults with multiple sclerosis (MS), Nabilone for chemotherapy-induced nausea and vomiting, and Epidyolex for severe treatment-resistant epilepsy, i.e. Lennox-Gastaut syndrome and Dravet syndrome [2]. In 2021, there were just 977 patients in England receiving CBPM prescriptions on the NHS, according to research from the Cannabis Industry Council [<u>34</u>].

In contrast, there were at estimated 35,000 UK patients receiving private prescriptions of CBPMs in late 2023 [35]. This is thought to have increased to 45,000 patients, as of October 2024.

These NICE guidelines have been criticised by patients, campaigners and some doctors as too limiting.

Many question the narrow choice of recommended products and the lack of recommendation of medical cannabis specifically for the treatment of chronic pain, largely based on the perceived lack of costeffectiveness. This is because the previous QALY assessment carried out by NICE was performed using a very high licenced medicine cost, rather than a generic CBPM at a fraction of the cost, to perform the assessment.

In contrast, real world evidence (RWE) studies repeatedly and consistently show that chronic pain is the condition for which patients most often use CBPMs [3-5]. Its relative popularity in the treatment of pain may be attributed to a number of factors, including effectiveness, how common these conditions are, and a lack of existing adequate treatment options.

Emerging observational and real-world data demonstrate that individuals using medical cannabis report substantial reductions in pain and improvements in wellbeing [6]. Similarly, there is emerging evidence that the use of CBPMs is associated with a substantial reduction in the use of opioids [6] and benzodiazepines [7]. These data also suggest that any side effects attributed to medical cannabis are relatively mild [6].

Today, there is a growing body of RWE for the usage of CBPMs in the treatment of chronic pain, including its ability to decrease pain scores [8], substitute (or decrease) the use of opioid-based pain medications [9], and with a lower side effect burden [10] and with an increase in general quality of life measures [11]. A recent study found CBPMs preferable to other commonly used medications for chronic neuropathic pain, largely because the former contribute more to quality of life and have a more favourable side effect profile [12].

Despite this growing evidence of safety and effectiveness in real world settings - and the substantial numbers of people now obtaining legal access to these medications - most CBPMs remain unlicensed and are typically not funded by traditional healthcare funders in the UK, such as the NHS. NHS funding is generally conditional both on licensing and on Health Technology Assessments (HTA). An important consideration in HTA, in addition to safety and efficacy, is the extent to which treatments are cost effective.

NICE reviewed the use of CBPMs for chronic pain in 2019, and despite identifying potential benefits, concluded that the evidence base at the time was not sufficiently consistent or reliable for a positive decision to be made [2]. The cost effectiveness analyses upon which NICE's lack of recommendations for using CBPMs to treat chronic pain are focused solely on available RCT evidence, which has been repeatedly criticised [13,14,15]. CIC and Drug Science discussed in a previous paper why RWE may be required to fully understand the impacts CBPMs have on patients in real world settings. [5]

This discrepancy between the NICE recommendations based solely on RCT evidence, versus RWE of patients successfully using CBPMs to treat chronic pain provided the rationale for this early economic evaluation. By moving away from a sole focus on RCTs, and incorporating a broader, real world perspective, we can fully understand the potential cost effectiveness of CBPMs to treat chronic pain.



## Development of the Model Background

Health economic analyses are useful tools for developing an accurate picture of the economic impact of a new technology or product. For instance, this has been done in asthma management [17, 18], and in cardiac imaging [19].

Despite increasing numbers of people having access to and using unlicensed CBPMs to treat chronic pain, there have been just three clinical trials of their cost effectiveness. Tyree et al [21] concluded that cannabis is cost effective when used as an adjunct to neurological pain.

However, an evidence review conducted by NICE ([22] drew the opposite conclusion, stating that THC/CBD spray was not costeffective across all treatment and condition specific subgroups (although the same review did conclude it was cost effective for multiplesclerosis related spasticity). A third cost utility analysis [23] concluded that CBPMs were cost effective for the management of chronic knee pain.

In parallel with our project, Celadon Pharmaceuticals also commissioned a healtheconomics analysis of a feasibility study they held for a clinical trial, which was conducted over three months.

The base case in Celadon's model found CBPMs to be cost effective, alongside a reported 49.6% reduction in pain scores after just one-month.

#### Our model

We commissioned the York Health Economic Consortium (YHEC) to develop a costeffectiveness model, comparing medical cannabis with more prevalent treatments (e.g. analgesics, physiotherapy and cognitive behavioural therapy) for people with chronic pain, over a one-year period.

This working model predominantly uses data from Project Twenty21 (T21), a RWE study constituting the UK's largest medical registry

## Rationale

The model compares an intervention with medical cannabis, to the use of analgesics, physiotherapy and/or cognitive behavioural therapy (CBT). As well as providing an NHS perspective, the model is also able to include out-of-pocket costs and the costs of additional services.

The economic evaluation was aligned with the current NICE reference manual for health technology evaluations [24].

on cannabis based prescription medications (CBPMs). This model allows us to undertake an analysis of the predicted economic implications of prescribed CBPMs by the NHS.

This considers patient numbers, prescribing costs, prescription fulfilment and associated costs, as well as potential savings on alternative treatments, and impact on costs associated with ill health, such as reduced capacity to work.

In all scenarios, it is assumed that the cost of CBPMs for managing chronic pain would be borne by the NHS.

The model population is all adults with chronic pain (43.5% of adults, circa 22.7 million), although it is recognised that take up is likely to be incremental and subject to the personal choices of the patients concerned, and other considerations.

#### Table 1: Summary

Population	All adults with chronic pain
Perspective	<ul> <li>NHS only</li> <li>NHS + out-of-pocket</li> <li>NHS + additional services</li> <li>NHS + out-of-pocket + additional services</li> </ul>
Intervention	CBPMs with: • Analgesics and/or • Physiotherapy and/or • Cognitive behavioural therapy
Comparator(s)	<ul><li>Analgesics</li><li>Physiotherapy</li><li>Cognitive behavioural therapy</li></ul>
Outcomes	<ul> <li>Total cost per person</li> <li>Total QALYs per person</li> <li>Incremental cost-effectiveness ratios</li> <li>Net monetary benefit</li> <li>Net health benefit</li> </ul>
Time horizon	• One year

## **Modelling Approach**

The efficacy of the intervention was estimated using the Brief Pain Index (BPI) and used to determine the resource use and the utility of each chronic pain health state. While the model is designed to compare efficacy, the data used at present assesses effectiveness, due to the nature of RWE data collection methodologies.

Where possible, robust data sources were used, including national databases, formal submissions to NICE (for unit costs), and relevant academic research. All other inputs were based upon informed assumptions.

We generated incremental costs and qualityadjusted life years (QALYs). QALYs were chosen as these are a key metric used in HTAs internationally, including by NICE in the UK for quantifying the overall value of an intervention (both length of life and quality of life). The use of QALYs allows the benefits of treatments across a wide range of therapeutic areas to be compared using a common approach.

#### **Efficacy Parameters**

BPI interference scores and standard error for CBPM were sourced from T21 data [25].

In line with findings, a 5% improvement in efficacy was assumed for CBPMs.

Health state	Interference score	Baseline	3 months	6 months	9 months
No Pain	<1	0.2%	3.0%	4.1%	3.5%
Mild Pain (1-4)	1-4	18.1%	37.2%	41.3%	39.8%
Moderate Pain	5-6	34.8%	31.7%	30.7%	31.3%
Severe Pain	7-10	46.8%	28.1%	24.0%	25.3%

#### Table 2: Proportion of people in each health state: CBPMs

## **Cost and Resource Use Sources**

## Cannabis-based products for medicinal use in humans

The cost of CBPMs consisted of both consultations and grams of prescribed cannabis itself.

It was assumed that people in the 'no pain' health state did not require consultations or CBPMs. For those in pain, it was assumed they had one initial consultation, three general consultations and 12 repeat prescriptions per year. People in the 'mild pain', 'moderate pain' and 'severe pain' required 15 grams, 30 grams and 45 grams per month of CBPMs, respectively. The unit cost for these was sourced from MedBud [27].

#### Intervention and Comparator

In addition to CBPMs, the intervention can additionally include analgesics, physiotherapy sessions and CBT sessions, with the comparator including the same items. Unit costs represent the price paid by the NHS and are a known quantity.

#### **Other NHS Healthcare**

This included visits, prescriptions, alternative therapies and services. It was assumed that patients in the 'no pain' health state do not require any of these resources.

Visits per year included appointments with a GP, practice nurse, physiotherapy, hospital outpatient, accident and emergency (A&E), hospital day case and other hospital admissions, and assumptions were made regarding the type and frequency for each pain condition, based on evidence emerging from T21. Alternative therapies reimbursed by the NHS were also included in the model, as was the potential to consider residential rehab.

#### Out-of-Pocket Healthcare

This perspective captures all the resource use that is paid for by the person directly. Out-ofpocket expenses (e.g. over-the-counter medicines, exercise, mental health support and residential care) are not routinely considered by decision-makers in the UK, but can represent a significant consideration for patients, and are therefore included here.

Resources paid for by other organisations were not considered in the current scenarios.

## **Quality of Life Sources**

QALYs are calculated by multiplying the utility a person experiences with the time that they experience it. Utilities range from one, which equates to perfect health, to zero, which is equivalent to no quality of life or death.

#### Quality-Adjusted Life Years

The population norms used for age and gender-adjustment utilities were sourced from the NICE DSU [29] which provides values specific to the UK population.

The 'no pain' health state utility assumes no decrement relative to that of an age and gender-matched person. The 'mild pain', 'moderate pain' or 'severe pain' health state utilities were sourced from the Twenty21 study [25] and applied to the comparator arm of the model. The utility values for the CBPMs were estimated using the utility values for the comparator with a utility increment applied. The increment was assumed to be 0.02 and was only applied to the 'mild pain', 'moderate pain' or 'severe pain' health state. An increment is applied to the CBPMs arm to reflect functionality improvements demonstrated with CBPMs use that are not reflected well in the EQ-5D measure.

### **Lost Productivity**

The model also includes the total number of hours taken off work in order to attend sessions and visits (e.g. GP appointments or physiotherapy sessions), in addition to days taken off work due to having chronic pain per se. According to the Health and Safety Executive, people with musculoskeletal disorders take, on average, 15.20 days off work a year due to having chronic pain [30].

#### Table 3: Societal perspective: days off work and median hourly earnings

Parameter	Value	Source
Days off work due to chronic pain	£15.20	Health and Safety Executive [14]
Median hourly earnings	£14.77	ONS [15]

#### Assumptions

The most noteworthy assumptions included in the economic model are as follows:

- The prevalence of chronic pain being 43.5%, sourced from the Fayaz et al study [32]. This equates to 22,787,025 people.
- Between 10.4% 14.3% have moderately/ severely disabling chronic pain, also sourced from the Fayez et al study. This equates to 5,447,932 people (at 10.4% lower level).
- The efficacy of the intervention was sourced from the T21 study data.
- It is assumed that the 'no pain' health state used no resources and the 'severe pain' health states used the most resources.



## **Results** Interpreting Results

The following primary outcomes were generated in the model:

- Total and incremental QALYs per person.
- Total and incremental costs per person.

The model also considers secondary outcomes, including total hours taken off work and total income loss (per person).

To measure the cost-effectiveness of CBPMs, the costs and QALYs generated by CBPMs were compared to those generated by the standard of care. This was done by calculating the incremental cost-effectiveness ratio (ICER) and the net monetary benefit (NMB). The NMB represents the value of an intervention in monetary terms, against the threshold value. A positive incremental NMB indicates that CBPMs are cost-effective compared with the standard of care.

While the net health benefit (NHB) is a summary statistic that represents the impact on population health of introducing a new intervention. A positive incremental NHB indicates that overall population health would be increased through the use of CBPMs.

#### **Base case**

The model shows that CBPMs are costeffective and result in a net health benefit to the overall population.

Table 4 below displays the results over a oneyear time horizon for a population of 22,787,025. Using a 5% assumed increase in efficacy when using CBPMs, there was a utility gain of 0.02 per year related to functionality improvements.

Results from the model indicate that CBPMs would save £332 per person. An additional 0.04 QALYs per person are gained when CBPMs are used in addition to analgesics, physiotherapy and CBT. Table 4 also shows that CBPMs are 'dominant', meaning that it is estimated to be both less costly and more effective, compared with analgesics, physiotherapy and CBT alone.

This means that use of CBPMs would increase overall population health, both by increasing the health of those using it, and freeing up resources for people with other conditions. CBPMs also result in 27.51 fewer hours taken off work, in order to attend appointments or residential rehabilitations, saving £406.37 per year, when compared to analgesics, physiotherapy and CBT.

Overall, the model identifies a net monetary benefit of £1,037 per person.

Outcome	Intervention	Comparator	Incremental
Cost per person	£22,506	£22,838	-£332
QALYs per person	0.51	0.48	0.04
Total cost of cohort	£512,837,079,689	£520,405,142,675	-£7,568,062,986
Total QALYs of cohort	11,671,043	10,867,943	803,100
Total hours taken off work (per person)	947.37 hours	974.88 hours	-27.51
Total income loss (per person)	£13,993	£14,399	-£406.37
Incremental cost-effectiveness ratio (ICER)			Dominant
Net monetary benefit (per person)			£1,037
Net health benefit (per person)			0.052

#### **Table 4: Summary of Base Case Results**

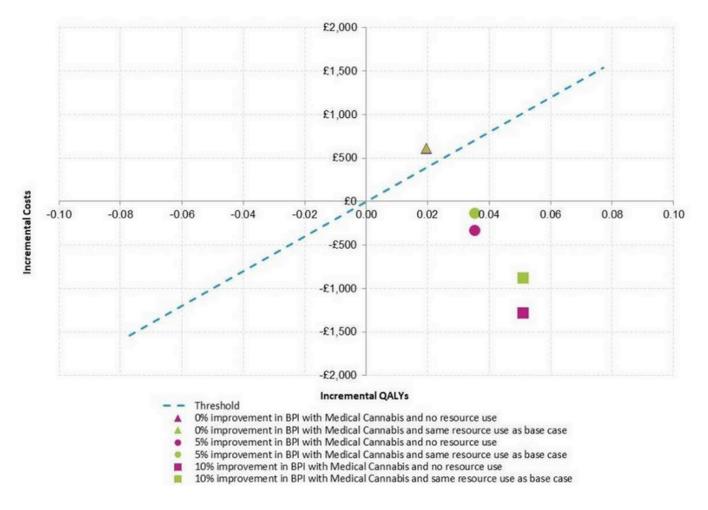
As well as the Base Case, other scenarios were modelled, including varying improvements in BPI, and consideration of only the NHS perspective. In terms of BPI, a 0% improvement in BPI leads to medical cannabis not being cost effective, while a 10% improvement in BPI results in it being even more cost effective than the Base Case.

When considering only the NHS perspective, medical cannabis was still cost effective and brought notable savings:

Outcome	Intervention	Comparator	Incremental
Cost per person	£15,020	£15,044	-£25
QALYs per person	0.51	0.48	0.04
Total cost of cohort	£342,254,398,290	£342,815,502,370	-£561,104,080
Total QALYs of cohort	11,671,043	10,867,943	803,100
Total hours taken off work (per person)	947.37 hours	974.88 hours	-27.51
Total income loss (per person)	£13,993	£14,399	-£406.37
Incremental cost-effectiveness rati	Dominant		
Net monetary benefit (per person)			£729
Net health benefit (per person)			0.036

#### Table 5: Scenario 2: only the NHS perspective is considered





Note: Any result to the right of the threshold is considered cost effective.

# Conclusion

The percentage improvement in the Brief Pain Index (BPI) with CBPMs is the major driver of the primary model results. CBPMs remained cost-effective and dominant in scenarios where the percentage improvement was 5% (or greater). As the efficacy of CBPMs rises, so do savings on comparative healthcare spending.

As a 5% increase in effectiveness has been demonstrated in prior pain research, we predict with confidence that the use of CBPMs represent a substantial cost saving. Higher improvements can be expected as prescribing practices and product availability are increasingly refined and improved, and as prescribing and prescription fulfilment prices decrease. This is a very conservative baseline improvement; T21 data showed an 18% improvement in symptoms [25], but 5% was chosen as a minimum improvement estimate to account for lack of placebo control.

The model results indicate that over a one-year horizon, CBPMs are estimated to be less costly when compared to analgesics, physiotherapy and CBT alone, and also more effective. Therefore, CBPMs have the potential to provide benefits to those in the UK and result in a net health benefit to the overall population with reduced overall costs.

There were cost savings of £332 per person per year, where a 5% increment in efficacy is observed. However, when external benefits are considered, such as the reduction in time off work caused by chronic pain, then the overall savings rise to £1037 per person. If all those with moderately/severely disabling chronic pain (5.45 million) were beneficiaries, this would equate to a potential saving of  $\pounds$ 3.97 billion to the NHS and  $\pounds$ 5.65 billion to the economy each year.

Across both the base case and the various scenarios, CBPMs are associated with less hours taken off work to attend sessions or residential rehab and, therefore, less income loss per person. If CBPMs lead to more people moving to the lower levels of pain, such as 'no pain' or 'mild pain' health states, less resource use is required.

It is also worth noting that additional benefits are also predicted, based on the findings on RWE to date, in addition to a reduction in pain levels. These include better quality and duration of sleep, increased appetite, improved mobility and higher quality of life scores [6].

While this model was based on UK costs, populations, and typical NHS treatment patterns, it has been designed so it can be modified to be used in other healthcare systems and funding models around the world. It is therefore hoped that such modelling can help inform policy decision-making on the accessibility of CBPMs generally, and not just in the UK.

The potential cost effectiveness of CBPMs needs to be taken seriously, as our early economic model suggests.

Further high-quality clinical trials and systematic comprehensive capture of clinical

experience with CBPMs is clearly warranted, but nevertheless, our results strongly indicate that CBPMs can be cost effective for the treatment of chronic pain, taking the substantial body of RWE into the equation.

This in turn indicates that the NICE assessment, based solely on RCT evidence, might not be the most helpful approach to help both patients and healthcare systems in need.

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