



cb2insights

Real-World Evidence Shows  
Patients Seeking Cannabis  
For Mood Disorders



# CB2 INSIGHTS – PREDICTIVE ANALYTICS FOR THE GLOBAL CANNABIS INDUSTRY. BETTER DATA. BETTER INSIGHTS.

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## About CB2 Insights

CB2 Insights has a mission to simplify the medical cannabis journey across the value chain through a suite of healthcare technology products and services delivered through three distinct brands – each serving a unique vertical. Canna Care Docs is a leading cannabis evaluation and education group operating in 12 jurisdictions. Canna Care Docs has served more than 265,000 patients looking to integrate cannabis into their treatment regimen. Sail offers a cannabis-specific clinic management platform and data collection tools to support clinics and clinicians across multiple countries. Tokeln is the industry’s only app-based customer loyalty and engagement platform used by cannabis retailers. The parent brand, CB2 Insights, works to build predictive analytics tools through real-world evidence based on the controlled data input ingested from each of its sub-brands which are used to deliver actionable insights both to its customer base and the industry at-large.

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## **REAL-WORLD EVIDENCE SHOWS PATIENTS SEEKING CANNABIS FOR MOOD DISORDERS.**

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All too often we hear that there isn't enough clinical evidence surrounding cannabis and its effectiveness as a medical treatment. Doctors continue to echo that they are waiting for clinical trials to prove the drug's efficacy even though state legislators continue to create new medical cannabis frameworks at a rapid pace. And with millions of Americans finding symptom relief from cannabis across the country, it is important to take a step back and be sure that patient needs, medical data and government regulations are aligned.

Earlier this month, the US Federal Drug Administration outlined their strategic framework to advance more effective ways to leverage electronic tools that gather vast amounts of health-related data. This new concept of real-world data (RWD) and the insights derived from it – real-world evidence (RWE) is set to guide new proof points of efficacy for a variety of treatments in a much more cost-effective, reliable and rapid pace. RWE is essentially the middle ground between complex clinical trials and patient-driven and often times subjective anecdotal data. This method of data analysis is thought to shed light on otherwise blind spots in the medical world where clinical studies are not available or assessments of more practical applications of treatments are needed in order to guide future clinical trial designs. This provides an ideal arena for cannabis research as cannabinoid therapy continues to permeate the mainstream while still remaining a Schedule I drug federally in the United States.

CB2 Insights provides a unique view of RWD within the medical cannabis sector. The company operates 28 cannabis evaluation and education centers across Massachusetts, Maine, Connecticut, Maryland, Illinois, Pennsylvania, Delaware and several other states, providing services to more than 65,000 patients each year. CB2 has also deployed a proprietary electronic health record platform and data collection technology to track patient history, current behaviours and follow-on improvements. Together, CB2 Insights has a front-row seat to assess what patients are seeking in terms of cannabinoid therapy.



The following is a study that was conducted over a 4-week period across 4 states in which patients seeking cannabis treatment went through a complete evaluation process with a licensed healthcare practitioner. [Please see full study details below.]

### **Real Understanding Can Be Difficult to Navigate**

Cannabis is inherently complex. Unlike traditional pharmaceuticals, cannabis is believed to assist with a myriad of conditions, has thousands of strains and multiple consumption methods. It often creates many more questions than it does answers. So, whether patients are seeking treatment for pain-related, neurological, sleep-related or mood-related issues, the need to navigate cannabis as a medicine is more crucial than ever.

As we will illustrate below, state regulations still hold immense variance when it comes to regulating qualifying conditions. Taking a look at patient encounters across CB2 Insights' evaluation centers (o/a Canna Care Docs) over a 4-week period, the company found the majority of patients (34.77%) sought cannabinoid therapy for mood-related disorders – that compared to pain-related conditions at 33.05% and sleep-related disorders in a distant third at 15.33%. While most states have approved chronic and intractable pain as a qualifying condition for cannabis usage, the vast majority list PTSD as the only qualifying mood-related condition and two states do not allow for mood-related conditions to qualify at all. This begins to show the discrepancy in legislative constraints and patient needs.

### **The (Not-So?) United States of America**

Medical cannabis legalization is truly still in its infancy. Although 33 states plus Washington D.C. have established legal frameworks for a medical program, one of the major variances state-to-state is the long list of qualifying conditions. While most Americans agree that legislation of this type should be handled at a state level, with such incongruity among each state, it is important to take a closer look at which states are providing access to the conditions most patients are seeking treatment for.



In all, there are at least 70 various conditions listed across the 34 jurisdictions – with some states listing as little as 8 conditions and others as many as 39 – not one state mirrors another fully. There are nine states (along with DC) that allow for physicians and other healthcare practitioners to provide recommendations to patients for any ailment deemed appropriate for cannabis treatments by the practitioner. This divergence can work in the positive in early-stage medical programs. Both to illustrate where research should turn focus to and where states should broaden their regulations. This is where real-world data comes into place. If Massachusetts allows a physician to hold full authority over which conditions qualify for treatment and nearby Maryland restricts to only 8 qualifying conditions, there must be some information one can glean from the medical cannabis treatment that has been dispensed over many years between these two states and what meets the needs of the patients.

### **Cannabis and Mood – How Involved Should Government Be?**

There have been several studies on cannabis and its effects on mood. Even recent studies such as Mammen, G. et al.'s “Cannabis Worsens Mood and Anxiety Disorders in Long Run” published in June of this year, however with such restraints on standardized clinical trials with cannabis, researchers had to combine 12 separate longitudinal studies with various structures in order to substantiate their claim. While the title of the study assumes a compelling outcome, there is an admittance of limitations within this view based on an understanding of the amount of cannabis that was used by the patient, an inability to determine the composition of cannabis used and the drug-to-drug interaction outcomes of other medications the patients were taking throughout the studies.

Another study by researchers Turna, Patterson and Van Ameringen points out that anxiety and mood disorders are “not commonly recognized by governing bodies” when it comes to cannabis therapy. So, while there is a major spotlight on mental illness throughout the US, there is a potential of overlooking alternative therapies for common mood disorders. The study by Turna et al. found that CBD as well as a synthetic cannabis compound, nabilone showed improvement for patients with mood disorders and yet vast majority of states with legal frameworks do not allow for patients with mood disorders to qualify for cannabinoid treatment.



Across all 34 medical frameworks in the US, Alaska and Michigan are the only states to not list mood disorders as a qualifying condition. 22 states list PTSD as a qualifying condition but list no other mood-related disorders. The remaining 10 are covered by a ruling allowing physicians to have full authority over whether a patient could benefit from cannabis treatment regardless of their underlying condition. When looking at the data from this study, more than 90% of patients assessed were from states with this broader framework (Massachusetts and Maine). This provides for an ideal look as to what conditions patients seek out cannabinoid therapy for outside of states with more stringent regulatory frameworks.

The government's acute attention on mental illness within the US is in large part due to the effects of long-term dependence on anti-depressant medication. The Center for Disease Control (CDC) found in a study from 2011 to 2014 released in August 2017 that 12.7% of individuals over the age of 12 had taken antidepressant medication within the past month. Federal statistics show that 15.5 million of Americans who are taking anti-depressants have been doing so for more than 5 years. And while Zoloft and Prozac have become household names, there are close to 50 FDA-approved anti-depressant medications on the market today. The CDC also found that usage of antidepressants had risen by 65% since 1999. This increased proclivity to adding antidepressants to a treatment regimen and the heightened dependency suggests that mood disorders should be more commonly recognized by government bodies.

Just this year, the CDC also released a study looking at suicide rates in the US over close to two decades. The study found a rise of more than 30% in the number of suicides in 25 states and nationwide, suicide now sits in the top 10 causes of death and some studies have shown that it is a direct contributor to the decrease in life expectancy in the US. In March of 2014, Dr. Erikki Isometsa published a study that illustrated between half and two-thirds of all suicides "are by people who suffer from mood disorders". So while there is little known correlation between cannabis and mood disorders, there is certainly enough data to support further exploration and Real World Data may be the key to filling the gaps left by restrictions on traditional, randomized clinical trials.



## As Clinical Trials Lag, Real-World Evidence Must Advance

Cannabis still represents a wide open space for research. But unlike other medications to hit the market, the proliferation of cannabis as a medicine has leapfrogged the structure of traditional clinical studies. Today, millions of patients are benefiting from cannabis as a medicine and two-thirds of US states have approved its usage. As such, data and technology companies are able to leverage RWD through electronic medical records, insurance claim forms, patient applications and other sources to study how cannabis is actually impacting those using it as a treatment.

And while chronic pain remains the primary attention-getter when it comes to cannabinoid therapy, mood disorders are proving to be the most prominent condition patients seek treatment for. And if cannabinoid therapy can help influence the growth rate in highly addictive antidepressant medication and even help to slow the suicide rate throughout the country, it is hard to ignore that it deserves to step deep into the spotlight.

Source: Mammen, G., et al. Cannabis Worsens Mood and Anxiety Disorders in the Long Run. June 22, 2018 <https://www.jwatch.org/na46954/2018/06/22/cannabis-worsens-mood-and-anxiety-disorders-long-run>

Source: Turna, J. BSc, PhD(c)1,2, Patterson, B. BScN, MSc1,3, Van Ameringen M. MD, FRCPC1,3,4 Is Cannabis Treatment for Anxiety, Mood, and related Disorders Ready for Primetime? June 2017 [https://www.theroc.us/researchlibrary/Turna\\_et\\_al-2017-Depression\\_and\\_Anxiety.pdf](https://www.theroc.us/researchlibrary/Turna_et_al-2017-Depression_and_Anxiety.pdf)

Source: Center for Disease Control. Antidepressant Use Among Persons Aged 12 and Over: United States, 2011-2014. August 2017. <https://www.cdc.gov/nchs/products/databriefs/db283.htm>

Article: New York Times. Many People Taking Antidepressants Discover They Cannot Quit. April 7, 2018. <https://www.nytimes.com/2018/04/07/health/antidepressants-withdrawal-prozac-cymbalta.html>

Source: Center for Disease Control. Antidepressant Use Among Persons Aged 12 and Over: United States, 2011-2014. August 2017. <https://www.cdc.gov/nchs/products/databriefs/db283.htm>

Source: Center for Disease Control. Suicide rising across the US. June 2018. <https://www.cdc.gov/media/releases/2018/p0607-suicide-prevention.html>

Source: Isometsa, E. MD, PhD1. Suicidal Behaviour in Mood Disorders – Who, When and Why? March 2014. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4079239/>



## STUDY SUMMARY.

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### Thesis

A large number of patients seeking cannabis treatment suffer from a mood-related disorder (ex. Anxiety, Stress, Depression, PTSD, ADHD, Hepatitis C and General Mood Disorders). Note: Hepatitis C is generally not a mood-related condition, however patients within the study had the following secondary conditions: ADD, Anxiety, Mood Disorders. Therefore, we are categorizing the condition-type in these specific cases as mood-related.

Of the 34 medical cannabis frameworks in effect throughout the US, no state lists any mood-related conditions as a qualifying condition for cannabis treatment with the exception of post-traumatic stress disorder (PTSD). However, because the majority of patients within this study were from Massachusetts and Maine, it is important to note that both of these states allow for Healthcare Practitioners (HCPs) to have broad authority in issuing cannabis recommendations for any condition they deem appropriate for this treatment. This is the case for 9 states plus Washington DC, leaving 24 states that do not account for non-PTSD mood disorders for using cannabis as a viable treatment option. This gives us an ability to assess whether states that limit practitioners to specific conditions are preventing certain conditions highly sought by patients.

If so, it is important to then take a look at whether there are trends within the broader healthcare market related to those conditions or treatments associated with these mood-related conditions. In doing so, we see that there has been a 65% increase in anti-depressant usage across the US over the past 15 years. The CDC also shows that suicide rates in the US are at their highest rate in decades – and studies show that suicides are often directly related to mood disorders.

We will take a look at whether adding cannabis to those states that currently do not include Anxiety, Stress and Depression as qualifying conditions would benefit the general public by doing so.



### Study Protocols

Sixteen medical cannabis clinics in regions of the United States that have legalized the use of medical cannabis provided data over a 4-week period. For patients who were eligible to receive medical cannabis, data was collected by a licensed healthcare practitioner utilizing standardized electronic case report forms.

The primary condition, secondary condition, current medication, previous cannabis experience, and other patient characteristics were captured. Descriptive statistics were tabulated by a data analyst.

### The Basics

#### The Basics - Study Specific

Patient Count	463
Number of States in Study (MA, ME, CT, DE)	4
Number of Clinics in Study	16
Time Period - November 19 to December 17, 2018	4 weeks
Number of Primary Conditions	30
Number of Condition Categories	6

#### The Basics - Macro-Environment

States with Legal Medical Cannabis Frameworks	33 (plus DC)	Includes South Carolina
States with Full HCP Control Over Recommendations	7 (plus DC)	
States with NO Mood-Related Qualifying Conditions	2	
States with PTSD as the only Mood-Related Condition	24	
States with no Legal Medical Cannabis Framework	17	

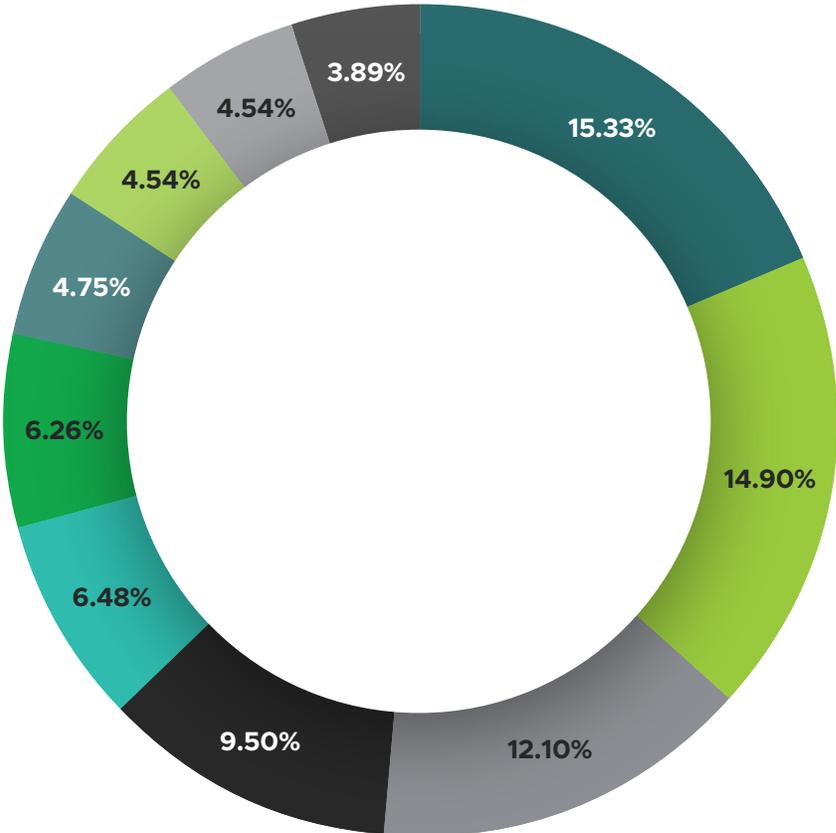
## Primary Condition Overview

Condition	Type	Number	Percentage
Insomnia	Sleep Related	71	15.33%
Chronic Pain	Pain Related	69	14.90%
Anxiety	Mood Related	56	12.10%
Depression	Mood Related	44	9.50%
Stress	Mood Related	30	6.48%
Back & Neck Problems	Pain Related	29	6.26%
Migraines	Pain Related	22	4.75%
Arthritis	Physiological	21	4.54%
Post Traumatic Stress Disorder	Mood Related	21	4.54%
Muscle Spasms	Physiological	18	3.89%
Headaches	Pain Related	12	2.59%
Chronic Nausea	Physiological	10	2.16%
Neuropathic Pain	Pain Related	10	2.16%
Appetite Stimulation	Appetite Related	9	1.94%
ADD/ADHD	Mood Related	8	1.73%
Cancer Related Pain	Pain Related	6	1.30%
Irritable Bowel Syndrome	Physiological	6	1.30%
Auto Accident(s)	Pain Related	3	0.65%
Multiple Sclerosis	Physiological	3	0.65%
Tremors	Neurological	3	0.65%
Obsessive Compulsive Behaviour	Neurological	2	0.43%
Spinal Cord Injury / Disease	Pain Related	2	0.43%
Anorexia	Appetite Related	1	0.22%
Cachexia / Wasting Syndrome	Appetite Related	1	0.22%
Epilepsy	Neurological	1	0.22%
Hepatitis C	Mood Related	1	0.22%
Mood Disorders	Mood Related	1	0.22%
Movement Disorder	Physiological	1	0.22%
Parkinsons Disease Symptoms	Neurological	1	0.22%
Scoliosis	Physiological	1	0.22%
<b>TOTAL</b>		<b>463</b>	<b>100.00%</b>

Note: Certain primary conditions were categorized based largely on secondary conditions and detailed physician notes that led to an underlying ailment that cannabis was sought to treat. For example, those with ADD/ADHD most commonly sought treatment for mood-related disorders such as depression and stress; those with Hepatitis C also sought treatment for mood-related disorders such as anxiety and stress; those with Auto Accident listed as a primary condition all had pain-related conditions as a secondary listing such as chronic pain and migraines; cancer was always listed as an underlying pain-related condition such as chronic pain, headaches and migraines.

**Top 10 Primary Conditions**

- Insomnia
- Chronic Pain
- Anxiety
- Depression
- Stress
- Back & Neck Problems
- Migraines
- Arthritis
- Post Traumatic Stress Disorder
- Muscle Spasms



## Condition Category Assessment

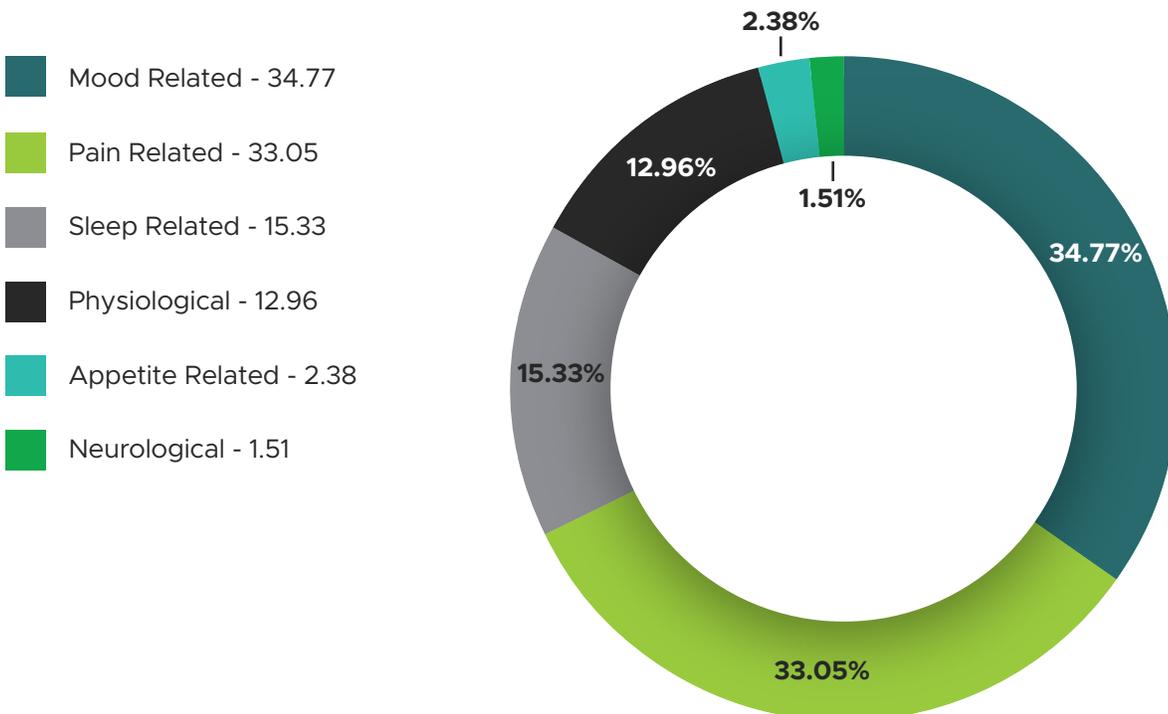
Condition	Type	Number	Percentage
Appetite Stimulation	Appetite Related	9	
Anorexia	Appetite Related	1	
Cachexia / Wasting Syndrome	Appetite Related	1	
		<b>11</b>	<b>2.38%</b>
Anxiety	Mood Related	56	
Depression	Mood Related	44	
Stress	Mood Related	30	
Post-Traumatic Stress Disorder	Mood Related	21	
ADD / ADHD	Mood Related	8	
Hepatitis C	Mood Related	1	
Mood Disorders	Mood Related	1	
		<b>161</b>	<b>34.77%</b>
Tremors	Neurological	3	
Obsessive Compulsive Behaviour	Neurological	2	
Epilepsy	Neurological	1	
Parkinsons Disease Symptoms	Neurological	1	
		<b>7</b>	<b>1.15%</b>
Chronic Pain	Pain Related	69	
Back & Neck Problems	Pain Related	29	
Migraines	Pain Related	22	
Headaches	Pain Related	12	
Neuropathic Pain	Pain Related	10	
Cancer Related Pain	Pain Related	6	
Auto Accident(s)	Pain Related	3	
Spinal Cord Injury/Disease	Pain Related	2	
		<b>153</b>	<b>33.05%</b>
Insomnia	Sleep Related	71	
		<b>71</b>	<b>15.33%</b>



Condition	Type	Number	Percentage
Arthritis	Physiological	21	
Muscle Spasms	Physiological	18	
Multiple Sclerosis	Physiological	3	
Movement Disorder	Physiological	1	
Chronic Nausea	Physiological	10	
Scoliosis	Physiological	1	
Irritable Bowel Syndrome	Physiological	6	
		<b>60</b>	<b>12.96%</b>
<b>TOTAL</b>		<b>463</b>	

Note: Certain primary conditions were categorized based largely on secondary conditions and detailed physician notes that led to an underlying ailment that cannabis was sought to treat. For example, those with ADD/ADHD most commonly sought treatment for mood-related disorders such as depression and stress; those with Hepatitis C also sought treatment for mood-related disorders such as anxiety and stress; those with Auto Accident listed as a primary condition all had pain-related conditions as a secondary listing such as chronic pain and migraines; cancer was always listed as an underlying pain-related condition such as chronic pain, headaches and migraines.

### Top Condition Type





# State by State Overview

## Macro-Environment for Qualifying Conditions

### States with Medical Framework (33 + DC)

Note: Includes South Carolina

Alaska	Maryland	Ohio
Arizona	Massachusetts	Oklahoma
Arkansas	Michigan	Oregon
California	Minnesota	Pennsylvania
Colorado	Missouri	Rhode Island
Connecticut	Montana	South Carolina
Delaware	Nevada	Utah
DC	New Hampshire	Vermont
Florida	New Jersey	Washington
Hawaii	New Mexico	West Virginia
Illinois	New York	
Maine	North Dakota	

### States with Full Authority of HCPs

Note: Providers can make the assessment on any condition

California	Massachusetts	Oklahoma
Colorado	Minnesota	Utah
DC	Missouri	
Maine	Nevada	

### States with Limited Broad Authority of HCPs

Note: Primarily Pain, Nausea and Seizure Related Only

Alaska	Michigan	South Carolina
Arizona	New Hampshire	Vermont
Arkansas	New Jersey	Washington
Delaware	New York	West Virginia
Florida	North Dakota	
Hawaii	Rhode Island	

### States with Broad Authority at Discretion of State

Note: States will assess whether a non-qualifying condition will be accepted on a case-by-case basis

Rhode Island	South Carolina
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# CONTACT AND DISCLAIMER INFORMATION.

**For more information, please contact:**

Dan Thompson  
Chief Marketing Officer, CB2 Insights  
[dan.thompson@cb2insights.com](mailto:dan.thompson@cb2insights.com)

**For media inquires:**

Raquel Cona  
KCSA Strategic Communications  
[cb2@kcsa.com](mailto:cb2@kcsa.com)

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The views and opinions expressed in this document are meant to generate thought and discussion and are in no way meant to provide substantive medical opinion to patients, healthcare practitioners or other readers. Medical cannabis has many applications, product strains and consumption methods and it is the opinion of CB2 Insights that despite millions of Americans who look to medical cannabis as a treatment option, a deeper understanding towards the efficacy of cannabinoid therapy is still required before providing full guidance in this area. Please consult with your physician before integrating cannabis into any treatment regimen.

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