Medical Marijuana Program

450 Columbus Blvd., Suite #901, Hartford, CT 06103-1840 • (860) 713-6066
Fax: (860) 706-5361 • **E-mail**: dcp.mmp@ct.gov • **Website**: www.ct.gov/dcp/mmp

Petition to Add a Medical Condition, Medical Treatment or Disease to the List of Debilitating Conditions

INSTRUCTIONS: Please complete each section of this Petition and attach all supportive documents. All attachments must include a title referencing the Section letter to which it responds. Any Petition that is not fully or properly completed will not be submitted to the Board of Physicians.

Please Note: Any individually identifiable health information contained in a Petition shall be confidential and shall not be subject to disclosure under the Freedom of Information Act, as defined in section 1-200, Connecticut General Statutes.

Section A: Petitioner's Information

Name (First, Middle, Last): [redacted]			
Home Address (including Apartment or Suite #): [redacted]			
City: [redacted]		State: [redacted]	Zip Code: [redacted]
Telephone Number: [redacted]	E-mail Address: [redacted]		

Section B: Medical Condition, Medical Treatment or Disease

Please specify the medical condition, medical treatment or disease that you are seeking to add to the list of debilitating medical conditions under the Act. Be as precise as possible in identifying the condition, treatment or disease.

See attached

Section C: Background

Provide information evidencing the extent to which the condition, treatment or disease is generally accepted by the medical community and other experts as a valid, existing medical condition, medical treatment or disease.

- Attach a comprehensive definition from a recognized medical source.
- Attach additional pages as needed.

See attached

Section D: Negative Effects of Current Treatment

If you claim a treatment, that has been prescribed for your condition causes you to suffer (i.e. severe or chronic pain, spasticity, etc.), provide information regarding the extent to which such treatment is generally accepted by the medical community and other experts as a valid treatment for your debilitating condition.

- Attach additional pages as necessary.
- If not applicable, please indicate N/A.

See attached

Section E: Negative Effects of Condition or Treatment

Provide information regarding the extent to which the condition or the treatments thereof cause severe or chronic pain, severe nausea, spasticity or otherwise substantially limits one or more major life activities.

- Attach additional pages as necessary.

See attached

Section F: Conventional Therapies

Provide information regarding the availability of conventional medical therapies, other than those that cause suffering, to alleviate suffering caused by the condition or the treatment thereof.

- Attach additional pages as necessary.

See attached

Section G: General Evidence of Support for Medical Marijuana Treatment

Provide evidence, generally accepted among the medical community and other experts, that supports a finding that the use of marijuana alleviates suffering caused by the condition or the treatment thereof.

- Attach additional pages as necessary.

See attached

Section H: Scientific Evidence of Support for Medical Marijuana Treatment

Provide any information or studies regarding any beneficial or adverse effects from the use of marijuana in patients with the condition, treatment or disease that is the subject of the petition.

- Supporting evidence needs to be from professionally recognized sources such as peer reviewed articles or professional journals.
- Attach complete copies of any article or reference, not abstracts.

See attached

Section I: Professional Recommendations for Medical Marijuana Treatment

Attach letters in support of your petition from physicians or other licensed health care professionals knowledgeable about the condition, treatment or disease at issue.

See attached

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Section J: Submission of Petition

In the event you are unable to answer or provide the required documentation to any of the Sections above (excluding Section D); provide a detailed explanation indicating what you believe is "good cause" for not doing so.

- Attach additional pages as necessary.

I hereby certify that the above information is correct and complete.

My signature below attests that the information provided in this petition is true and that the attached documents are authentic. I formally request that the commissioner present my petition and all supporting evidence to the Board of Physicians for consideration.

Signature	Date Signed:
[redacted]	11/3/22

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Section B

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5496281/
Vulvar Lichen Sclerosus et Atrophicus

Abstract

Vulvar lichen sclerosus (VLS) is a chronic inflammatory dermatosis characterized by ivory-white plaques or patches with glistening surface commonly affecting the vulva and anus. Common symptoms are irritation, soreness, dyspareunia, dysuria, and urinary or fecal incontinence. Anogenital lichen sclerosus (LS) is characterized by porcelain-white atrophic plaques, which may become confluent extending around the vulval and perianal skin in a figure of eight configuration. Thinning and shrinkage of the genital area make coitus, urination, and defecation painful. LS is not uncommon in India and present as an itchy vulvar dermatosis which a gynecologist may mistake for candidal vulvovaginitis. There is often a delay in diagnosis of VLS due to its asymptomatic nature and lack of awareness in patients as well as physicians. Embarrassment of patients due to private nature of the disease and failure to examine the genital skin properly are the other reasons for delay in diagnosis. There is no curative treatment for LS. Various medications available only relieve the symptoms. Chronic nature of the disease affects the quality of life. Proper and regular follow-up is required as there are chances of the development of squamous cell carcinoma.

My comments for Section B. The medical treatment for Lichen Sclerosis is a corticosteroid, Clobetasol. This medication thins the skin and creates soreness, discomfort and affects quality of life.

Section C

https;//www.ncbi.nlm.nih.gov/pmc/articles/PMC5496281/

Pathophysiology

Inflammation and altered fibroblast function in the papillary dermis leads to fibrosis of the upper dermis. Hypoxia, ischemia, and vascular damage are due to increased GLUT1 and decreased vascular endothelial growth factor (GF) expression in affected skin.[5] The effect of cell-mediated cytotoxicity has also been defined.[6] Although many authors have described LS and scleroderma as closely related entities or even their associations have been seen, there is no systemic involvement in LS

My comments for Section D. The prescribed medication is Clobetasol, a corticosteroid that causes thinning of the skin along with burning, stinging and cracking which leads to further problems. Dysuria and difficulty voiding can occur especially when there is fusion of labia minora over the urethra with advanced disease. It is also not advisable to be on Clobetasol for a long time. The treatment for Lichen Sclerosis is everyday application for 2 weeks followed by three times a week. Stopping this medication is not advised due to the chronic inflammatory nature of this disease.

Section E

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5496281/

Clinical Features

VLS is one of the chronic inflammatory (lymphocyte-mediated) dermatoses with a prevalence estimated to range from 1 in 300 to 1 in 1000 of all patients referred to dermatology departments. It often remains undetected for years.

Dysuria and difficulty in voiding can occur, especially when there is a fusion of the labia minora over the urethra with advanced disease. Nine percent of cases may be asymptomatic.[10] Others present with symptoms such as intractable pruritus which is worse at night, pruritus ani, irritation, soreness, dyspareunia, dysuria, and urinary or fecal incontinence. There may also be thinning and shrinkage of the genital area that makes coitus, urination, and defecation painful. On sexual intercourse or defecation, painful skin fissures develop. Painful defecation, anal fissures, and rectal bleeding are common complaints that require extensive

gastrointestinal evaluation and sometimes hemorrhoidectomy or repair of an anal fissure.

Dyspareunia is often a late symptom associated with introital stenosis, fissures, or posterior deflection of fused labial tissues. Fusion over the clitoris can also cause diminished sexual sensation or even anorgasmia. Marked dyspareunia may occur in peri- or post-menopausal women with estrogen deficiency in addition to LS.

LS commonly affects the vulva and around the anus with ivory-white plaques or patches with glistening surface. The lesions occur on the inner aspects of labia majora, labia minora, and clitoris while perianal lesions occur in 30% of cases.[3]

It usually begins as white, polygonal papules that coalesce into plaques. Evenly spaced dells or comedo-like plugs correspond to obliterated appendiceal ostia which may be easily identified with dermoscopy. With time, the plugs and dells will disappear and leave a smooth, porcelain-white plaque. The size of the plaque or plaques may vary widely and from a few millimeters resembles lichen nitidus.

Anogenital LS is characterized by shiny porcelain-white atrophic plaques, which may become confluent extending around the vulval and perianal skin in a figure of eight configuration.[3] Atrophic plaque may have a cellophane paper-like texture, wrinkled, and fragile surface which is associated with telangiectasia, purpura, erosions, fissuring, or ulceration.[23]

My comments for Section F. Estrace cream medication would be another treatment for Lichen Sclerosis but it does not address the chronic inflammatory aspect of the disease.

Section G

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2828614/

Cannabis, commonly known as marijuana, is a product of the *Cannabis sativa* plant and the active compounds from this plant are collectively referred to as **cannabinoids**. For several centuries, marijuana has been used as an alternative medicine in many cultures and, recently, its beneficial effects have been shown in: the treatment of nausea and vomiting associated with cancer chemotherapy; anorexia and cachexia seen in HIV/AIDS patients; and in neuropathic pain and spasticity in multiple sclerosis [1–4]. Cannabinoid pharmacology has made important advances in recent years after the discovery of the **cannabinoid**

receptors (CB1 and CB2). Cannabinoid receptors and their endogenous ligands have provided an excellent platform for the investigation of the therapeutic effects of cannabinoids. It is well known that CB1 and CB2 are heterotrimeric $G_{i/o}$-protein-coupled receptors and that they are both expressed in the periphery and the CNS. However, CB1 expression is predominant in the CNS, especially on presynaptic nerves, and CB2 is primarily expressed on immune cells [5,6].

Cannabinoids are potent anti-inflammatory agents and they exert their effects through induction of apoptosis, inhibition of cell proliferation, suppression of **cytokine** production and induction of T-regulatory cells (Tregs). In this review, we provide an in-depth description of all four different mechanisms and we further discuss the immunosuppressive properties of cannabinoids in the context of inflammatory and **autoimmune disease** states, triggered by cellular rather than humoral components of the immune system.

Cannabinoid action on cytokines

Cytokines are the signaling proteins synthesized and secreted by immune cells upon stimulation. They are the modulating factors that balance initiation and resolution of **inflammation**. One of the possible mechanisms of immune control by cannabinoids during inflammation is the dys-regulation of cytokine production by immune cells and disruption of the well-regulated immune response [25]. Furthermore, cannabinoids may affect immune responses and host resistance by perturbing the balance between the cytokines produced by T-helper subsets, Th1 and Th2. *In vitro* studies were performed to compare the effect of THC and cannabinol on cytokine production by human T, B, $CD8^+$, NK and eosinophilic cell lines. However, the results were variable, depending on the cell line and the concentration used [26]. Both pro-inflammatory and anti-inflammatory effects of THC were demonstrated in this study, proposing that different cell populations have varied thresholds of response to cannabinoids. Generally, TNF-α, GM-CSF and IFN-γ levels decreased with drug treatment. Interestingly, while the anti-inflammatory cytokine IL-10 decreased following THC treatment, there was an increase in the proinflammatory cytokine IL-8. In other studies, cannabinoid CP55,940 at nanomolar concentrations was shown to have a stimulatory effect on several cytokines in the human promyelocytic cell line HL-60 [27]. At the molecular level, THC has also been shown to inhibit LPS-stimulated mRNA expression of IL-1α, IL-1β, IL-6 and TNF-α in cultured rat microglial cells; however, the effect was independent of the cannabinoid receptors [28]. In a different study, mice were challenged with *Corynebacterium parvum, in vivo*, following the administration of the synthetic cannabinoids WIN55,212-2 and HU210. The animals were then challenged with LPS. The results showed decreased levels of TNF-α and IL-12 but

increased levels of IL-10 in the serum [29]. This effect was shown to be CB1 receptor dependent. During chronic inflammation, IL-6 suppression can decrease tissue injury [30].

My comments for Section G. Lichen Sclerosis may be connected to autoimmune disease and Cannabis has a therapeutic effect on the immune system through cannabinoid receptors. Also the CBD in marijuana addresses inflammation and the THC addressed pain (dyspareunia)

Section H

https://www.pubmed.ncbi.nlm.nih.gov/33426502/

Cannabis and Vulvodynia Symptoms: A Preliminary Report

Abstract

Medical marijuana has a long history of use as an analgesic for chronic pain disorders, including dyspareunia (pain during intercourse), a hallmark of the rare chronic pain disorder vulvodynia. Many women's health topics remain under investigated. Few studies address cannabis's potential to treat vulvodynia symptoms despite their dramatic impact on quality of life. Women who had used cannabis and who reported experiencing vulvodynia symptoms (N = 38) completed an online survey assessing symptoms, expectancies regarding cannabis-associated relief from vulvodynia symptoms, cannabis use, and cannabis-related problems. Generally, women expected cannabis to have moderate to large effects on vulvodynia symptoms (d = .63-1.19). Nevertheless, women expected greater relief for burning/stabbing pain than for itching and pain associated with tampon insertion, as well greater relief for dyspareunia than for pain associated with tampon insertion. Those whose symptoms were worse expected more relief from cannabis treatment. Expectations of cannabis-induced relief did not increase frequency of use or problems. These data support the idea that further work is warranted, including placebo-controlled randomized clinical trials to rule out any placebo effects and identify potential adverse side effects from a cannabis treatment for vulvodynia.

My comments for Section H. For this question, I am comparing the similarities between Vulvodynia and Lichen Sclerosis and the role that marijuana plays. Medical marijuana is used as an analgesic for chronic pain disorders including dyspareunia which is common in Vulvodynia and Lichen Sclerosis. Vulvodynia is on the list for the State of CT Debilitating Conditions.

Lichen sclerosus of the vulvar and anal tissue is a chronic dermatological condition that can have a lifelong negative impact. It typically manifests with pain, irritation, itching, urinary symptoms, and sexual dysfunction. Although it can occur in both genders at any age, these patients are usually postmenopausal women. The cause for this is unknown although it is thought to be autoimmune-induced. Gold standard treatment of lichen sclerosus involves routine use of a topical steroid cream which can help prevent progression of the disease and provide some relief from the discomfort. Topical estrogen cream may also be used to help provide vibrancy and elasticity to the tissues that have become dry and fragile. Vulvodynia is a chronic pain and discomfort in these same genital areas that lasts for at least 3 months and has no discernable cause. Topical steroids and topical estrogens may also provide relief from vulvodynia as well. As of 2019, the terms "Vulvodynia" and "Vulvar Burning" are listed under Debilitating Medical Conditions that qualify patients for Connecticut Department of Public Health's Medical Marijuana Program. Cannabinoid receptors are widespread in the skin and activation of these receptors have been shown to relieve pain and itching. Although ultimately the progression of lichen sclerosus is lessened with the use of topical steroids, the associated pain and itching may be relieved by topical cannabinoid formulations, especially since they provide relief for vulvodynia which expresses similar symptoms.

To Whom This May Concern,

Lichen sclerosus (LS) is a chronic, progressive, inflammatory condition affecting the anogenital skin. Left untreated, it has the potential to cause significant and permanent scarring as well as deformity of anogenital structures. Progressive disease in adult women may cause significant alteration in vulvar architecture including fusion of the labia minora, entrapment of the clitoris under scar tissue and stenosis and narrowing of the vaginal introitus (Lee & Fischer, 2018). In men, long standing disease can lead to progressive fibrous phimosis and meatal stenosis. This can progress to involve the entire length of the urethra spreading proximally as far back as the prostate (Lee & Fischer, 2018). While a variety of treatment options exist, they are often unsatisfactory and do not provide a cure.

This condition is rarely asymptomatic and is most commonly associated with severe pruritus, dysuria and dyspareunia. Recent studies highlight the fact that complete healing of LS occurs in a minority of patients treated with standard pharmacological treatments (Corazza, et. al., 2021). Therefore, there is a substantial rate of individuals with sustained and symptomatic disease. Persistent symptomatic disease effects quality of life, well-being, and perception of self. While limited literature exists, providing alternative therapeutic treatment options to help individuals cope with the dyspareunia and sexual dysfunction associated with this condition may help improve quality of life.

[redacted]

Sources:

Corazza M, Schettini N, Zedde P, Borghi A. Vulvar Lichen Sclerosus from Pathophysiology to Therapeutic Approaches: Evidence and Prospects. Biomedicines. 2021 Aug 3;9(8):950. doi: 10.3390/biomedicines9080950. PMID: 34440154; PMCID: PMC8394941.

Lee A, Fischer G. Diagnosis and Treatment of Vulvar Lichen Sclerosus: An Update for Dermatologists. Am J Clin Dermatol. 2018 Oct;19(5):695-706. doi: 10.1007/s40257-018-0364-7. PMID: 29987650.