

Minnesota Medical Cannabis Program Petition to Add a Qualifying Medical Condition

Making Your Petition

Any person may petition the Minnesota Department of Health (“the Department” or “MDH”) to add a qualifying medical condition to those listed in subdivision 14 of Minnesota Statutes section 152.22. Petitions will be accepted only between June 1, 2022, and July 31, 2022. Petitions received outside of these dates will not be reviewed.

Use this online form to submit requested information.

Instructions

Complete each section of this petition and attach all supporting documents where noted in this form. Clearly indicate which section of the petition an attachment is for. You can save your submission as a PDF, which you can print or keep for your records. Each petition is limited to one proposed qualifying medical condition. If your petition includes more than one medical condition, it will be dismissed. If you are petitioning for the addition of a medical condition that was considered but not approved in a prior year's petition process, you must include new scientific evidence or research to support your petition or describe substantially different symptoms. The MDH website has the petitions for each petitioned medical condition reviewed in prior years. See Petitions to Add Qualifying Medical Conditions. Petitions that do not include new scientific evidence or research to support your petition or describe substantially different symptoms will not be considered. If the petition is accepted for consideration, MDH will send the petition documents to the Medical Cannabis Review Panel (“Review Panel”). MDH staff will also provide information to the Review Panel about the proposed qualifying condition, its prevalence, and the effectiveness of current treatments. You may withdraw your petition any time before the Review Panel's first public meeting of the year by submitting a written statement to MDH stating that you want to withdraw it.

Petition Review Process

An appointed citizens Review Panel will meet to review all eligible petitions and supporting documentation. MDH will post notice of the public meetings of the Review Panel on its medical cannabis website. After the public meeting and by Nov. 2, 2022, the Review Panel will provide the Commissioner of Health a written report of findings.

The Commissioner will approve or deny the petition by Dec. 1, 2022.

Section A: Petitioner's Information

This information has been redacted.

Section B: Medical Condition You Are Requesting Be Added

Please specify the name and provide a brief description of the proposed qualifying medical condition. Be as precise as possible in identifying the condition. Optional: Include diagnostic code(s), citing the associated ICD-9 or ICD- 10 code(s), if you know them.

K31.84

A disorder characterized by an incomplete paralysis of the muscles of the stomach wall resulting in delayed emptying of the gastric contents into the small intestine.

Section C: Symptoms of the Proposed Medical Condition and/or Its Treatment

Describe the extent to which the proposed qualifying medical condition or the treatments cause suffering and impair a person's daily life.

Gastroparesis, or delayed gastric emptying, is a condition that slows or stops the movement of food from your stomach to your small intestine, even though there is no blockage in the stomach or intestines. Diabetic gastroparesis is well studied, however, other idiopathic cases of gastroparesis have no obvious connection to underlying disease. Suggested causes include vagus nerve damage, history of eating disorders, hypothyroidism, antidepressants, post-surgical complications, and others.

One study, completed in 2008, from Olmsted County, Minnesota found that the age-adjusted prevalence of gastroparesis was 9.6 cases per 100,000 persons for men and 37.8 cases per 100,000 persons for women, a similar disease burden as inflammatory bowel disease (a condition already covered under the state's medical cannabis program). Beyond identifying probable cases of gastroparesis in the general population, the study found that 25 percent of identified patients required therapeutic interventions. Additionally, overall survival was significantly lower than the age- and sex-specific expected survival computed from the Minnesota white population. The five-year survival of the cohort was 67 percent.

Symptoms of this condition range from very mild, including bloating, heartburn, and nausea, to very extreme, including severe abdominal pain, bezoars, and long episodes of vomiting resulting in malnutrition and dehydration requiring the use of a feeding tube and hospitalization. While generally mild, the prevalence of these symptoms degrade quality of life, are highly impactful to day-to-day activities, and interfere in many daily activities like personal hygiene, nutrition, childcare, job performance, social events, chores and errands. One study found that more than 10 percent of patients reported being disabled due to their condition and hospitalizations for gastroparesis have increased more than 300 percent between 1997 and 2013.

Gastroparesis also commonly presents as flares, making symptom management challenging. On good days, many food options and daily activities create no symptoms. However, on bad days,

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even foods that are generally considered "safe" can cause debilitating symptoms. Anecdotally, my personal case keeps me in a remote working situation to ensure I can respond to flare ups and treat them accordingly. In one case study, an individual with diabetic gastroparesis reported a flare up associated with a COVID-19 infection, which is likely to transition to its endemic phase in the near future.

Sources:

<https://www.niddk.nih.gov/health-information/digestive-diseases/gastroparesis/treatment>

(Jung, H. K., Choung, R. S., Locke, G. R., 3rd, Schleck, C. D., Zinsmeister, A. R., Szarka, L. A., Mullan, B., & Talley, N. J. (2009). The incidence, prevalence, and outcomes of patients with gastroparesis in Olmsted County, Minnesota, from 1996 to 2006. *Gastroenterology*, 136(4), 1225-1233. <https://doi.org/10.1053/j.gastro.2008.12.047>)

Song, Jun MDa,*; Bhuta, Rajiv MDb; Baig, Kamal MDb; Parkman, Henry P. MDb; Malik, Zubair MDb COVID-19 infection manifesting as a severe gastroparesis flare, *Medicine*: April 09, 2021 - Volume 100 - Issue 14 - p e25467 doi: 10.1097/MD.00000000000025467

<https://www.aha.org/duke-health-addresses-covid-19-endemic-and-ongoing-need-vaccinations>

Section D: Availability of Conventional Medical Therapies

Describe conventional medical therapies available and the degree to which they ease the suffering caused by the proposed qualifying medical condition or its treatment.

Conventional therapies for gastroparesis are limited and are typically focused on managing symptoms as no known cure for gastroparesis exists. For mild to moderate cases, treatment typically includes over the counter and prescription anti-emetics (Pepto-Bismal, Zofran, etc.) and dietary changes, including extremely limited fat

and fiber intake. Since most whole and fresh foods feature high fiber, the result of this is a high-sodium diet of processed foods, which can have longer-term health impacts. In more extreme cases, oral, nasal, and jejunostomy tube feeding and parenteral nutrition is utilized along with gastric electrical stimulation.

Commonly prescribed medications include Zofran, Metoclopramid, Domperidone, Erythromycin, antibiotics, some antidepressants, and pain medicines. There are known interactions and limitations to commonly prescribed medications including significant side effects and exacerbation of common symptoms. Domperidone is limited to

specific use cases and is not currently a legally marketed human drug in the United States. This leaves some patients ordering this drug online for their treatment.

Ultimately, conventional therapy for gastroparesis is significantly lacking and does not provide consistent relief to most patients. There are currently multiple studies evaluating the efficacy and safety of trazpiroben (TAK 906 maleate).

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Sources:

<https://www.niddk.nih.gov/health-information/digestive-diseases/gastroparesis/treatment>
<https://clinicaltrials.gov/ct2/show/study/NCT03544229>
<https://pubmed.ncbi.nlm.nih.gov/33462988/>

Section E: Anticipated Benefits from Medical Cannabis

Describe the anticipated benefits from the medical use of cannabis specific to the proposed qualifying medical condition.

A commonly accepted benefit to medical cannabis is its near immediate relief of nausea and pain relief. Minnesota Medical Cannabis Program Data found over half of patients participating in the program reported at least a 30 percent reduction in nausea and a third achieved that reduction for the four month observational period. A study by Mayo Clinic found that 12 percent of patients with symptoms of gastroparesis already manage their symptoms using marijuana. These users reported higher levels of nausea/vomiting and upper abdominal pain and a perception that marijuana was beneficial for their symptoms. Reducing nausea and pain through the safe, effective, and regulated medical cannabis program can help gastroparesis patients mitigate the most common symptoms of the disease while minimizing the risk of side effects of cannabis.

Sources:

<https://mayoclinic.pure.elsevier.com/en/publications/marijuana-use-in-patients-with-symptoms-of-gastroparesis-prevalen>

Section F (optional): Scientific Evidence of Support for Medical Cannabis Treatment

Strengthen your petition by including evidence generally accepted by the medical community and other experts supporting the use of medical cannabis to alleviate suffering caused by the proposed medical disease or its treatment. Please include citations and links (if available) to peer-reviewed published journals or other completed medical studies.

It is important to first acknowledge that scientific evidence of the efficacy of medical cannabis on a range of health impacts has been limited in decades past due to federal regulations. Given gastroparesis is a thoroughly understudied disease, scientific evidence is also limited. One study focused on the relationship between cannabinoids and gastroparetic abdominal pain, which was published in the American Journal of Gastroenterology and found that more than 80 percent of patients with gastroparesis reported abdominal pain and that cannabinoids provided a statistically significant improvement in abdominal pain. Other academic and clinical research is available for symptoms commonly associated with gastroparesis, but not the disease specifically.

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Sources:

https://journals.lww.com/ajg/fulltext/2018/10001/cannabinoids_lead_to_significant_improvement_in.1204.aspx

<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6970440/#:~:text=In%20conclusion%2C%20cannabinoids%20dramatically%20improve,novel%20therapeutic%20options%20in%20gastroparsis.>

Section G (optional): Letters in Support of Adding the Medical Condition

Upload letters of support for the use of medical cannabis from persons knowledgeable about the proposed qualifying medical condition, such as a licensed health care professional. (Please combine letters of support into one file before you upload.)

Section H: Acknowledgment and Signature

Please note: Any individually identifiable health information relating to any past, present, or future health condition or health care contained in this petition is classified as a health record under Minnesota Statutes §144.291, and is not subject to public disclosure.

I certify that the information provided in this petition is true and accurate to the best of my knowledge.

This information has been redacted. (Submitted 07/29/2022)

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