Office of Medicaid
BOARD OF HEARINGS

Appellant Name and Address:

[redacted]

Appeal Decision:	Approved	**Appeal Number:**	2201725
Decision Date:	6/23/2022	**Hearing Date:**	05/25/2022
Hearing Officer:	Christine Therrien	**Record Open to:**	06/08/2022

Appearance for Appellant:
Pro se, [redacted]

Appearance for MassHealth:
Kaye George, RN
Noah Jones, Sarah Ortiz, Observers

The Commonwealth of Massachusetts
Executive Office of Health and Human Services
Office of Medicaid
Board of Hearings
100 Hancock Street, Quincy, Massachusetts 02171

APPEAL DECISION

Appeal Decision:	Approved	**Issue:**	Prior Authorization – GES
Decision Date:	6/23/2022	**Hearing Date:**	05/25/2022
MassHealth's Rep.:	Kaye George, RN	**Appellant's Rep.:**	Pro se, father
Hearing Location:	All parties appeared by phone		

Authority

This hearing was conducted pursuant to Massachusetts General Laws Chapter 118E, Chapter 30A, and the rules and regulations promulgated thereunder.

Jurisdiction

Through a notice dated 3/2/22, Fallon Heath, a MassHealth Managed Care entity, denied the appellant's prior authorization for a gastric electrical stimulator (GES) because Fallon Health determined that the GES falls under Fallon Health's Experimental and Investigational Clinical Coverage Criteria that excludes coverage of experimental/investigational procedures due to their lack of reliable or detailed clinical evidence of superior clinical outcomes and therefore does not meet medical necessity regulations. 130 CMR 450.204 and Exhibit 1. The appellant filed this appeal in a timely manner on 3/7/22. 130 CMR 610.015(B) and Exhibit 2. Denial of a prior authorization is valid grounds for appeal. 130 CMR 610.032.

Action Taken by MassHealth

Fallon Heath denied the appellant's request for prior authorization for a GES.

Issue

The appeal issue is whether Fallon Heath was correct, pursuant to 130 CMR 450.204 in determining that the GES does not meet the criteria for medical necessity.

Summary of Evidence

Fallon Health was represented by their Board of Hearings Appeal's Nurse. The Fallon representative testified that this appeal is the result of a prior authorization denial issued in 2021. The appellant filed a prior authorization request for a Gastric Electrical Stimulator (GES). The appellant received a letter dated 9/29/21 from Fallon Health which stated that "the following service(s) has been denied: Gastric Electrical Stimulator (43647) with Dr. Steven Yood for 10/11/21 for the diagnosis of gastroparesis (K31.84)." Exhibit 4, p. 6. A 2/17/22 letter from Fallon Health indicated that the appellant's request for an expedited internal appeal would take up to 14 days, not the typical 72 hours, so Fallon Health could schedule a peer-to-peer review with Dr. Yood. Exhibit 4, p. 11. The appellant received a determination from Fallon Health on 3/2/22 indicating the requested GES will not be covered "based on Fallon Health's Experimental and Investigational Clinical Coverage Criteria. There is no objective reliable evidence showing that the proposed request for a gastric stimulator consistently and significantly improves health outcomes. The data in the literature is inconclusive and consistently and significantly documenting improved health outcomes in the use of gastric stimulation in the management of gastroparesis." Exhibit 4, p. 9. The Fallon representative testified that the device is a Humanitarian Use Device (HUD) which implies it is not the standard of care nor is it approved by the FDA. The Fallon representative testified that per 130 CMR 450.204(B) this device does not meet the medical necessity guidelines because it does not "meet the professionally recognized standards of health care and per the Fallon Health's Experimental and Investigational Clinical Coverage Criteria regarding this specific CPT code 4364 [sic], this device is specifically excluded from coverage." Exhibit 4, pp. 34-47.[1] The Fallon representative testified that per Massachusetts "General Laws Part I: Administration of Government, Title 22: Corporations, Chapter 175: Insurance, Section 110L: Clinical Trials; Definition; Coverage, a qualified clinical trial meets the conditions if number one, the clinical trial is intended to treat cancer." Exhibit 4, pp. 49-50. The Fallon representative testified that the appellant is an under 65 year old female who "has a diagnosis of idiopathic gastroparesis, which is a disease or condition that can arise spontaneously for which a cause is unknown" this causes the appellant near constant abdominal pain associated with nausea and vomiting. The Fallon representative testified that a gastric emptying study performed in 2021 revealed delayed gastric emptying. The Fallon representative testified that the appellant follows a low fat and gluten free diet and takes Domperidone for nausea and vomiting; Zofran for nausea; Linzess for constipation; Dexilant and Pepcid for heartburn caused by GERD. The appellant also takes Levothyroxine for Hashimoto's Disease and is allergic to milk, Bactrim, Penicillin, Cipro, Sertraline, Erythromycin, Keflex, Gabapentin, BuSpar and Reglan. Exhibit 4, p. 17.[2] The Fallon representative testified that per the MES Peer Review Services report the appellant's physician indicated the appellant lost 50 lbs. due to the gastroparesis. The Fallon representative testified that the MES Peer Review Services

[1] See. Fallon Health Experimental and Investigational Clinical Coverage Criteria "Fallon Health excludes coverage of experimental/investigational procedures due to their lack of reliable or detailed clinical evidence of superior clinical outcomes. Fallon Health evaluates many different types of clinical evidence in determining if a procedure or treatment has a greater safety or efficacy than conventional treatments. This is inclusive but not limited to published technological assessments, randomized control studies, published peer literature, and expert opinions. Fallon Health will evaluate available, peer-reviewed scientific literature in relation to an overall clinical outcome and its acceptance of use in a clinical setting. Prior authorization is required for the use of any service or procedure as outlined in this policy. These requests must be supported by the treating provider(s) medical records…All services outlined in this policy are excluded from coverage unless approved by a Fallon Health Medical Director as outlined above."

[2] Hashimoto's disease is an autoimmune disorder affecting the thyroid gland. Mayo Clinic Staff, *Hashimoto's Disease,* https://www.mayoclinic.org/diseases-conditions/hashimotos-disease/symptoms-causes/syc-20351855 (accessed June 14, 2022).

report states that the GES is a HUD and requires IRB approval which implies it is not the standard of care and therefore experimental. Exhibit 4, p. 21. The MES Peer Review Services report further states:

1. **Is this request for the use of a gastric simulator [sic] done with robotic assisted laparoscopy considered experimental/investigational for this member's diagnosis?**
   Yes. The request for the use of a gastric stimulator done with robotic assisted laparoscopy is experimental/investigational for the member's diagnosis. The device is labeled as a humanitarian use device which implies it is not standard of care. The placement of a gastric stimulator is being placed under Humanitarian Use Device (HUD) and an IRB and as such considered experimental/investigational. Corporate policy does not cover experimental/investigational procedures with unproven outcomes.

2. **Has this procedure been shown to be safe, clinically effective, and improved health outcomes in the peer reviewed scientific literature?**
   No. The available studies have mixed conclusions. While some show an 80% response rate with 97% of patients experiencing greater than [>] 80% reduction in vomiting and nausea others have not shown similar results.

   The device was approved by the Food and Drug Administration (FDA) as a humanitarian device exemption in patients with refractory symptoms of gastroparesis of diabetic or idiopathic etiology in 2000 based on two studies…An initial meta-analysis suggested substantial benefits for gastroparesis, but identified that, among 13 included studies, 12 lacked controls and only 1 was blinded and randomized. A more recent meta-analysis on gastric stimulation showed similar results and identified diabetic patients as the most responsive to gastric stimulation, both subjectively and objectively, while the idiopathic and post-surgical subgroups were less responsive. This provider indicated that he has 80% success rate with gastric stimulation. Both meta-analyses and review of the literature indicate that further controlled studies are required to confirm the clinical benefits of high frequency gastric electrical stimulation.

3. **In particular, is there objective, reliable evidence showing that the proposed request for a gastric simulator [sic] consistently and significantly improves health outcomes?**
   No. There is no objective, reliable evidence showing that the proposed request for a gastric stimulator consistently and significantly improves health outcomes.

   Both meta-analyses and review of the literature indicate that further controlled studies are required to confirm the clinical benefits of high frequency gastric electrical stimulation. The data in the literature is inconclusive in consistently and significantly documenting improved health outcomes in the use of gastric stimulation in the management of gastroparesis.

4. **Based upon your understanding of the member's condition as presented in the**

medical records and based upon your appreciation of the state of the art and the state of current literature, does the requested a [sic] gastric simulator meet the requirements of FCHP's Criteria?

No. The requested gastric stimulator request does not meet the requirements of FCHP's criteria.

The requested services is a humanitarian use device and is therefore not accepted standard of care and given inconclusive literature based on etiology of the gastroparesis, it has to be considered experimental/investigational. The long term effects on the stomach musculature with high energy stimulation is unknown if desired outcome is not obtained. In addition, it does not appear that erythromycin has been attempted short term. Acupuncture has also been shown to work in some cases although the level of evidence is low for this approach. Patients with gastroparesis should be screened for the presence of diabetes mellitus, thyroid dysfunction, neurological disease, prior gastric or bariatric surgery, and autoimmune disorders. Patients should undergo biochemical screen for diabetes and hypothyroidism; other tests are indicated clinically. A detailed work up is not supported by the clinicals reviewed. As last resort, refractory (after all efforts have been exhausted) gastroparesis may benefit at times from an experimental device such as the gastric electrical stimulation.

The appellant testified that she tried multiple different medications and has found no relief from her symptoms. The appellant testified that the Peer Review Report suggested she tries erythromycin and have a thyroid disfunction test performed. The appellant testified that she is allergic to erythromycin and she is already being treated for Hashimoto's Disease which is auto-immune disorder affecting the thyroid. The appellant stated that in a two-week period she lost 11 lbs. because she could not keep any food down. The appellant testified that she lost 50 lbs. within the first few months after she became sick in 2020. The appellant testified that her physician stated that the GES is the best last option. The appellant testified that her doctor stated his success rate is 80% and she wishes she had a 30% or 40% success rate so she can at least go out. The appellant stated that she requires therapy and is in a major depression and the GES will improve her quality of life. The appellant stated that within 500 miles of her there are 7 states that approve this procedure. The appellant stated that her physician is the only doctor in Massachusetts who performs this surgery. The appellant testified that she has been dealing with this for two years and she looks nine months pregnant due to the bloating because her stomach does not process the food. The appellant stated that her treatment without the GES will cost MassHealth and Fallon so much more because she has secondary health issues from the vomiting, like rotting teeth, visits to the ER for hydration and medication, hair loss from malnutrition. The appellant testified that she is taking Domperidone which is not approved by the FDA and she pays for out it of pocket. The appellant quoted one study listed in the peer to peer review, that stated within one month post-surgery the patient no longer required any medications and two months post-surgery the patient no longer required a restricted diet and was symptom free and six months post-surgery the patient had normal gastric emptying. The appellant stated that she knows it is a controversial surgery but there is no other option. The appellant testified that she is applying for disability because she is unable to work and is unable to leave the house. The appellant testified that because gastroparesis is such a rare disease it is considered a disability. The appellant testified that not all surgeries have a 100% success rate. The appellant underwent multiple tests performed before she was diagnosed after the gastric emptying study. The appellant testified that the gastric emptying study showed that after 4 hours she still had 27% of the food left in her stomach. The appellant testified that she has tried all available medications to

treat the gastroparesis.

The Fallon representative was asked what other less costly options were available to the appellant and she listed two medications: Metoclopramide and Cisapride. Further discussion revealed that the appellant is allergic to Metoclopramide (brand name Reglan) and Cisapride has been withdrawn from U.S. markets.

The Fallon representative testified that BCBS of MA and Tufts do not pay for the GES, but the larger health insurance companies like UHC, Aetna, and Cigna. The Fallon representative testified that Fallon Health specifically denies the GES, and she does not know the magic treatment. The Fallon representative testified that it has more to do with this treatment not being the standard of care. The Fallon representative testified that it must be approved by the FDA. When the appellant's father challenged the statement the Fallon representative testified that is it not approved by the FDA for that use. The Fallon representative testified that it does not meet the Fallon Health's Experimental and Investigational Clinical Coverage Criteria and the CPT code is listed, and "because a clinical trial, which you'd want to do, is intended to treat cancer." The Fallon representative testified that she is not suggesting that Cisapride would work, she is not trying to diagnose the appellant, she just does not think the appellant has tried everything. The Fallon representative testified that she is not suggesting a treatment, "I named a couple of things that are alternatives, which in order for us to pay, have to be tried." The Fallon representative testified that the GES is experimental and investigational with unproven outcomes. Exhibit 4, p.21.

The appellant's father testified that the appellant has exhausted every possible medication. The appellant's father testified that Dr. Yood recommends the procedure and he has been performing the procedure for 15 years. The appellant's father testified that even if the GES only helps a little it will be better than no relief at all. The appellant's father stated that the appellant cannot work and cannot go out into society and relies on her parents to pay her bills.

The Fallon representative testified that the use of a HUD must be approved by an Institutional Review Board (IRB) and can only be used for the specific rare disease it is intended for. The Fallon representative testified that she would submit articles that show that not one had a chance of being 50% successful.

The record was left open to allow both the appellant and Fallon Health to submit studies to support their assertions.

The appellant submitted several studies with the following summaries:

> Based on this meta-analysis, the substantial and significant improvement of symptoms and gastric emptying, and the good safety we observed, indicate that high-frequency GES is an effective and safe method for treating refractory gastroparesis. DG patients seem the most responsive to GES, both subjectively and objectively, while the IG and PSG subgroups are less responsive and need further research. Chu, H., Lin, Z., Zhong, L., McCallum, R., & Hou, X. (2011). Treatment of high-frequency gastric electrical stimulation for gastroparesis. *Journal of Gastroenterology and Hepatology,* 27(6), 1017-

1026.[3]

> Presented herein is a case report of a laparoscopic gastric electrical stimulator implantation for drug-refractory gastroparesis. Technical aspects of the procedure, as well as a review of the existing literature, are discussed. Gastric electrical stimulation offers a new alternative for the treatment of drug-refractory gastroparesis. Gastroparesis can be an incapacitating condition for many patients. Although medical therapy should first be attempted, it often is not successful. Gastric electrical stimulation is a viable alternative. Laparoscopic implantation confers the recognized advantages of a minimally invasive approach. de Csepel, J., Shapsis, A., & Jordan, C. (2005). Gastric Electrical Stimulation: A Novel Treatment for Gastroparesis. *Journal of the Society of Laparoscopic and robotic Surgeons,* 9(3), 364–367.

Exhibit 6.

Fallon Health submitted multiple studies. Summaries of the first two are provided below.

> In a randomized crossover study, we found that GES reduced the frequency of refractory vomiting in patients with and without diabetes, although it did not accelerate gastric emptying or increase of quality of life. Chronic vomiting remains a clinical challenge when usual diet recommendations and pharmacologic options fail to improve patients' symptoms, and it may ultimately lead to impaired nutritional status. Chronic vomiting episodes are often related to delayed gastric emptying, a condition in which vomiting is associated with dyspeptic symptoms and weight loss. In some patients, vomiting is associated a normal gastric emptying. Ducrotte P., Coffin B., Bonaz B., Fontaine S., Bruley Des Varannes S., Zerbib F., Caiazzo R., Grimaud J.C., Mion F., Hadjadj S., Valensi P.E., Vuitton L., Charpentier G., Ropert A., Altwegg R., Pouderoux P., Dorval E., Dapoigny M., Duboc H., Benhamou P.Y.,…Guerci B., & ENTERRA Research Group. (2020). Gastric Electrical Stimulation Reduces Refractory Vomiting in a Randomized Crossover Trial. *Gastroenterology*, 158(3), 506-514.

> In patients with intractable DGP, 6 weeks of GES therapy with Enterra significantly reduced vomiting and gastroparetic symptoms. Patients had improvements in

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[3] "One of the more well-known of these is students ending reports or essays on scientific studies, principles or theories by saying "more research is needed," or some variation thereof. Countless science students end up using this pseudo-insightful conclusion this at some point, often for good reason. Firstly, it's invariably correct: you seldom get *any* scientific study which is both completely comprehensive and conclusive, so there's always scope for more research. Even something as familiar and established as Einstein's General Theory of Relativity is still being researched a century later. Secondly, it implies the student is aware of limitations and the wider gaps in the field and is also willing/able to criticise more established scientists, but without being specific (or directly insulting) in any way. The problem is that it's essentially meaningless. Unless a paper or study claims to answer a specific question once and for all and with absolute certainty, more research will *always* be needed. Dean Burnett, *The Guardian, More research is needed': empty cliché or words to live by?,* https://www.theguardian.com/science/brain-flapping/2016/mar/16/more-research-needed-cliche-science-higher-education (accessed June 14, 2022).

> subjective and objective parameters with chronic stimulation after 12 months of GES, compared with baseline. The current results represent only patients with diabetic gastroparesis. Caution should be used when interpreting these results because they may not apply to the broader gastroparesis population of nondiabetic etiology.
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> To date, only one double-blind study, the Worldwide Anti-vomiting Electrical Stimulation Study (WAVESS), has evaluated the efficacy of GES in patients with gastroparesis. That study included 33 patients (17 diabetic and 16 idiopathic) who, after surgery to implant the device, immediately underwent 2 consecutive months of a randomized, placebo-controlled, double-blind, cross-over trial followed by a 10-month, open-label period. During the blinded phase of the study, GES achieved a significant reduction in weekly vomiting frequency (WVF) and the majority of patients preferred the ON month. At 12 months, 70% of diabetic patients and 77% of idiopathic patients reported more than 50% improvement in median vomiting frequency…Apart from the WAVESS double-blind trial, all of the published literature on the efficacy of GES consists of open-label studies, mainly from centers with substantial experience with this device. Follow-up data for a period of 1 to 10 years postimplant uniformly show consistent improvement in symptoms. McCallum R.W., Snape W., Brody F., Wo J., Parkman H.P., & Nowak T. (2010). Gastric electrical stimulation with Enterra therapy improves symptoms from diabetic gastroparesis in a prospective study. *Clin Gastroenterol Hepatol,* 8(11), 947-54.

Fallon health stated in post hearing submissions that "[t]he consensus among the 3 systematic reviews and 1 meta-analysis below is that high quality, large clinical trials are needed to establish the efficacy of this therapy and to identify the patients for whom this therapy is appropriate." Exhibit 7, p. 5. Fallon health included the following excepts from the study abstracts with the post-hearing submissions. Exhibit 7, pp. 6-8.

> In conclusion, gastric pacemaker is a potential treatment option for patients with medically refractory gastroparesis. As noted from the results of our study, nausea/vomiting, weight loss, and overall GCSI scores have shown marked improvement with gastric electrical stimulation (GES). Nevertheless, more extensive research is needed to understand better the full extent of this device's use as a viable treatment option for patients suffering from gastroparesis. Rajamanuri M., Mannava S.M., Chhabra J., Karwarker G.V., Chahal M., Maligireddy A.R., Dai E., & Alfonso M. (2021). A Systematic Review of the Therapeutic Role of Gastric Pacemakers in Adults with Gastroparesis. *Cureus*, 13(9), e18152.
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> Conclusion: Independent of the treatment modality, baseline symptom severity impacts treatment results in gastroparesis. Considering the skewed population with refractory symptoms, regression to the mean likely contributes to the substantial discrepancies between the reported results of controlled and open label GES studies, raising questions about the use of GES outside of defined clinical trials. Levinthal D.J., Bielefeldt K. (2017). Systematic review and meta-analysis: Gastric electrical stimulation for gastroparesis. *Autonomic Neuroscience*, 202, 45-55.

> Conclusion: The evidence in support of gastric electrical stimulation is limited and heterogeneous in quality. While current evidence has shown a degree of efficacy in these patients, high-quality, large clinical trials are needed to establish the efficacy of this therapy and to identify the patients for whom this therapy is inappropriate. A consensus view on essential preoperative assessment and postoperative measurement is needed. Lal N., Livemore S., Dunne D., Khan I. (2015). Gastric Electrical Stimulation with the Enterra System: A Systematic Review. *Gastroenterol Research and Practice*, 762972. doi:10.1155/2015/762972.
>
> Conclusions: Results show substantial benefits for high frequency GES in the treatment of gastroparesis. However, caution is necessary in interpreting the results, primarily due to the limitations of uncontrolled studies. Further controlled studies are required to confirm the clinical benefits of high-frequency GES. O'Grady G., Egbuji J.U., Du P., Cheng L.K., Pullan A.J., & Windsor J.A., (2009). High-frequency gastric electrical stimulation for the treatment of gastroparesis: a meta-analysis. *World Journal of Surgery*, 33, 1693–1701.
>
> Conclusions: Based on this meta-analysis, the substantial and significant improvement of symptoms and gastric emptying, and the good safety we observed, indicate that high frequency GES is an effective and safe method for treating refractory gastroparesis. DG patients seem the most responsive to GES, both subjectively and objectively, while the IG and PSG subgroups are less responsive and need further research. Chu et al., 2012.

Fallon Health submitted the following except from the "Summary of Evidence" and one recommendation from the "Summary of Recommendations" stated in a study entitled "Clinical guideline: management of gastroparesis." Exhibit 7, pp. 7-8.

> GES delivers high frequency (Table 7) (several fold higher than the intrinsic gastric electrical frequency), lower energy electrical stimulation to the stomach. The device was approved by the FDA as a humanitarian device exemption in patients with refractory symptoms of gastroparesis of diabetic or idiopathic etiology in 2000 based on two studies (158). The first, an open-labeled study showed improvement in both specific and global gastroparesis symptoms and gastric emptying (137). The second, a double blind, randomized, crossover study reported improvement of weekly vomiting frequency (WVF) and quality of life in DG and in the whole patient cohort, but not in the IG subgroup. The study sample size enrolled only about 50 % of what had originally been planned and was underpowered (159). Most subsequent reports have been open-label studies, including long-term efficacy reports of several hundred patients, suggesting that GES enhances symptom control and quality of life and improves oral tolerance of feeding (155). An initial meta-analysis (157) suggested substantial benefits for gastroparesis, but identified that, among 13 included studies, 12 lacked controls and only 1 was blinded and randomized. A more recent meta-analysis on GES showed similar results and identified DG patients as the most responsive to GES, both subjectively and objectively, while the IG and PSG

subgroups were less responsive (160). Both meta-analyses and review of the literature indicate that further controlled studies are required to confirm the clinical benefits of high-frequency GES.

Recommendations: GES may be considered for compassionate treatment in patients with refractory symptoms, particularly nausea and vomiting. Symptom severity and gastric emptying have been shown to improve in patients with diabetic gastroparesis (DG), but not in patients with idiopathic gastroparesis (IG) or postsurgical gastroparesis (PSG). (Conditional recommendation, moderate level of evidence). Camilleri M., Parkman H.P., Shafi M.A., et al. (2013). Clinical guideline: management of gastroparesis. *American Journal of Gastroenterology*, 108(1), 18-37.

Fallon Health cited additional studies. The following conclusions were taken directly from the studies.

Gastric electrical stimulation therapy led to the improvement of symptoms of gastroparesis and a better quality of life. Patients were able to decrease the use of prokinetic and narcotic medications and achieve long-term satisfaction. Diabetic patients who develop symptomatic gastroparesis have a high mortality rate over time. Shada A., Nielsen A, Marowski S, et al. (2018). Wisconsin's Enterra Therapy Experience: A multi-institutional review of gastric electrical stimulation for medically refractory gastroparesis. *Surgery*, 164(4), 760-765.

In this cohort of patients with refractory gastroparesis, GES improved symptoms in 75% of patients with 43% being at least moderately improved. Response in diabetics was better than in nondiabetic patients. Nausea, loss of appetite, and early satiety responded the best. Heckert J, Sankineni A., Hughes W.B., et al. (2016). Gastric electric stimulation for refractory gastroparesis: a prospective analysis of 151 patients at a single center. *Digestive Diseases and Sciences,* 61(1), 168-75.

High-frequency/low-energy gastric electrical stimulation significantly decreased vomiting frequency and gastrointestinal symptoms and improved quality of life in patients with severe gastroparesis. Abell T., McCallum R., Hocking M., Koch K., Abrahamsson H., Leblanc I., Lindberg G., Konturek J., Nowak T., Quigley E.M.M., Tougas G., Starkebaum W., (2003). Gastric electrical stimulation for medically refractory gastroparesis. *Gastroenterology*, 125, 421–428.

Electrical stimulation of the stomach has an immediate and potent anti-emetic effect. It offers a safe and effective alternative for patients with intractable symptomatic gastroparesis. Abell T.L., Van Cutsem E., Abrahamsson H., Huizinga J.D., Konturek J.W., Galmiche J.P., VoelIer G., Filez L., Everts B., Waterfall W.E., Domschke W., Bruley des Varannes S., Familoni B.O., Bourgeois I.M., Janssens J., Tougas T., (2002). Gastric electrical stimulation in intractable symptomatic gastroparesis. *Digestion*, 66, 204–212.

The FDA approved the gastric electrical stimulation (GES) system for a Humanitarian Device

Exemption in 2000. The GES is "indicated for treatment of chronic, intractable (drug refractory) nausea and vomiting secondary to gastroparesis of diabetic or idiopathic etiology." Exhibit 7, p. 5.[4] The FDA website cited by Fallon Health defines the Humanitarian Use Devices (HUD) program which "was established in 1990 with passage of the Safe Medical Devices Act." The HUD program "creates an alternative pathway for getting market approval for medical devices that may help people with rare diseases or conditions." 21 CFR 814.3(n), and updated by the 21st Century Cures Act, defines a HUD as a "medical device intended to benefit patients in the treatment or diagnosis of a disease or condition that affects or is manifested in not more than 8,000 individuals in the United States per year. The applicant must provide documentation, with appended authoritative references, to demonstrate that the device meets this definition a HUD." Exhibit 7, p. 5.[5]

Fallon Health provided a link to the FDA "Humanitarian Use Exception (HDE) Program Guidance for Industry and Food and Drug Administration Staff." Exhibit 7, p. 5. This guidance states:

> FDA has also published guidance with respect to making benefit-risk determinations for [Investigational Device Exemption] IDE applications. However, unlike an IDE, which permits a device to be shipped lawfully for the purpose of conducting a clinical investigation of the device's safety and/or effectiveness, an approved HDE application is a marketing authorization. Accordingly, the two applications have different statutory and regulatory standards and, as a general matter, earlier stages of device development and investigational study under an IDE are typically associated with greater uncertainty than an HDE. Approval of an IDE application to permit investigational use of a device may be appropriate where it is unknown if subjects are likely to benefit from the use of the device, if the risks to the subjects are outweighed by the anticipated benefits to the subjects and the importance of the knowledge to be gained, and the IDE application otherwise satisfies the requirements of 21 CFR part 812.66. In contrast, approval of the HDE application, which authorizes the marketing of a device, requires, among other things, a demonstration that there is probable benefit and that the probable benefit outweighs the risk of injury or illness from its use, taking into account the probable risks and benefits of currently available devices or alternative forms of treatment.

This guidance states that "[a] requirement that before "use" of a HUD to treat or diagnose patients at a facility, an IRB must approve such use. For purposes of this guidance, approving the "use" of a HUD (as opposed to approving the "investigational use" or a "clinical investigation" of a device) refers to use of the HUD in the course of routine clinical care to treat or diagnose patients." Exhibit 7, p. 5.[6,7]

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[4] U.S. Food and Drug Administration, *Humanitarian Device Exemption (HDE). GASTRIC ELECTRICAL STIMULATION (GES) SYSTEM,* https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfhde/hde.cfm?id=H990014 (accessed June 14, 2022).

[5] U.S. Food and Drug Administration, *Humanitarian Use Device (HUD) Designation Program*, https://www.fda.gov/industry/developing-products-rare-diseases-conditions/humanitarian-use-device-hud-designation-program, (accessed June 14, 2022).

[6] *Id.* at https://www.fda.gov/media/74307/download.

[7] "It is important for the IRB institutional officials, the device sponsor, and local users of the HUD to understand the unique role of the IRB in this setting. This is the only situation where federal regulations require the IRB to approve and

Fallon Health cited an excerpt from the Medtronic Gastric Electrical Stimulation Commonly Billed Codes 2022 manual, "Humanitarian Device: The Enterra Therapy system for gastric electrical stimulation is authorized by Federal law for use in treatment of chronic intractable (drug refractory) nausea and vomiting secondary to gastroparesis of diabetic or idiopathic etiology. The effectiveness of this device for this use has not been demonstrated." Exhibit 7, p.9.[8]

Fallon Health stated in summary that the "GES may be considered for compassionate treatment in patients with refractory symptoms, particularly nausea and vomiting. Symptom severity and gastric emptying have been shown to improve in patients with diabetic gastroparesis (DG), but not in patients with Idiopathic Gastroparesis (IG) or post-surgical gastroparesis (PSG)." Exhibit 7, p. 9.

Lastly, Fallon Health summarized the reasons the request for a GES device is being denied:

1. The devise is labeled as a HUD and considered experimental/investigational per the FDA;
2. There is no objective, reliable evidence showing that the proposed request for the GES consistently and significantly improves health outcomes in patients with Idiopathic Gastroparesis;
3. The request does not meet Fallon Health's criteria (i.e. MassHealth only covers clinical trials when treating cancer; and
4. [The appellant] has not exhausted other treatment modalities (i.e. pharmacological, physical, or psychological).

Findings of Fact

Based on a preponderance of the evidence, I find the following:

1. The appellant has idiopathic gastroparesis. Idiopathic mean this is a disease or condition that can arise spontaneously for which a cause is unknown. "Gastroparesis or gastric stasis is the delayed transit of the ingested contents through the stomach in the absence of mechanical obstruction. It can have multiple etiologies, most commonly idiopathic (ID) and diabetic (DM). Gastroparesis can cause significant distress to patients as it leads to symptoms like intractable nausea and vomiting, weight loss, abdominal bloating, early satiety, etc." The Gastroparesis causes the appellant near constant abdominal pain associated with nausea and vomiting. Testimony and Rajamanuri et al., (2021).

2. The appellant is an under 65-year old female.

3. The appellant filed a prior authorization request for a Gastric Electrical Stimulator (GES).

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monitor an activity that is clearly not research. an approved application authorizes the applicant to market the device and local physicians to use the device to treat or diagnose a medical condition." Elizabeth A. Bankert & Robert Amdur, *Institutional Review Board: Management and Function,* 431 (2nd ed., Jones & Bartlett Learning 2006).

[8] Medtronic, *Gastric Electrical Stimulation, Commonly Billed Codes, 2022,* https://asiapac.medtronic.com/content/dam/medtronic-com/professional/documents/enterra-therapy-reimbursement-guide.pdf (accessed June 15, 2022).

Testimony.

4. The appellant received a letter dated 9/29/21 from Fallon Health which stated that "the following service(s) has been denied: Gastric Electrical Stimulator (43647) with Dr. Steven Yood for 10/11/21 for the diagnosis of gastroparesis (K31.84)." Exhibit 4, p. 6.

5. A 2/17/22 letter from Fallon Health indicated that the appellant's request for an expedited internal appeal would take up to 14 days, not the typical 72 hours, so Fallon Health could schedule a peer-to-peer review with Dr. Yood. Exhibit 4, p. 11.

6. The appellant received a determination from Fallon Health on 3/2/22 indicating the requested GES will not be covered "based on Fallon Health's Experimental and Investigational Clinical Coverage Criteria. There is no objective reliable evidence showing that the proposed request for a gastric stimulator consistently and significantly improves health outcomes. The data in the literature is inconclusive and consistently and significantly documenting improved health outcomes in the use of gastric stimulation in the management of gastroparesis." Testimony and Exhibit 4, p. 9.

7. The GES device is classified a Humanitarian Use Device (HUD) by the FDA in 2000. Exhibit 7.

8. "Fallon Health's Experimental and Investigational Clinical Coverage Criteria" specifically excluded this specific CPT code 43647 from coverage. Testimony and Exhibit 4, pp. 34-47.

9. General Laws Part I: Administration of Government, Title 22: Corporations, Chapter 175: Insurance, Section 110L: Clinical Trials; Definition; Coverage, a qualified clinical trial meets the conditions if number one, the clinical trial is intended to treat cancer." Testimony and Exhibit 4, pp. 49-50.

10. A gastric emptying study performed in 2021 revealed delayed gastric emptying. Testimony and Exhibit 4, p. 17.

11. The appellant follows a low fat and gluten free diet and takes Domperidone for nausea and vomiting; Zofran for nausea; Linzess for constipation; Dexilant and Pepcid for heartburn caused by GERD and Ibuprofen or Tylenol for pain. Testimony and Exhibit 4, p. 17.

12. The appellant also Levothyroxine for Hashimoto's Disease and is allergic to milk, Bactrim, Penicillin, Cipro, Sertraline, Erythromycin, Keflex, Gabapentin, BuSpar and Reglan. Testimony and Exhibit 4, p. 17.

13. The appellant has tried all available medications, which she is not allergic to, with little relief. Testimony and Exhibit 4, pp. 16-17.

14. The appellant's clinical record states she underwent testing and no functional problems were discovered. Exhibit 4, p. 16.

15. The appellant's clinical record states she underwent psychiatric treatment and was provided

antianxiety medications that did not relieve the symptoms associated with gastroparesis. Exhibit 4, p. 16.

16. The appellant continues to have daily nausea, pain and intermittent vomiting. Testimony and Exhibit 4, p. 16.

17. The appellant lost 50 lbs. due to the gastroparesis when it first began in March 2020. Testimony and Exhibit 4, p. 16.

18. The appellant cannot work due to her gastroparesis and has had to move in with her parents Testimony.

19. Both Fallon Health and the appellant submitted clinical studies and meta-analyses of the GES. Exhibits 6 & 7.[9]

Analysis and Conclusions of Law

The appellant's physician submitted a PA request for a GES. The appellant's physician prescribed the GES for the treatment of Gastroparesis. The GES "is a potential treatment option for patients with medically refractory gastroparesis" which provides "marked improvement" of nausea, vomiting, weight loss, and overall Gastroparesis Cardinal Symptom Index scores. (Rajamanuri et al. 2021).[10] Fallon Health denied the PA request on 3/2/22, indicating the requested GES will not be covered because "based on: Fallon Health's Experimental and Investigational Clinical Coverage Criteria. There is no objective reliable evidence showing that the proposed request for a gastric stimulator consistently and significantly improves health outcomes. The data in the literature is inconclusive and consistently and significantly documenting improved health outcomes in the use of gastric stimulation in the management of gastroparesis." The Fallon representative testified that per 130 CMR 450.204(B) this device does not meet the medical necessity guidelines because it does not "meet the professionally recognized standards of health care."

[9] Meta-analysis is a quantitative, formal, epidemiological study design used to systematically assess previous research studies to derive conclusions about that body of research. Outcomes from a meta-analysis may include a more precise estimate of the effect of treatment or risk factor for disease, or other outcomes, than any individual study contributing to the pooled analysis. The examination of variability or heterogeneity in study results is also a critical outcome. The benefits of meta-analysis include a consolidated and quantitative review of a large, and often complex, sometimes apparently conflicting, body of literature. The specification of the outcome and hypotheses that are tested is critical to the conduct of meta-analyses, as is a sensitive literature search. A failure to identify the majority of existing studies can lead to erroneous conclusions; however, there are methods of examining data to identify the potential for studies to be missing; for example, by the use of funnel plots. Rigorously conducted meta-analyses are useful tools in evidence-based medicine. The need to integrate findings from many studies ensures that meta-analytic research is desirable and the large body of research now generated makes the conduct of this research feasible. Haidich A.B. (2010, December 14). Meta-analysis in medical research. *Hippokratia,* 14(Supplement 1), 29-37.

[10] Medically refractory gastroparesis can be defined as persistent symptoms in the context of objectively confirmed gastric emptying delay, despite the use of dietary adjustment and metoclopramide as a first-line therapeutic agent. Lacy B.E., Tack J. & Gyawali, P. (2021, October). AGA Clinical Practice Update on Medically Refractory Gastroparesis. *Clinical Gastroenterology and Hepatology,* 20(3), 491-500.

130 CMR 450.204 is the regulation defining medical necessity. "The MassHealth agency does not pay a provider for services that are not medically necessary and may impose sanctions on a provider for providing or prescribing a service or for admitting a member to an inpatient facility where such service or admission is not medically necessary."

(A) A service is medically necessary if

(1) it is *reasonably calculated to prevent, diagnose, prevent the worsening of, alleviate, correct, or cure conditions in the member that endanger life, cause suffering or pain*, cause physical deformity or malfunction, threaten to cause or to aggravate a handicap, or result in illness or infirmity; and

(2) *there is no other medical service or site of service, comparable in effect, available, and suitable for the member requesting the service, that is more conservative or less costly to the MassHealth agency.* Services that are less costly to the MassHealth agency include, but are not limited to, health care reasonably known by the provider, or identified by the MassHealth agency pursuant to a prior-authorization request, to be available to the member through sources described in 130 CMR 450.317(C), 503.007: *Potential Sources of Health Care*, or 517.007: *Utilization of Potential Benefits.*

(B) *Medically necessary services must be of a quality that meets professionally recognized standards of health care and must be substantiated by records including evidence of such medical necessity and quality.* A provider must make those records, including medical records, available to the MassHealth agency upon request. (*See*42 U.S.C. 1396a(a)(30) and 42 CFR 440.230 and 440.260.)

(C) A provider's opinion or clinical determination that a service is not medically necessary does not constitute an action by the MassHealth agency.

(D) Additional requirements about the medical necessity of MassHealth services are contained in other MassHealth regulations and medical necessity and coverage guidelines.

(E) Any regulatory or contractual exclusion from payment of experimental or unproven services refers to any service for which there is insufficient authoritative evidence that such service is reasonably calculated to have the effect described in 130 CMR 450.204(A)(1).

(emphasis added)

Fallon Health conveniently broke down the denial into four parts which will be analyzed in turn.

1. The devise is labeled as a HUD and considered experimental/investigational per the FDA.

The Safe Medical Devices Act of 1990 established the Humanitarian Use Devices (HUD) program. The HUD program was designed to "encourage the discovery and use of devices intended to benefit patients in the treatment and diagnosis of diseases or conditions that affect not more than 8,000 individuals in the United States." 21 U.S.C. 360j(m)(1). The HUD program "creates an alternative pathway for getting market approval for medical devices that may help people with rare diseases or conditions." Per Section 520(m)(2)(C) of the FD&C Act applications for the HUD program must show "that the device will not expose patients to an unreasonable or significant risk of illness or injury and the probable benefit to health from the use of the device outweighs the risk of injury or illness from its use, taking into account the probable risks and benefits of currently available device[s] or alternative forms of treatment." 21 U.S.C. 360j(m)(2)(C). In 2000, the FDA approved the

Humanitarian Device Exemption (HDE) application for the GES to be labeled a HUD. The GES is indicated for treatment of chronic, intractable (drug refractory) nausea and vomiting secondary to gastroparesis of diabetic or idiopathic etiology. The FDA has another program for experimental devices entitled Investigational Device Exemption (IDE). The HDE and IDE "have different statutory and regulatory standards and, as a general matter, earlier stages of device development and investigational study under an IDE are typically associated with greater uncertainty than an HDE."[11] The "Humanitarian Use Exception (HDE) Program Guidance for Industry and Food and Drug Administration Staff," states that "for purposes of this guidance, approving the "use" of a HUD (as opposed to approving the "investigational use" or a "clinical investigation" of a device) refers to use of the HUD in the course of routine clinical care to treat or diagnose patients." U.S. Food and Drug Administration (2019). A simple search of Section 520(m) of the FD&C Act reveals that the words "experimental" and "investigational" do not appear once." 21 U.S.C. 360j(m). The U.S. Code, the FD&C act, and the FDA do not consider a HUD investigational or experimental.

Fallon Health has mischaracterized the label Humanitarian Use Device. The Fallon representative is incorrect that a HUD implies it is not the standard of care, per 130 CMR 450.204(B), nor is it approved by the FDA. A HUD is simply the designation the FDA gives to a device meant to treat rare disorders such as gastroparesis. The appellant is correct in her assertion that the GES is approved by the FDA for treatment of gastroparesis.

The term "standard of care" is borne out of malpractice law. The Supreme Judicial Court of Massachusetts found that "[a] general medical practitioner is to be held to the standard of care and skill of the average qualified practitioner, and a medical specialist is to be held to the standard of care and skill of the average practitioner of the specialty, taking into account with respect to either the general practitioner or the specialist the advances in the profession and the medical resources available to him." Brune v. Belinkoff, 235 N.E.2d 793, 798 (Mass. 1968). The GES is specifically designed to treat the condition the appellant was diagnosed with in 2021. The appellant has been unsuccessful with all the recommended drugs to treat her symptoms of nausea and vomiting. As noted in the Peer to Peer Review, the GES is a last resort for treating symptoms that do not respond to drug therapy. The FDA considers a HUD to be used during routine clinical care to treat a condition. U.S. Food and Drug Administration (2019). Collectively, the GES meets the bar for "standard of care" as it is the "quality that meets professionally recognized standards of health care." 130 CMR 450.204(B).

2. There is no objective, reliable evidence showing that the proposed request for the GES consistently and significantly improves health outcomes in patients with Idiopathic Gastroparesis.

A service is medically necessary if "it is reasonably calculated to prevent, diagnose, prevent the worsening of, alleviate…conditions in the member that endanger life, cause suffering or pain,…or result in illness or infirmity." 130 CMR 450.204(A)(1). As established in 21 U.S.C. 360j(m)(2)(C) a HUD must "show probable benefit to health from the use of the device [that] outweighs the risk of injury or illness from its use." The GES is specifically used to alleviate nausea and vomiting caused by gastroparesis that are not alleviated by drugs.

[11] *Id.* https://www.fda.gov/media/74307/download.

According to multiple studies provided by Fallon Health and the appellant the GES is effective. Only one of these studies does not plainly state that the GES alleviates symptoms. The one systemic review and meta-analysis published in January 2017 concluded that "[c]onsidering the skewed population with refractory symptoms, regression to the mean likely contributes to the substantial discrepancies between the reported results of controlled and open label GES studies, raising questions about the use of GES outside of defined clinical trials." Levinthal & Bielefeldt, 2017.[12] Subsequent, to this systemic review and meta-analysis a large, randomized, double-blind, crossover-designed, controlled trial was conducted. The results published in 2020 concluded that "GES reduced the frequency of refractory vomiting in patients with and without diabetes, although it did not accelerate gastric emptying or increase of quality of life." Ducrotte et al. 2020.[13]

- "Results show substantial benefits for high frequency GES in the treatment of gastroparesis." O'Grady et al. 2001.

- "Electrical stimulation of the stomach has an immediate and potent anti-emetic effect. It offers a safe and effective alternative for patients with intractable symptomatic gastroparesis. Abell et al. 2002.

- "High-frequency/low-energy gastric electrical stimulation significantly decreased vomiting frequency and gastrointestinal symptoms and improved quality of life in patients with severe gastroparesis. Abell et al. 2003.

- "Gastric electrical stimulation is a viable alternative. Laparoscopic implantation confers the recognized advantages of a minimally invasive approach." de Csepel et. al 2005.

- "During the blinded phase of the study, GES achieved a significant reduction in weekly vomiting frequency (WVF) and the majority of patients preferred the ON month. At 12 months, 70% of diabetic patients and 77% of idiopathic patients reported more than 50% improvement in median vomiting frequency." McCallum et al. 2010.

- "Based on this meta-analysis, the substantial and significant improvement of symptoms and gastric emptying, and the good safety we observed, indicate that high frequency GES is an effective and safe method for treating refractory gastroparesis. DG patients seem the most responsive to GES, both subjectively and objectively, while the IG and PSG subgroups are less responsive and need further research." Chu et al., 2012.

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[12] "Methods: We searched PubMed and Embase for articles published in English (1990-2014) using "gastroparesis" as a search term restricted to "clinical trial". We included studies describing repeated patient-based symptom ratings before and during standardized treatments of at least one week duration." Levinthal & Bielefeldt, 2017.

[13] "Background & Aims: There have been conflicting results from trials of gastric electrical stimulation (GES) for treatment of refractory vomiting, associated or not with gastroparesis. We performed a large, multicenter, randomized, double-blind trial with crossover to study the efficacy of GES in patients with refractory vomiting, with or without gastroparesis." Ducrotte et al. 2020.

- "Most subsequent reports have been open-label studies, including long-term efficacy reports of several hundred patients, suggesting that GES enhances symptom control and quality of life and improves oral tolerance of feeding." Camilleri et al. 2013.

- "[C]urrent evidence has shown a degree of efficacy in these patients." Lal et al. 2015.

- "In this cohort of patients with refractory gastroparesis, GES improved symptoms in 75% of patients with 43% being at least moderately improved. Response in diabetics was better than in nondiabetic patients." Heckert et. Al 2016.

- "Gastric electrical stimulation therapy led to the improvement of symptoms of gastroparesis and a better quality of life. Patients were able to decrease the use of prokinetic and narcotic medications and achieve long-term satisfaction." Shada et al. 2018.

- "This large, randomized, double-blind, crossover-designed, controlled trial shows that high-frequency GES, performed with standard stimulation parameters, was effective to reduce the frequency of both vomiting and nausea in diabetic and nondiabetic patients with refractory vomiting with or without delayed gastric emptying." Ducrotte et al. 2020.

- The "gastric pacemaker is a potential treatment option for patients with medically refractory gastroparesis. As noted from the results of our study, nausea/vomiting, weight loss, and overall GCSI scores have shown marked improvement with gastric electrical stimulation (GES)." Rajamanuri et. al 2021.

Based on the nature of a HUD and the scientific studies submitted as evidence the GES meets Section (A)(1) of the medical necessity regulations under 130 CMR 405.204 since "it is reasonably calculated to prevent, diagnose, prevent the worsening of, alleviate, correct, or cure conditions in the member that endanger life, cause suffering or pain, cause physical deformity or malfunction, threaten to cause or to aggravate a handicap, or result in illness or infirmity."[14]

3. The request does not meet Fallon Health's criteria (i.e. MassHealth only covers clinical trials when treating cancer).

While Fallon Health is correct that Mass. Gen. Laws ch. 175, § 110L (2002) only covers clinical trials for treating cancer the appellant's PA was not requesting access to a clinical trial. Fallon Health testified that the GES does not meet Fallon Health's Experimental and Investigational Clinical Coverage Criteria and the CPT code is excluded. The medical necessity regulations under 130 CMR 405.204 are controlling in this case as Fallon Health is an Accountable Care Organization for MassHealth.

[14] The GES also meets Section (E) that states "[a]ny regulatory or contractual exclusion from payment of experimental or unproven services refers to any service for which there is insufficient authoritative evidence that such service is *reasonably calculated to have the effect described in 130 CMR 450.204(A)(1)*" because it meets Section (A)(1).

4. [The appellant] has not exhausted other treatment modalities (i.e. pharmacological, physical, or psychological).

Section (A)(2) of the medical necessity regulation stated that a service is medically necessary "if there is no other medical service or site of service, comparable in effect, available, and suitable for the member requesting the service, that is more conservative or less costly to the MassHealth agency." 130 CMR 450.204(A)(2). The appellant's medical records and testimony indicates that she has tried all available medications, which she is not allergic to, with little relief; has undergone testing and no functional problems were discovered; and underwent psychiatric treatment and was provided antianxiety medications that did not relieve the gastroparesis. The appellant continues to have daily nausea, pain, and intermittent vomiting. The Fallon Health Peer Review Report concluded with "[a]s last resort, refractory (after all efforts have been exhausted) gastroparesis may benefit at times from an experimental device such as the gastric electrical stimulation." The appellant has unsuccessfully tried all the other less costly and more conservative recommended treatments to address her nausea, pain, and intermittent vomiting. The appellant is now seeking the last resort to alleviate her symptoms. For this reason, the GES meets Section (A)(2) of medical necessity regulations.

The appellant's appeal is approved

Order for MassHealth

Rescind the denial notice dated 3/2/22.

Implementation of this Decision

If this decision is not implemented within 30 days after the date of this decision, you should contact your MassHealth Enrollment Center. If you experience problems with the implementation of this decision, you should report this in writing to the Director of the Board of Hearings, at the address on the first page of this decision.

Christine Therrien
Hearing Officer
Board of Hearings

cc:
MassHealth Representative: Fallon Health, Member Appeals and Grievances, 10 Chestnut Street, Worcester, MA 01608