

STATE OF MICHIGAN
DEPARTMENT OF INSURANCE AND FINANCIAL SERVICES
Before the Director of Insurance and Financial Services

In the matter of:

██████████,
Petitioner,

v

File No. 152540-001

Total Health Care USA, Inc.,
Respondent.

Issued and entered
this 14th day of April 2016
by Sarah Wohlford
Special Deputy Director

ORDER

I. BACKGROUND

██████████ (Petitioner) was denied coverage for a procedure to treat her fecal incontinence by her health plan, Total Health Care USA, Inc. (THC).

On March 4, 2016, the Petitioner filed a request with the Director of Insurance and Financial Services for an external review of that denial under the Patient's Right to Independent Review Act, MCL 550.1901 *et seq.*

The Petitioner receives group health care benefits through THC, a health maintenance organization. The Director immediately notified THC of the external review request and asked for the information it used to make its final adverse determination. THC responded on March 10, 2016. After a preliminary review of the information submitted, the Director accepted the request on March 11, 2016.

The case involves medical issues, so it was assigned to an independent review organization, which provided its analysis and recommendation to the Director on March 25, 2016.

II. FACTUAL BACKGROUND

The Petitioner's health care benefits are defined in an *HMO Certificate of Coverage* issued by THC (the certificate).

The Petitioner's physician prescribed a surgical procedure called sacral nerve stimulation (also known by the trade name InterStim) to treat her fecal incontinence. THC declined to cover it because the information it received did not confirm that the Petitioner had "tried and failed adequate conservative management" of her condition.

The Petitioner appealed the denial through THC's internal grievance process. At the conclusion of that process, THC maintained its denial and issued a final adverse determination dated January 26, 2016. The Petitioner now seeks a review of that final adverse determination from the Director.

III. ISSUE

Did THC correctly deny authorization for the Petitioner's proposed sacral nerve stimulation procedure?

IV. ANALYSIS

Petitioner's Argument

In the request for an external review the Petitioner indicated:

Back in January 2001 I had my first colonoscopy . . . and ever since then I have suffered with a leakage from my rectum. From 2001 until this day in 2016 nothing has changed. After years of seeking help from different gastroenterology doctors there were no help to be found until my family physician referred me to Dr. Amer Alame. For the first time in 14 years I finally found a doctor that could help me. But now the Total Health Care denied the procedure.

Also, I spoke with Dr. Alame and he assured me that this procedure would work for me because it helped patients with worse conditions than mine. There were patients who suffered with actual bowel leakage and this same procedure helped the patients.

Respondent's Argument

In its January 26, 2016, final adverse determination THC explained its denial of coverage to the Petitioner:

All the information available about the request you appealed has been reviewed. A physician who was not involved in the first request for care and who is [] Board Certified in Gastroenterology reviewed the information. This physician determined that the first decision would remain the same. The request for coverage of Interstim Trial is again denied. The reason for this decision is:

Based on the information supplied, medical necessity has not been established. There are no documented results of your work-up which would include endoscopy, ultrasound, manometry, biofeedback, etc.

This decision is based on nationally developed and internally adopted Interstim Trial criteria. The criteria are based on physician-reviewed journal articles, scientific studies and national standards. . . .

Director's Review

The Petitioner's health plan does not cover services or supplies that are not medically necessary (certificate, p. 45). "Medically necessary" is defined in the certificate (p. 7) as "health care services provided by the Plan which adhere to nationally recognized and scientific evidence-based standards, appropriate in terms of type, amount, frequency, level, setting, and duration for the Member's diagnosis or condition."

THC says the Petitioner did not meet medical necessity criteria for coverage of the sacral nerve stimulation procedure. To review that decision, the Director assigned the case to an independent review organization (IRO), as required by section 11(6) of the Patient's Right to Independent Review Act, MCL 550.1911(6).

The IRO physician reviewer is board-certified in colon and rectal surgery and has been in active practice for more than 8 years. The IRO report contained the following analysis and recommendation:

The Health Plan indicated that the member does not meet its criteria for coverage of these services. The Health Plan explained that based on the information supplied, medical necessity has not been established. The Health Plan indicated that there were no documented results of the member's work-up, which would include endoscopy, ultrasound, manometry and biofeedback. . . .

* * *

Recommended Decision:

The MAXIMUS physician consultant determined that sacral nerve stimulation (InterStim implantation) is not medically necessary for treatment of the member's condition.

* * *

The results of the physician consultant's review indicate that this case involves a ■ year-old female who has a history of fecal incontinence. At issue in this appeal is whether sacral nerve stimulation (InterStim implantation) is medically necessary for treatment of the member's condition.

The Health Plan's criteria for sacral nerve stimulation for urinary problems require symptoms for at least 12 months as well as significant disability and that pharmacotherapies with at least 2 drugs and behavioral treatments must fail prior to consideration of a stage I InterStim trial. The MedTronic InterStim insert with indications for bowel control states that it is indicated for treatment of chronic fecal incontinence in patients who have failed or are not candidates for more conservative treatments. The MAXIMUS physician consultant explained that these criteria are in line with the American Society of Colon and Rectal Surgeons Clinical Practice Guideline for the Treatment of Fecal Incontinence, which includes specific recommendations that: 1. A detailed physical examination is an essential component of the evaluation of patients with fecal incontinence. Examples of a detailed rectal examination include presence of patulous anus upon spreading the buttocks, rough estimate of anal resting and squeeze pressures with digital rectal exam, etc. 2. Anorectal physiology testing (manometry, anorectal sensation, volume tolerance, compliance) can be considered to help define the elements of dysfunction and guide management. 3. Dietary and medical management are recommended as first-line therapy for patients with fecal incontinence. 4. Bowel management programs to aid in rectal evacuation are useful in select patients. 5. Biofeedback should be considered as an initial treatment for patients with incontinence and some preserved voluntary sphincter contraction. 6. Sacral neuromodulation may be considered as a first line surgical option for incontinent patients with and without sphincter defects. The physician consultant also explained that the concept of further workup with anorectal physiology testing and conservative medical management, including physical therapy or biofeedback, prior to consideration of surgical treatment with sacral nerve stimulation is also supported by two narrative reviews.

One article evaluated outcomes associated with InterStim placement for medically refractory fecal incontinence using a prospective database from a colorectal surgery practice. This was a highly selected cohort since all patients failed supplemental fiber for anti-diarrheal medicines and 73% failed pelvic floor biofeedback. In addition, the etiology of incontinence in this article was primarily due to obstetric injuries (81%) or rectal prolapse (11%). In this highly selected cohort, InterStim placement resulted in a decrease in the mean number of incontinence episodes measured over a 2 week period. The physician consultant explained that this article is in contrast to this member's case, in which the fecal incontinence was reported to have occurred after colonoscopy and there was no documented failure of medical management or biofeedback.

The consultant indicated that in this member's case, there is information lacking on detailed rectal examination, anorectal physiology testing, which would determine the role for biofeedback, and the use of conservative treatments including dietary changes, medical management with fiber supplementation or anti-diarrheal medications and bowel management programs. The physician

consultant explained that if these conservative treatments fail, then consideration for sacral neuromodulation as a first line surgical option would be appropriate.

Pursuant to the information set forth above and available documentation, the MAXIMUS physician consultant determined that sacral nerve stimulation (InterStim implantation) is not medically necessary for treatment of the member's condition at this time. [References omitted]

The Director is not required to accept the IRO's recommendation. *Ross v Blue Care Network of Michigan*, 480 Mich 153 (2008). However, the IRO's recommendation is afforded deference by the Director. In a decision to uphold or reverse an adverse determination the Director, must cite "the principal reason or reasons why the [Director] did not follow the assigned independent review organization's recommendation." MCL 550.1911(16)(b).

The IRO's analysis is based on extensive experience, expertise and professional judgment. Furthermore, it is not contrary to any provision of the Petitioner's certificate of coverage. MCL 550.1911(15). The Director, discerning no reason why the IRO's recommendation should be rejected, finds that the requested sacral nerve stimulation (InterStim implantation) procedure is not medically necessary at this time and is therefore not a covered benefit.

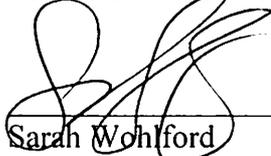
V. ORDER

The Director upholds THC's final adverse determination of January 26, 2016.

This is a final decision of an administrative agency. Under MCL 550.1915, any person aggrieved by this Order may seek judicial review no later than 60 days from the date of this Order in the circuit court for the Michigan county where the covered person resides or in the circuit court of Ingham County. A copy of the petition for judicial review should be sent to the Department of Insurance and Financial Services, Office of General Counsel, Post Office Box 30220, Lansing, MI 48909-7720.

Patrick M. McPharlin
Director

For the Director:



Sarah Wohlford
Special Deputy Director