

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. 145612-001

United Healthcare Insurance Company
Respondent

Issued and entered
this 4th day of February 2015
by **Randall S. Gregg**
Special Deputy Director

ORDER

I. PROCEDURAL BACKGROUND

On January 5, 2015, ██████████, authorized representative of his patient, ██████████ (Petitioner), filed a request with the Director of Insurance and Financial Services for an external review under the Patient's Right to Independent Review Act, MCL 550.1901 *et seq.*

The Petitioner receives health care benefits under a group plan underwritten by United Healthcare Insurance Company (United). The Petitioner's benefits are defined in United's *Choice Plus* certificate of coverage.

The Director notified United of the external review request and asked for the information used to make its final adverse determination. United furnished the requested information on January 5 and 12, 2015. After a preliminary review of the material submitted, the Director accepted the case for external review on January 12, 2015. United submitted additional information on January 30, 2015.

The case involves medical issues so the Director assigned the matter to an independent review organization, which completed its review and submitted its recommendation to the Director on January 26, 2015.

II. FACTUAL BACKGROUND

On October 11, 2013, the Petitioner underwent surgery to remove fibroid tumors from her uterus. The surgery is a radiofrequency ablation procedure and is known by its commercial name, the Acessa System.

United denied coverage, ruling that the procedure is experimental and unproven for the treatment of the Petitioner's condition. The Petitioner appealed the denial through United's internal grievance process. At the conclusion of the internal review process, United issued its final adverse determination

November 20, 2014, affirming its decision. The Petitioner now seeks a review of that adverse determination from the Director.

III. ISSUE

Did United correctly deny coverage for the Petitioner's radiofrequency ablation procedure using the Acessa procedure?

IV. ANALYSIS

Respondent's Argument

In its final adverse determination, United wrote:

[Our] medical director...who specializes in Thoracic and Cardiovascular Surgery, reviewed your appeal. This decision was made based on [our medical policy] Abnormal Uterine Bleeding and Uterine Fibroids. [The medical director's] determination is as follows:

You had removal of tumors in your uterus on October 11, 2013. This used a technique called radiofrequency ablation. This service is not proven effective for your condition. This is because the medical scientific studies do not have comparison groups called control groups. The studies are in small numbers of patients. The studies are not over long timeframes. Your plan medical policy guidelines have concluded further studies are needed on this treatment before it can meet your plan definition of a proven treatment. Your plan requires that proven treatments are supported by careful studies where groups of patients are compared after two or more treatments. This is ideally done if the groups are chosen at random. This treatment has not been studied in this careful way and therefore is considered unproven by your plan. Services that are not proven effective are not covered benefits under your plan.

Petitioner's Argument

The request for external review includes a December 15, 2014 letter from the Petitioner's physician, a portion of which is quoted below:

[Petitioner] is a 48 year old female who presented to this office in September of 2013 with a longstanding history of menorrhagia and uterine fibroids. A pelvic ultrasound performed on 9/11/13 showed a large fibroid measuring 7.4 x 8.21 x 7.21 cm.

[Petitioner] was counseled on the subject of fibroid treatment options including hysterectomy, myomectomy, and uterine artery embolization. She strongly desired preservation of her uterus, as well as, a minimally invasive treatment that would allow her to rapidly return to her normal activities. The Acessa procedure was performed on October 11, 2013. At a follow up appointment on March 19th, 2014, she reported no

menorrhagia, dysmenorrhea, and no bleeding. An ultrasound done that day showed that the fibroid had decreased significantly in size.

As background, the RF Ablation for Uterine Fibroids is a minimally invasive, uterine sparing outpatient alternative for patients with symptomatic uterine fibroids. The procedure utilizes radio frequency energy to destroy each fibroid through a small needle array; the needle is inserted into the abdomen and deployed into each fibroid. Intra-abdominal ultrasound and laparoscopy provide for visualization and guidance of the needle into the fibroids. After the fibroid is ablated, the needle is withdrawn, and the destroyed tissue is reabsorbed by the body. The patient typically resumes normal activity within a week, has significant resolution of symptoms, and dramatic improvements in their quality of life. One advantage of RF ablation is that the destructive energy is directed only to the individual fibroids and thus, unlike uterine artery embolization (UAE), does not affect blood flow to the uterus and the ovaries. As such there is no risk of RF ablation of uterine fibroids affecting ovarian function which is important to many women who worry about early menopause that may be associated with UAE.

It should be brought to the reviewer's attention that United HealthCare's current policy does not encompass recent clinical studies or literature regarding the use of radio frequency (RF) ablation of uterine fibroids. Please refer to the attached Publication Portfolio and Clinical Study Summary. In reviewing the peer-reviewed literature, you will note that three independent studies show consistent 12-month follow-up data. The Chudnoff publication notes the study to be the largest trial conducted to date addressing radio frequency ablation of myomas with a high level of patient satisfaction, low re-intervention rate, and significant improvement in mean blood loss through 12 months.

Director's Review

The *Choice Plus* certificate (page 22) excludes coverage for “experimental or investigational or investigational services.” The question of whether radiofrequency ablation of uterine fibroids utilizing the Acessa procedure was experimental for the treatment of the Petitioner's condition was presented to an independent review organization (IRO) for analysis as required by section 11(6) of the Patient's Right to Independent Review Act, MCL 550.1911(6).

The IRO reviewer is a physician in active practice who is certified by the American Board of Obstetrics and Gynecology and is an assistant professor at a university based school of medicine. The reviewer is a member of the American College of Obstetrics and Gynecology, the Society of Maternal Fetal Medicine, and the Society for Gynecologic Investigation. The reviewer has been published in peer-reviewed literature. The reviewer's report included the following analysis and recommendation:

The use of radiofrequency ablation (The Acessa System) to treat uterine fibroids would be considered experimental/investigational for menorrhagia in the setting of uterine fibroids. This therapy is still under evaluation and is not recommended as an alternative to hysterectomy in the management of symptomatic leiomyomas (fibroids). The Acessa procedure is still under post market study for determination of efficacy and outcomes.

There are no long term outcomes reported for this procedure. There are six ongoing studies registered at clinicaltrials.gov to study the use of Acesa in management of women with leiomyomata (fibroids).

In this case, the enrollee had a diagnosis of menorrhagia. Based upon the recommendations of the American College of Obstetricians and Gynecologists (ACOG) for women who are 40 years of age to menopause, the following therapies would be attempted prior to consideration of surgical intervention. "Late perimenopausal patients may be treated with cyclic progestin therapy, low-dose oral contraceptive pills, the levonorgestrel IUD, or cyclic hormone therapy." Each of these therapies offers advantages of menstrual control and endometrial protection. Although only the contraceptive pill and the levonorgestrel IUD provide contraception, the others provide relief from perimenopausal symptoms, such as hot flashes, night sweats, and vaginal atrophy. The choice of therapy often is guided by the patient's priorities in combination with a consideration of safety. In 120 perimenopausal women who were given continuous estrogen and cyclic progestin or cyclic progestin alone, 86% of women in the combined treatment group experienced cyclic menstrual bleeding, as well as a reduction in vasomotor symptoms. In addition, 76% of these women rated their bleeding as normal in amount and duration.

The efficacy of the levonorgestrel IUD was evaluated in 56 obese perimenopausal women with abnormal uterine bleeding (AUB). The mean age was 42 years and the mean body mass index was greater than 30. At the 48-month follow-up, the satisfaction rate was 75%; amenorrhea and hypomenorrhea were noted with longer use. Thus, there would be medical intervention prior to surgical intervention. If the myoma was 85% in the cavity, the surgical treatment of choice would be resection by hysteroscopic resection of the myoma. Thus, the standard of care would require a trial of medical therapy followed by surgical resection by hysteroscopic resection if medical therapy failed at the time of this presentation.

The Acesa System has not been cleared for premarket approval by the US Food and Drug Administration (FDA) for use in the treatment of fibroid. There is a 510k approval for the Acesa Guidance system for prescription use. Premarket Approval (PMA) is the most stringent type of device marketing application required by FDA. A PMA is an application submitted to FDA to request approval to market. Unlike premarket notification, PMA approval is to be based on a determination by FDA that the PMA contains sufficient valid scientific evidence that provides reasonable assurance that the device is safe and effective for its intended use or uses per the FDA website. Thus, this medical device has received an FDA 510k approval but not a PMA.

There are no long term outcomes or efficacy studies for the Acesa System to demonstrate [that] the benefits of this system are likely to be more beneficial than medical therapy followed by hysteroscopic resection if medical therapy failed. There is no medical or scientific evidence to support the use of the Acesa system in management of leiomyomas for long term efficacy or benefit to the patient at this time.

Thus, there would be medical intervention prior to surgical intervention. If the myoma was 85% in the cavity, the surgical treatment of choice would be resection by hysteroscopic resection of the myoma. Thus, the standard of care would require a trial of medical therapy followed by surgical resection by hysteroscopic resection if medical therapy failed at the time of this presentation. This is based upon American College of Obstetricians and Gynecologists (ACOG) Practice Bulletins as referenced below.

Recommendation:

It is the recommendation of this reviewer that the denial issued by United Healthcare Insurance Company for the use of radio frequency ablation (The Acessa System) of uterine fibroids be upheld. [Citations omitted]

The Director is not required to accept the IRO's recommendation. However, a recommendation from the IRO 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. The Director can discern no reason why the IRO's recommendation should be rejected in the present case.

The Director finds that radiofrequency ablation of uterine fibroids using the Acessa procedure is an experimental treatment and is, for that reason, not a covered benefit.

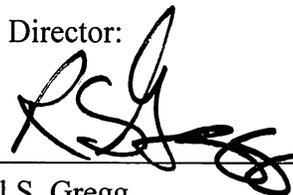
V. ORDER

The Director upholds United Healthcare Insurance Company's November 20, 2014, final adverse determination.

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 sixty days from the date of this order in the circuit court for the 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.

Annette E. Flood
Director

For the Director:



Randall S. Gregg
Special Deputy Director