RICK SNYDER
GOVERNOR

STATE OF MICHIGAN
DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS
MICHIGAN ADMINISTRATIVE HEARING SYSTEM
Christopher Seppanen
Executive Director

SHELLY EDGERTON
DIRECTOR

[redacted]

Date Mailed: March 27, 2017
MAHS Docket No.: 17-000917
Agency No.: [redacted]
Petitioner: [redacted]

ADMINISTRATIVE LAW JUDGE: Steven Kibit

DECISION AND ORDER

This matter is before the undersigned Administrative Law Judge pursuant to MCL 400.9 and 42 CFR 431.200 *et seq.,* and upon the Petitioner's request for a hearing.

After due notice, a telephone hearing was held on March 14, 2017. Petitioner appeared and testified on her own behalf. [redacted], Appeals Review Officer, represented the Respondent Department of Health and Human Services (DHHS or Department). [redacted] testified as a witness for the Department.

ISSUE

Did the Department properly deny Petitioner's prior authorization request for a spinal electrical bone stimulator?

FINDINGS OF FACT

The Administrative Law Judge, based upon the competent, material and substantial evidence on the whole record, finds as material fact:

1. Petitioner is a forty-seven-year-old Medicaid beneficiary. (Exhibit A, page 8).

2. On November 15, 2016, the Department received a prior authorization request for a spinal electrical bone stimulator submitted on Petitioner's behalf. (Exhibit A, pages 8-21).

3. In that prior authorization form, Petitioner was identified as having been diagnosed with intraoperative and post-procedural complications and disorders of the musculoskeletal system. (Exhibit A, page 8).

4. Petitioner had back surgery in June of 2006. (Testimony of Petitioner).

5. Supporting medical documentation was also submitted along with the prior

authorization request, but any imaging studies could not be read because they were illegible. (Exhibit A, pages 15-19; Testimony of Petitioner; Testimony of Department's witness).

6. The medical documentation did include progress notes related to an October 10, 2016 medical visit and Petitioner's history of neck and back pain since April 7, 2013. (Exhibit A, pages 11-15).

7. On December 16, 2016, the Department sent Petitioner written notice that the request for a spinal electrical bone stimulator was denied. (Exhibit A, pages 6-7).

8. The reason given in the notice was that much of the notes and images in the request were illegible and there was no clear explanation for why the device was both indicated and not experimental or investigational. (Exhibit A, page 6).

9. On January 18, 2017, the Michigan Administrative Hearing System (MAHS) received the request for hearing filed in this matter regarding that denial. (Exhibit A, pages 5-7).

CONCLUSIONS OF LAW

The Medical Assistance Program is established pursuant to Title XIX of the Social Security Act and is implemented by Title 42 of the Code of Federal Regulations (CFR). It is administered in accordance with state statutes, the Social Welfare Act, the Administrative Code, and the State Plan under Title XIX of the Social Security Act Medical Assistance Program.

The policy regarding coverage osteogenesis stimulators like the one requested by Petitioner is found in the Medicaid Provider Manual (MPM) and, with respect to such devices, the applicable version of the MPM states in part:

2.29 OSTEOGENESIS STIMULATORS

Definition	An Osteogenesis Stimulator is a device that provides electrical or ultrasonic signal stimulation to augment bone repair. Osteogenesis stimulators include: ▪ Noninvasive electrical stimulator characterized by an external power source which is attached

	to a coil or electrodes placed on the skin or on a cast or brace over a fracture or fusion site; or ▪ Noninvasive electrical multi-level spinal stimulator which involves three or more vertebrae (e.g., L3-L5, L4-S1, etc.); or ▪ Noninvasive low intensity ultrasound stimulator which produces pulsed ultrasonic signals rather than electricity to stimulate bone repair by applying the signal to the skin surface at the fracture site. A long bone is limited to the clavicle, humerus, radius, ulna, femur, tibia, fibula, metacarpal, or metatarsal. The FDA classifies osteogenesis stimulators as Class III devices.
Standards of Coverage	A **noninvasive, nonspinal electrical or low intensity ultrasonic osteogenesis stimulator** may be covered when other treatment methods have been ineffective and when one of the following applies: ▪ There is a nonunion of a long bone fracture with radiographic evidence which indicates that the fracture healing has ceased for three or more

	months prior to starting treatment with the osteogenesis stimulator. ▪ There is a nonunion of a nondisplaced scaphoid fracture. ▪ If there is failed fusion of a joint, other than in the spine, where a minimum of nine months has elapsed since the surgery. ▪ Congenital Pseudoarthrosis not due to lack of skeletal maturity. ▪ The fracture gap is < = 1 cm. ▪ A nonunion of a long bone fracture as described by the appropriate ICD code. Treatment using the above stimulators may not be provided concurrently. A **spinal electrical osteogenesis stimulator** may be covered when other treatment methods have been ineffective and when one of the following applies: ▪ There is a failed spinal fusion where a minimum of nine months has elapsed since the last surgery.

	▪ Following multi-level (three or more vertebrae) spinal fusion surgery without instrumentation. ▪ Clinical indication in cervical spine fusions with instrumentation (reviewed on case by case basis). ▪ Following spinal fusion surgery where there is a history of a previously failed spinal fusion at the same level(s). How long ago was the failure? ▪ May also be indicated as an adjunct to high-risk fusion; cases that meet one or more of the following criteria: ➢ Smoking (cessation attempts) ➢ Diabetes ➢ Metabolic disease where bone healing is likely to be compromised ➢ Grade III or greater spondylolisthesis Treatment using the above stimulator may not be provided concurrently with nonspinal osteogenesis stimulators.
Covered Conditions	The current International Classification of Diseases (ICD) code related to the

	type and location of the fracture must be reported by the physician on the prescription/order and in the medical documentation . . .

* * *

Non-Covered Conditions	Medicaid does not cover the use of a bone growth stimulator for any of the following indications as it is considered experimental, investigational, or unproven (not all inclusive): ▪ Fresh fractures (other than when using ultrasound bone stimulation for the tibia or radius) ▪ Toe fractures ▪ Sesamoid fractures ▪ Avulsion fractures ▪ Osteochondral lesions ▪ Stress fractures ▪ Displaced fractures with malalignment ▪ Synovial pseudoarthrosis ▪ Fractures related to malignancy ▪ The bone gap is either > 1 cm or > one-half the diameter of the bone ▪ Primary surgeries with

	current internal fixation techniques (i.e., pedical screw fixation and variants) ▪ Lack of skeletal maturity (refer to congenital pseudoarthrosis)
Documentation	Documentation must be less than 90 days old and include all of the following: ▪ Diagnosis/medical condition related to the need for the device. ▪ Alternative treatment methods tried and results. ▪ For a diagnosis of fracture nonunion, reports of sequential x-ray results for a period of no less than 90 days and office records, including previous treatments and operative procedures (if any). ▪ For a spinal fusion procedure, pertinent office and/or hospital records as well as a legible, complete description of indications for electrical stimulation. A copy of the operative report(s) may be required. ▪ Other modalities still to be used (include type and location).
PA Requirements	PA is required and

	evaluated on a case by case basis.
Payment Rules	Osteogenesis stimulators are **rental only** items (up to three months) and are inclusive of the following: ▪ All accessories needed to use the unit (e.g., electrodes, wires, cables, coupling gel, etc.). ▪ Education on the proper use and care of the equipment. ▪ Routine servicing and all necessary repairs or replacements to make the unit functional based on manufacturer warranty. For consideration of rental beyond the initial three months, a new MSA-1653-B must be submitted, along with physician documentation establishing medical reason(s) for continued need.

MPM, October 1, 2016 version
Medical Supplier Chapter, pages 65-66

Here, the Department denied Petitioner's prior authorization request for a spinal electrical bone stimulator pursuant to the above policies. Specifically, its witness testified that the biggest issue with the request was that all of the images and some of the notes were illegible, which made it impossible to determine whether Petitioner's request met the above criteria. The Department's witness also testified that the Department needs a specific and detailed explanation as to why the bone stimulator is being requested, why it is necessary, and how it meets the above standards of coverage.

In response, Petitioner agreed that all of the images and some of the pages submitted

along with the prior authorization request are illegible. She also indicated that she could not explain why such poor copies were sent, but that she has been trying to get a bone stimulator for years and will have a new request submitted, along with her new prescription and legible medical information.

Petitioner bears the burden of proving by a preponderance of the evidence that the Department erred in denying the prior authorization request. Moreover, the undersigned Administrative Law Judge reviews the Department's decision in light of the information that was available at the time the decision was made.

Given the available evidence and applicable policies in this case, the undersigned Administrative Law Judge finds that Petitioner has failed to meet that burden of proof and the Department's decision must therefore be affirmed. As indicated by the Department, and undisputed by Petitioner, the imaging studies submitted along with the prior authorization are completely unreadable and therefore fail to support Petitioner's request. Moreover, while the portions of the medical documentation that are legible do generally describe Petitioner's history of pain since April of 2013, the general progress notes fail to satisfy the documentation requirements found in the MPM and are insufficient to establish that the applicable standards of coverage are met. Accordingly, based on what the Department received, its decision was proper.

To the extent that Petitioner's has new or updated information she wants to provide, she and her doctor are free to submit a new prior authorization request at any time along with that information. However, with respect to the decision at issue in this case, Petitioner has failed to show that the Department erred and the Department's decision must therefore be affirmed.

DECISION AND ORDER

The Administrative Law Judge, based on the above Findings of Fact and Conclusions of Law, decides that the Department properly denied Petitioner's prior authorization request.

IT IS, THEREFORE, ORDERED that:

The Department's decision is **AFFIRMED**.

SK/tm

Steven Kibit
Administrative Law Judge
for Nick Lyon, Director
Department of Health and Human Services

NOTICE OF APPEAL: A party may appeal this Order in circuit court within 30 days of the receipt date. A copy of the circuit court appeal must be filed with the Michigan Administrative Hearing System (MAHS).

A party may request a rehearing or reconsideration of this Order if the request is received by MAHS within 30 days of the date the Order was issued. The party requesting a rehearing or reconsideration must provide the specific reasons for the request. MAHS will not review any response to a request for rehearing/reconsideration.

A written request may be mailed or faxed to MAHS. If submitted by fax, the written request must be faxed to (517) 335-6088; Attention: MAHS Rehearing/Reconsideration Request.

If submitted by mail, the written request must be addressed as follows:

Michigan Administrative Hearings
Reconsideration/Rehearing Request
P.O. Box 30763
Lansing, Michigan 48909-8139

DHHS Department Rep.

[redacted]

[redacted]

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