

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. 149215-001

Blue Cross Blue Shield of Michigan,

Respondent.

Issued and entered
this 4th day of September 2015
by Joseph A. Garcia
Special Deputy Director

ORDER

I. PROCEDURAL BACKGROUND

 (Petitioner) was denied coverage for mental health treatment by his health plan. On August 5, 2015, he 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 Director reviewed the request and accepted it on August 12, 2015.

The Petitioner receives health care benefits through a group health plan underwritten by Blue Cross Blue Shield of Michigan (BCBSM). The Director notified BCBSM of the external review request and asked for the information used to make its final adverse determination. BCBSM provided its response on August 19, 2015.

To address the medical issue in the case, the Director assigned the matter to an independent medical review organization which provided its analysis and recommendation on August 26, 2015.

II. FACTUAL BACKGROUND

The Petitioner's health care benefits are defined in the *MESSA Choices / Choices II Group Insurance for School Employees* coverage booklet. New Directions Behavioral Health (New Directions) administers the plan's mental health and substance abuse benefits for BCBSM.

The Petitioner has a recurrent major depressive disorder. On June 1, 2015, his psychiatrist started him on transcranial magnetic stimulation (TMS) to treat his condition. He continued TMS therapy through July 14, 2015 (30 treatments).

When the Petitioner asked for coverage of the TMS, New Directions, acting for BCBSM, denied the request on the basis that TMS was not medically necessary. The Petitioner appealed the denial

through the plan's internal grievance process. At the conclusion of that process, New Directions maintained its denial in a final adverse determination dated July 14, 2015. The Petitioner now seeks a review of that final adverse determination from the Director.

III. ISSUE

Is TMS medically necessary to treat the Petitioner's condition?

IV. ANALYSIS

Petitioner's Argument

In an August 17, 2015, letter, submitted for this external review, the Petitioner's psychiatrist explained the need for the TMS:

I first saw [the Petitioner] on May 12, 2015 where he was very, very depressed, frustrated by the side effects from his medicine, as well as the lack of efficacy of the different antidepressants he had tried. At that time, he scored 16 on the Hamilton Depression Rating Scale, which indicated moderate depression. He scored 29 on the Beck Depression Inventory, which is also considered moderate depression from 21-30, and just barely off of severe depression of 31-40.

[The Petitioner] underwent 30 treatments of TMS beginning June 1, 2015 on a daily basis with the last treatment on July 14, 2015.

To say that he did well and his depression improved is quite an understatement as he had an excellent response, felt so much better, had more energy, regained hopefulness, began to decrease his antidepressant medications, and his libido began to return. His rating scale scores reflected this change as he scored 3 on the Hamilton Depression Rating Scale (normal is 0-7) and 4 on the Beck Depression Inventory (1-10 classified as "normal ups and downs") at the end of treatment, scores much, much lower than before TMS treatments.

* * *

In summary, my original feeling was that these treatments were medically warranted and would be beneficial. This was certainly proven true by [the Petitioner's] excellent response to TMS treatment and greatly decreased depression.

BCBSM's Argument

In its final adverse determination, New Directions told the Petitioner:

. . . Under the terms, conditions, and limitations of your MESSA plan, a service must be medically necessary to be covered. A service that is "medically necessary" is one that provides safe and adequate care in the least restrictive and most appropriate setting.

New Directions has completed its review of your standard level internal appeal. . . . This review was completed by a different board certified psychiatrist at New Directions not involved in the previous decision. . . .

Based upon that review, this letter confirms that New Directions is upholding its original determination that Transcranial Magnetic Stimulation (rTMS) services provided on May 28, 2015 to completion of treatment . . . are not medically necessary

Specifically, the clinical information that New Directions received did not meet the requirements set forth in Michigan's Medical Policy for Transcranial Magnetic Stimulation (rTMS). After reviewing Michigan's Medical Policy for rTMS that takes into account age, progress of treatment, diagnosis and other programs available, we have determined that your care can be provided in a less intensive restrictive setting, such as Psychiatric Outpatient due to the following reason(s):

There were no attempts at medication augmentation. Various Rating Scales were cited but it was unclear when they referred to and what stage(s) of treatment [the Petitioner] was in. There was no active psychotherapy coincident with the treatments. His psychiatric care is monitored by New Directions Behavioral Health and this organization has published guidelines that are consistent with the now well-known STAR*D protocol and that follows methodically sound and biochemically sophisticated procedures. The psychiatrist involved in [the Petitioner's] care did not follow the recommended protocols published by NDBH and in fact did not even follow the alternatives treatments that [another physician] also proposed. While it is certain that [the Petitioner] did / does suffer from a Major Depressive Disorder, his treatment did NOT qualify him to be referred to as a Treatment Resistant Depression nor was his immediate treatment history deemed to be consistent with the Medical Necessity Criteria as Outline by NDBH.

Director's Review

In order to be covered by BCBSM, a service must be medically necessary. Medically necessary, as it applies to professional provider services, is defined in the booklet (pp.74-75):

Health care services that a professional provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

- In accordance with generally accepted standards of medical practice;
- Clinically appropriate, in terms of type, frequency, extent, site and duration, and considered effective for the member's illness, injury or disease and
- Not primarily for the convenience of the member, professional provider, or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that member's illness, injury or disease.

NOTE: "Generally accepted standards of medical practice" means standards that, are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, physician or provider society recommendations and the views of physicians practicing in relevant clinical areas and any other relevant factors.

The question of whether TMS was medically necessary to treat the Petitioner was presented 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 psychiatry and has been in practice for more than 15 years. The IRO report included the following analysis and recommendation:

Recommended Decision:

The MAXIMUS physician consultant determined that the transcranial magnetic stimulation therapy services that the member received were medically necessary for treatment of his condition.

Rationale:

Transcranial magnetic stimulation is a non-invasive brain stimulating procedure utilized in the treatment of major depressive disorder. This procedure has been cleared by the United States Food and Drug Administration (FDA). The MAXIMUS physician consultant noted that transcranial magnetic stimulation (TMS) tends to be very well tolerated with fewer barriers than electroconvulsive therapy. The physician consultant indicated that TMS is likely cost effective when considering patient morbidity and lost productivity, coupled with the financial burden to the medical system due to ineffective medication management that manifests as more frequent clinic visits and multiple prescriptions, with the possible need for treatment in a more restrictive setting to address suboptimal treatment of clinical depression. Following the FDA clearance of this procedure, the American Psychiatric Association investigated this treatment and the available literature and endorsed TMS in 2010 for the acute phase treatment of major depressive disorder after failure of at least one antidepressant trial. The consultant explained that this endorsement is suggestive that there is sufficient evidence in the published, peer-reviewed medical literature to support the use of transcranial magnetic stimulation.

In this member's case, his chronic affective illness was not disputed. The physician consultant indicated that the member had pursued, but not exhausted other standard therapies used to combat depression. The consultant explained that considering the member's medical records, the endorsement from the American Psychiatric Association and the expanding peer-reviewed literature base, transcranial magnetic stimulation represented a safe, appropriate treatment that was consistent with good medical practice in the United States and that was reasonable expected to improve his condition and prevent a more serious episode of illness.

Pursuant to the information set forth above and available documentation, the MAXIMUS physician consultant determined that the transcranial magnetic stimulation therapy services that the member received were medically necessary for treatment of his condition. [Citations 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 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. In addition, the IRO's recommendation 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 in this case, finds that TMS therapy is medically necessary to treat the Petitioner's condition and is therefore a covered benefit.

V. ORDER

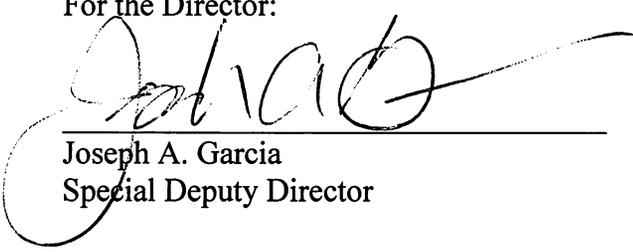
The Director reverses BCBSM's July 14, 2015 adverse determination. BCBSM shall immediately cover the Petitioner's TMS treatment from June 1 through July 14, 2015, subject to any applicable terms and conditions of the certificate, and shall, within 7 days of providing coverage, furnish the Director with proof it has implemented this Order.

To enforce this Order, the Petitioner may report any complaint regarding the implementation to the Department of Insurance and Financial Services, Health Care Appeals Section, at this toll free number: (877) 999-6442.

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 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:



Joseph A. Garcia
Special Deputy Director