

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

In the matter of:

[REDACTED]

Petitioner,

v

File No. 149107-001-SF

State of Michigan, Plan Sponsor,

and

Blue Cross Blue Shield of Michigan, Plan Administrator,

Respondents.

Issued and entered
this 31st day of August 2015
by Randall S. Gregg
Special Deputy Director

ORDER

I. PROCEDURAL BACKGROUND

[REDACTED] (Petitioner) was denied coverage by his health plan for a therapy to treat his glioblastoma. On July 30, 2015, Tanya Lane, the Petitioner's authorized representative, filed a request with the Director of Insurance and Financial Services for an external review of that denial under Public Act No. 495 of 2006 (Act 495), MCL 550.1951 *et seq.*

After a preliminary review of the information submitted, the Director accepted the Petitioner's request on August 6, 2015. Section 2(2) of Act 495, MCL 550.1952(2), authorizes the Director to conduct this external review as though the Petitioner were a covered person under the Patient's Right to Independent Review Act, MCL 550.1901 *et seq.*

The Petitioner receives health care benefits through a retiree health plan sponsored by the State of Michigan (referred to as "the State Health Plan PPO" or "the plan"), a self-funded governmental health plan as defined in Act 495. Blue Cross Blue Shield of Michigan (BCBSM) administers the plan. The Director immediately notified BCBSM of the external review request and asked for the information it used to make its final adverse determination. The Director received BCBSM's response on August 13, 2015.

To address the medical issue in this case, the Director assigned it to an independent medical review organization which provided its analysis and recommendation on August 20, 2015.

II. FACTUAL BACKGROUND

The Petitioner's benefits are described in a booklet called *Your Benefit Guide - State Health Plan PPO for Non-Medicare Retirees*¹ (the benefit guide).

In 2009 the Petitioner was diagnosed with glioblastoma multiforme (GBM), a type of malignant brain tumor. He had surgery, chemo-radiation therapy, and an autologous bone marrow transplant. In 2015 he was found to have recurrent GBM and his physician asked the plan to authorize treatment with Optune (also known as the NovoTTF-100A System), a form of noninvasive therapy that targets cancer cells in the brain with electronic waves called "tumor treating fields."

BCBSM denied the request, saying that Optune therapy was experimental or investigational and therefore not a covered benefit.

The Petitioner appealed the denial through the plan's internal grievance process. BCBSM held a managerial-level conference and then issued a final adverse determination dated June 23, 2015, upholding the denial. The Petitioner now seeks a review of that final adverse determination from the Director.

III. ISSUE

Did BCBSM correctly deny coverage for the Optune therapy?

IV. ANALYSIS

Respondent's Argument

In its final adverse determination, BCBSM told the Petitioner's authorized representative:

... After review, it was confirmed that the denial of authorization is correct. The BCBSM/BCN Joint Uniform Medical Policy Committee (JUMP) has determined that the requested procedure code E0766 - Electrical stimulation device used for cancer treatment is considered investigational / experimental. Investigational / experimental services are not a benefit according to the terms of [the Petitioner's] coverage.

* * *

An investigational status means that the safety and effectiveness of a particular technology has not been definitively determined. An established technology means that the safety and effectiveness have been definitively determined.

¹ Effective October 2014.

Investigational medical policies are reviewed regularly to guarantee that the investigational status continues to be supported by the evidence.

* * *

. . . [O]ur medical consultant reviewed the information included in your appeal and concluded:

The member has recurrent glioblastoma, a brain tumor. The provider is requesting to use Electrical Tumor Treatment Fields. According to the current BCBSM policy, "Tumor-Treatment Fields Therapy for Glioblastoma," this procedure is considered experimental and investigational. The clinical utility has not been fully demonstrated with the results of the published literature.

As outlined above, our medical consultant has determined that the services are investigational / experimental. Because [the Petitioner's] coverage specifically excludes services that are investigational / experimental in nature, authorization cannot be approved.

Petitioner's Argument

In his request for an external review, the Petitioner's authorized representative wrote:

Blue Cross Blue Shield Michigan is denying the FDA-Approved cancer treatment, Optune. Optune is an electrical stimulation device used for cancer treatment and has been prescribed by [the Petitioner's physician].

In a letter dated July 30, 2015, sent with the external review request, the Petitioner's authorized representative further said:

Please review the inclusion of the [Petitioner's] treatment in the NCCN Guidelines for Recurrent Glioblastoma as NEW information specific in obtaining coverage for Optune and associated services for treatment. The addition of this therapy within the NCCN Guidelines establishes this as a standard of care option for GBM patients. Please review for In Network EXCEPTION.

* * *

. . . The health outcomes are as good or better than usual treatments. . . .
Novocure has many current patients who have positive health effects.

. . . [C]overage for this condition has been approved, based on Medical Director review, physician to physician review, or outside review, by many payers. The fact that these payers, ranging in size from the largest insurers in the country to smaller more progressive plans, are covering this procedure indicates that there is enough "proven" evidence to warrant coverage . . . in treating recurrent glioblastoma.

The Petitioner's representative believes that Optune therapy is not experimental for treating recurrent GBM and should be covered by the plan.

Director's Review

The benefit guide (p. 38) has this provision under "What is not covered":

In addition to the exclusions listed with the benefit, the following services are not covered under the SHP PPO:

* * *

- Services, care, devices or supplies considered experimental or investigative

The benefit guide (p. 54) defines "experimental or investigational" as

a service, procedure, treatment, device or supply that has not been scientifically demonstrated to be safe and effective for treatment of the patient's condition. BCBSM makes this determination based on a review of established criteria, such as:

- Opinions of local and national medical societies, organizations, committees or governmental bodies
- Accepted national standards of practice in the medical profession
- Scientific data such as controlled studies in peer review journals or literature
- Opinions of the Blue Cross and Blue Shield Association or other local or national bodies

To determine if the Optune therapy was experimental or investigational for the treatment of Petitioner's glioblastoma, the Director presented the issue 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 physician reviewer is certified by the American Board of Psychiatry and Neurology, is extensively published in the peer reviewed literature, and is in active practice. The IRO report included the following analysis and recommendation:

It is the determination of this reviewer that treatment with the Optune electrical stimulation device is not considered experimental / investigational for treatment of the enrollee's condition.

Clinical Rationale for the Decision:

The Optune NovoTTF-100A has been thoroughly studied and verified in pre-

clinical testing using in vitro and animal systems and has been shown to disrupt tumor cell replication.

The National Comprehensive Cancer Network (NCCN) Guidelines for Treatment of Central Nervous System (CNS) Cancers reports from 2013, 2014 and 2015 included the use of NovoTTF-100A as an option for treatment of patients with recurrent or progressive GBM, citing Category 2B evidence in 2013 and 2015. The NCCN Guidelines are a very important practice guideline that are formulated by physicians from the National Comprehensive Cancer centers around the country, and so are looked at as a benchmark for cancer treatment options and approaches. Having the NovoTTF-100A device listed in the pathway for recurrent and progressive GBM is proving its legitimacy as a treatment option.

Once a patient with GBM has failed traditional chemo-radiation therapy (RT) and adjuvant temozolomide (TEM), there are very few FDA-approved options available for consideration. Additional chemotherapy is one option, consisting of BEV in most patients, especially if there is a large enhancing lesion with significant edema. However, this enrollee has already been exposed to BEV and still has recent tumor progression. Another FDA-approved chemotherapy approach is available, which involves surgical resection and receiving carmustine wafers. That Option is not possible in this enrollee's case, since his tumor is now considered inoperable. An additional FDA-approved option is to use "therapeutic treating fields," in particular the Optune NovoTTF-100A device.

The use of the NovoTTF-100A device is not experimental or investigational for the management and treatment of the enrollee's condition. The enrollee has a heavily pre-treated GBM that has been exposed to all of the other FDA-approved treatment approaches except for the use of the implantable carmustine wafers since his tumor is now inoperable. The NovoTTF-100A device is FDA-approved for use in recurrent or progressive GBM, and is also listed as a viable option in this clinical setting in the 2013, 2014, and 2015 NCCN CNS Tumor Guidelines. In the setting of recurrent or progressive GBM, the Optune electrical array device has the full approval of the FDA.

Since the enrollee has exhausted all of the FDA-approved chemotherapy choices and cannot receive RT or surgery, the use of the NovoTTF-100A device is now a necessary option. This device in this clinical setting is consistent with the latest NCCN CNS Tumor Guidelines. Using the Optune electrical array device is likely to be beneficial for this enrollee, as shown by the evidence discussed above, and in the references cited below. For these reasons, the use of the NovoTTF-100A is medically necessary, appropriate, and not considered experimental or investigational for the enrollee's condition.

Recommendation:

It is the recommendation of this reviewer that the denial issued by [BCBSM] for

treatment with the Optune electrical stimulation device be overturned.

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 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 to reject the IRO's recommendation, finds that Optune therapy is not experimental or investigational for treating the Petitioner's conditions and is, therefore, a covered benefit under the terms of the plan's benefit guide.

V. ORDER

The Director reverses BCBSM's final adverse determination of June 23, 2015. BCBSM shall immediately cover the Petitioner's Optune therapy and shall, within seven 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 its implementation to the Department of Insurance and Financial Services, Health Care Appeals Section, at this toll free telephone 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 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



Randall S. Gregg
Special Deputy Director