




Patient Reimbursement Guide

Brainsway Deep Transcranial
Magnetic Stimulation (TMS) Treatment

Obtain Coverage - the Right Way



Brainsway



Ever since Brainsway Deep TMS was approved by the FDA in 2013 for the treatment of depression, more and more health plans have been recognizing the efficacy of our treatment and adding coverage for Deep TMS to their benefits. The list of payers is constantly growing, and is regularly updated on the Brainsway website.

This guide will help you understand how to obtain insurance coverage for Brainsway Deep TMS treatment, take an active part in the reimbursement process and how to maximize its efficiency.



The guide does not replace consultation with a mental health professional, nor does it indicate that Brainsway Deep TMS is the right treatment for you. The Food and Drug Administration cleared Brainsway Deep TMS for the treatment of Major Depressive Disorder in patients who did not benefit from antidepressant treatment in the current depressive episode. Brainsway does not support any promotion of its system for off-label indications, and has a strict non-tolerance policy against any billing of third parties (including Medicare) for non-approved uses.



How Does Health Insurance Work?

- A health insurance policy (also called a "health plan") is an agreement between you or your employer and your health insurance company.
- The insurance policy specifies which services are covered and which are not. It may also include coverage guidelines for specific services.
- Every insurance policy includes a process for appealing decisions of non-coverage and claim denials.
- The insurance company is obligated to provide you with information on this process.



What is a Prior Authorization/Precertification Request?

A prior authorization request is a procedure under which a doctor asks the insurance company to confirm that an elective service, such as Deep TMS, will be covered, based on your insurance policy and medical history. Even when the insurance does not require prior authorization for outpatient services, many Deep TMS providers insist on receiving a written notice that the treatment is approved, in order to avoid non-payment for services rendered.



What is a Prior Authorization Request? - Continue

- The doctor should submit a letter of medical necessity (LOMN) with the prior authorization request.
- In the LOMN, the doctor should describe the patient's diagnosis, medical history, how they can benefit from Deep TMS and why this is the best treatment option.
- The insurance company will respond to the doctor or the patient.
- In general, when Deep TMS is included in the health plan and the patient is eligible for the treatment, obtaining coverage should be fairly simple.
- Nevertheless, since Deep TMS is considered a new technology, sometimes insurers may initially deny coverage for this treatment.
- In cases where the insurer does not recommend Deep TMS or where it is not considered to be the "treatment of choice" for the patient's clinical status, the doctor may determine that it is worthwhile to convince the insurance company that Deep TMS is medically necessary for this particular patient. This process is known as an appeal process.



What is The Appeal Process?

The appeal process is a formal process through which patients and their doctors can try to overturn the insurance company's denial for a certain service, such as Deep TMS.

- State and federal laws require the insurer to address appeals fairly and in a timely fashion.
- Besides the doctor, a patient's employer can also be involved in the appeal process. There are also patient advocacy groups that can support patients in handling appeals to insurance companies.

Every insurance company has its own standard for the appeal process, but most plans allow 3 levels of appeals:

1

First Level Appeal

- The doctor asks that an initial denial be reconsidered.
- The doctor supplies all relevant information about the patient's medical history and the treatment plan.
- The doctor may request that the case be considered individually.
- The patient writes a personal letter to accompany the appeal. The letter should explain the patient's condition in detail, why Deep TMS is needed and why the patient should be entitled to coverage under the insurance plan.

2

Second Level Appeal

- The doctor requests a full and fair review of the request. This is also called a peer-to-peer review, in which an expert doctor that is not affiliated with the insurer will review the case.
- During the review the expert should speak to the doctor and allow the case to be presented directly.
- The doctor can request that the insurer choose a psychiatrist who is experienced with treatment-resistant depression somatic methods (e.g. TMS/ECT/VNS) to review the appeal. However, the insurance company is not obligated to comply with this request.
- Oftentimes, this is the stage for the patient's employer to step in, as well as a patient advocacy group.

3

Third Level Appeal

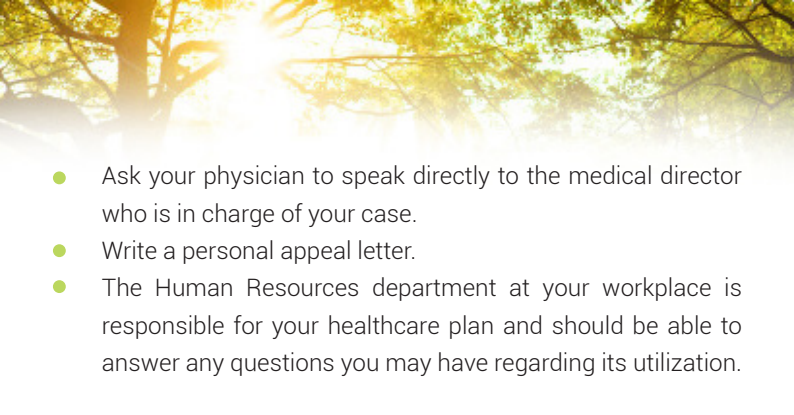
- The doctor appeals to an external organization to evaluate the case. In the case of commercial plans, this evaluation is performed by an Independent Review Organization (IRO); In the case of Medicare patients, level 3 is handled by a single Administrative Law Judge (ALJ), usually over the phone.
- After the third level appeal is submitted, the appeal process is fully utilized. The patient may ask for an expedited review to speed up the request, but the insurer is not obligated to meet this request.



What Can Patients Do to Succeed in the Appeal Process?

Your input is very important at all stages of the appeal process. Obviously, you must ensure that all representations made are accurate and do not embellish the truth regarding your case. That said, there are a few things you can do to keep the process moving and increase the chances of success for your appeal:

- Call the insurer's authorization department. Have them send you the information and forms you may need at different stages of the appeal.
- You can contact your local Division of Consumer Affairs or Office of the Ombudsman to help you understand the appeal process.
- Keep regular contact with the representative assigned to your case to make sure your case is being addressed properly.
- **Keep a record of all contacts with your insurer, as well as copies of every document you send them. Record every phone call you make, note the date, who you spoke to, the topics you discussed and the outcome of the call.**
- **Stay on top of the deadlines that you need to meet. Failing to meet a deadline may damage your right to appeal!**

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- Ask your physician to speak directly to the medical director who is in charge of your case.
 - Write a personal appeal letter.
 - The Human Resources department at your workplace is responsible for your healthcare plan and should be able to answer any questions you may have regarding its utilization.



Writing an Effective Appeal Letter

- Use your own words. Avoid catchphrases and standard wording. Be polite and informative.
- Review the denial letter and understand the reason for denial.
- Specify in your letter what decision you are appealing. Emphasize the facts truthfully and attach supporting evidence to your claim.
- Describe your condition and how it affects your life - relationships, daily routine and work. Detail your response to previous and current medications and the side effects you've experienced. Explain why you think Deep TMS would be beneficial for you, and why you think you're entitled to Deep TMS coverage under your healthcare policy.
- Address every inclusion/exclusion criterion in the policy to show that you meet all of the insurer's requirements for Deep TMS. If you are not sure what the criteria are, ask your Deep TMS physician to help you with this.



- Include the following information:
- Your physician's name, name of practice, medical license number and contact information, your insurance ID number and claim number, your contact information (address, fax, phone numbers, email)
- State that both you and your physician are available to answer questions.
- Label your appeal as URGENT or EXPEDITED.
- State the timeframe in which you expect to get a response.
- Send your appeal by certified mail. Save the delivery receipt and confirm that it was received



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Important: Brainsway provides its "Reimbursement on Demand" service and related information for your convenience only. These services and all related information are not recommendations regarding clinical practice. Brainsway does not make any representations or warranties regarding payment, and there are no guarantees of payment by any payer. It is the absolute and sole responsibility of the provider to ensure that appropriate claims and charges for services rendered are submitted. In the event that a favorable coverage determination is not achieved, Brainsway is not and shall not be liable for any cost whatsoever, including those related to the patient's medical treatment. Please be advised that Brainsway Deep TMS has been cleared for the treatment of Major Depressive Disorder (MDD) only, subject to the protocol approved by the FDA in its issuance of Brainsway's 510(k) clearance. Brainsway has not been cleared to date by the FDA for the treatment of any other indications, and may not promote or market the use of its products for the treatment of any such non-cleared indications. It is absolutely prohibited for providers to submit claims for reimbursement to any governmental or third-party payers for non-approved uses of the system.



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