

Sample Appeal Letters

Appeals

Payers who deny coverage usually do so for one of these three reasons:

- The therapy is investigational / experimental
- The therapy is not medically necessary
- The therapy is not a standard of care

If the reason for denial is that the therapy is considered “investigational / experimental,” the payer’s letter of coverage denial may include phrases such as:

- experimental
- investigational
- insufficient comparative data
- no evidence of a short and long-term efficacy
- has not been proven to be safe and effective
- not approved by the Food and Drug Administration (FDA)

In using such phrases, the payer signals that they think the therapy is only available as part of a clinical trial and its safety and efficacy has not been established.

In your response, you should indicate that the Reclaim™ DBS Therapy for Obsessive-Compulsive Disorder (OCD) is not investigational or experimental. It has been reviewed and approved by the Food and Drug Administration (FDA) through a process called Humanitarian Use Device/ Humanitarian Device Exemption (HUD/HDE). This process is somewhat different than the usual process for approval of medical devices because of the small patient population. The payer may not know that the FDA has designated the Reclaim™ DBS Therapy for OCD as a HUD, or, the payer might not know what a Humanitarian Use Device is. A Humanitarian Use Device is a medical device intended to treat or diagnose a disease or condition that affects, or is manifest in, fewer than 4,000 individuals per year in the United States.

Here is a sample letter for appeal addressing “investigational / experimental.”

Date:

Name of Payer:
Address:

Patient:
Policy Holder:
Insurance ID/Soc. Security #:

Dear _____:

I am writing to appeal your denial of services for payment of Reclaim™ DBS Therapy for the treatment of Obsessive-Compulsive Disorder (OCD) for my patient [name of patient] as stated in your letter of [date of letter and any other relevant correspondence number]. In your letter, you state that Reclaim™ DBS Therapy for OCD would not be covered because “the therapy is considered investigational / experimental” [or quote the language of the letter itself].

Medtronic Reclaim™ DBS Therapy for OCD is neither an investigational nor an experimental therapy. The Medtronic Reclaim™ DBS Therapy for OCD received a HUD designation (HUD 05-0149) filed on October 31, 2005 and received Food and Drug Administration (FDA) approval under an HDE (H050003) on February 19, 2009. A Humanitarian Device Exemption is a determination that a Humanitarian Use Device is safe, has probable benefit, and it is not considered investigational/experimental. Humanitarian Device Exemption products are considered by the FDA to be commercially released and are eligible for coverage and payment when Institutional Review Board (IRB) approval exists at the implant facility. Medtronic Reclaim™ DBS Therapy for OCD uses the same implantable neurostimulators that are used in Deep Brain Stimulation (DBS) for Parkinson’s disease, but the leads are specifically designed to target the anterior limb of the internal capsule (AIC). A probable benefit of Medtronic Reclaim™ DBS Therapy for OCD over a neurosurgical ablative approach is that neurostimulation therapy offers a non-destructive, adjustable and reversible alternative. Recent clinical studies of the effect of neurostimulation on patients whose Obsessive-Compulsive Disorder has failed to respond to conventional drug and behavioral therapies have shown probable benefit and acceptable safety.

I ask that you reconsider your denial immediately. If I do not hear from you within the week, I will follow-up by phone. Please call me [insert phone number] if you have any questions. I look forward to providing this therapeutic alternative to neuroablation for my patient, [insert patient’s name].

Sincerely,

[insert name], M.D.

If the reason for denial is that the therapy is considered “therapy is not medically necessary,” the payer’s letter of coverage denial may include phrases such as:

- not medically necessary or not medically appropriate
- does not meet generally accepted standards of practice
- not approved by the Food and Drug Administration (FDA)

In using such phrases, the payer signals that they think the patient will not gain any benefit from this therapy, or the payer is unfamiliar with this therapy, has not fully researched this therapy, or doesn’t know its clinical benefits.

In your response, you may be able to provide information to overcome the payer’s objection. In most denials of this type, the payer is unfamiliar with the therapy and needs more information or additional proof of its medical benefits. If unfamiliar with a therapy, payers may deny coverage using broad-based phrases often found in the benefit plan as the reason.

Here is a sample letter for appeal addressing “not medically necessary.”

Date:

Name of Payer:

Address:

Patient:

Policy Holder:

Insurance ID/Soc. Security #:

Dear _____:

I am writing to appeal your denial of services for payment of Medtronic Reclaim™ DBS Therapy for OCD for my patient [name of patient] as stated in your letter of [date of letter and any other relevant correspondence number]. In your letter, you stated that Medtronic Reclaim™ DBS Therapy for OCD would not be covered because “the therapy is not medically necessary” [or quote the language of the letter itself].

Perhaps I did not fully explain my patient’s situation and [his/her] limited options at this time. Obsessive-Compulsive Disorder is a chronic, disabling anxiety disorder characterized by recurrent obsessive thoughts and uncontrolled repetitive acts. OCD generally responds to antidepressants that block serotonin re-uptake in combination with cognitive behavioral therapies. However, my patient, [insert patient’s name] is one of the patients who has not benefited from these therapeutic approaches. He/she has suffered with this condition for [number of years] despite multiple courses of appropriate drug treatments and cognitive therapy. Recently, [his/her] condition has been worsening and [he/she] now spends the majority of [his/her] time in [describe the repetitive behavior]. For patients such as [name of patient], neurosurgical ablative techniques, such as anterior capsulotomy, were the only treatment options until recently. A neurosurgical ablative technique has the drawback of irreversible side effects and of reducing the patient’s future options for developing treatments. Medtronic Reclaim™ DBS Therapy for OCD received a Humanitarian Use Device (HUD) designation (HUD 05-0149) filed on

October 31, 2005 and received Food and Drug Administration (FDA) approval under a Humanitarian Device Exemption (HDE H050003) on February 19, 2009. Humanitarian Device Exemption products are considered by the FDA to be commercially released and are eligible for coverage and payment when Institutional Review Board (IRB) approval exists at the implant facility. Medtronic Reclaim™ DBS Therapy for OCD uses the same implantable neurostimulators that are used in Medtronic DBS Therapy for Parkinson's disease, with a lead that is specifically designed to target the anterior limb of the internal capsule (AIC). A probable benefit of Reclaim™ DBS Therapy for OCD over a neurosurgical ablative approach is that neurostimulation therapy offers a nondestructive, adjustable and reversible alternative.

As I indicated in my original letter requesting pre-determination of coverage/prior authorization I believe that my patient, [patient's name], is an ideal candidate for this therapy. This patient's medical condition falls within the FDA approved indication statement specified by the HDE for Medtronic Reclaim™ DBS Therapy for OCD. The facility where I propose to conduct this procedure has completed IRB approval requirements to do so. Details about [his/her] clinical presentation and courses of treatment are provided below.

[Personalize the letter for the specific patient using the information outline that follows. You may require one or more paragraphs for each of the headings listed.]

Address each of the following points in the body of the letter or in an attached report:

- Describe the patient's current status, including diagnosis, complaints, and level of impairment.
- Detail functional impairment, and state how quality of life, activities of daily living, and caregiver requirements (if applicable) are affected.
- List previous treatments that have been tried and failed.
- Document chronological history of patient's condition.
- Describe why patient findings demonstrate that this procedure is medically necessary.

Recommend Medtronic Reclaim™ DBS Therapy for OCD

- State how this therapy is an appropriate intervention at this point in the patient's care and describe the anticipated reduction in OCD symptoms.
- Note therapeutic goals, anticipated outcomes, risks of performing the procedure, risks of not performing the procedure, and possible complications.
- Describe the surgery itself, listing procedure codes Current Procedural Terminology (CPT) anticipated. Note the follow-up care associated with the therapy. This could be in an attachment rather than in the body of the letter.

Since [patient's name] has not responded to other measures, and performing a neuroablative procedure is destructive and permanent in nature, and would limit [her/her] future treatment options, I recommend that Reclaim™ DBS Therapy for OCD be

provided. I believe that information I have provided regarding [his/her] condition demonstrates coverage is both appropriate and necessary.

I ask that you reconsider your denial immediately. If I do not hear from you within the week, I will follow-up by phone. Please call me [insert phone number] if you have any questions. I look forward to providing this therapeutic alternative to neuroablation for my patient, [insert patient's name].

Sincerely,

[insert name], M.D.

If the reason for denial is that the therapy is considered “is not a standard of care,” the payer’s letter of coverage denial may include phrases such as:

- not a standard of care for the patient’s condition
- does not meet generally accepted standards of practice
- not approved by the Food and Drug Administration (FDA)

In using such phrases, the payer signals they think this is not the right therapy because other treatments are more typical for this condition, or they are unfamiliar with this therapy, or they don’t know the therapy’s clinical benefits.

In your response, you may be able to provide information to overcome the payer’s objection. In most denials of this type, the payer requires further information or additional proof of the medical benefits of the therapy. If unfamiliar with a therapy, payers may deny coverage using broad-based phrases often found in the benefit plan as the reason.

Here is a sample letter for appeal addressing “not medically necessary.”

Date:

Name of Payer:

Address:

Patient:

Policy Holder:

Insurance ID/Soc. Security #:

Dear _____:

I am writing to appeal your denial of services for payment of Medtronic Reclaim™ DBS Therapy for the treatment of OCD for my patient [name of patient] as stated in your letter of [date of letter and any other relevant correspondence number]. In your letter, you said that Reclaim™ DBS Therapy for OCD would not be covered because “the therapy is not a standard of care” [or quote the language of the letter itself].

The Medtronic Reclaim™ DBS Therapy for OCD received a Humanitarian Use Device (HUD) designation (HUD 05-0149) filed on October 31, 2005 and received Food and Drug Administration (FDA) approval under a Humanitarian Device Exemption (HDE H050003) on February 19, 2009. HDE products are considered by the FDA to be commercially released and are eligible for coverage and payment when Institutional Review Board (IRB) approval exists at the implant facility. Medtronic Reclaim™ DBS Therapy for OCD uses the same implantable neurostimulators as are used in Medtronic DBS for Parkinson’s disease. A probable benefit of Reclaim™ DBS Therapy for OCD over a neurosurgical ablative approach is that neurostimulation therapy offers a non-destructive, adjustable and reversible alternative. Recent clinical studies¹ of the effect of neurostimulation on patients whose Obsessive-Compulsive Disorder (OCD) has failed to respond to conventional drug and behavioral therapies have shown probable benefit and acceptable safety. I would agree that Reclaim™ DBS Therapy for OCD is not the old standard of care. Its HDE status is recent. But I would also argue that the ablation therapies, such as anterior capsulotomy, which have irreversible side effects and by definition are tissue destroying, should be used only as a last resort. It seems prudent to first try this newly approved therapy, rather than performing neuroablative procedures that are destructive and permanent in nature and may limit future treatment options.

I ask that you reconsider your denial immediately. If I do not hear from you within the week, I will follow-up by phone. Please call me [insert phone number] if you have any questions. I look forward to providing this therapeutic alternative to neuroablation for my patient, [insert patient’s name].

Sincerely,

[insert name], M.D.

¹ Greenberg BD, Gabriels LA, Malone DAJ et al. 2008. Deep brain stimulation of the ventral internal capsule/ventral striatum for obsessive-compulsive disorder: worldwide experience. Mol Psychiatry. 1-16