

**Letter of Medical Necessity**  
**Reclaim™ DBS Therapy for OCD Treatment**

Dear [insert payer here]:

I am writing to request prior authorization for the surgical implantation of a Medtronic Reclaim™ DBS System for the management of the symptoms of chronic, severe, treatment resistant Obsessive-Compulsive Disorder (OCD). Based on the medical history described below, I feel that [patient name] is an excellent candidate for Medtronic Reclaim™ Deep Brain Stimulation (DBS) Therapy for OCD.

Reclaim™ DBS Therapy for OCD uses DBS technology to manage the symptoms of chronic, severe, treatment resistant OCD. It has been designated a Humanitarian Use Device (HUD number 05-0149) by the FDA and has been approved by the FDA under the Humanitarian Device Exemption (HDE number H050003) for the treatment of chronic, severe, treatment-resistant OCD in adult patients who have failed at least three selective serotonin reuptake inhibitors (SSRIs). The therapy is delivered by an implanted neurostimulator, similar to a cardiac pacemaker, implanted near the collarbone. Electrical stimulation is sent through a thin, flexible lead that is precisely placed in the anterior limb of the internal capsule (AIC), one lead is placed on each side of the brain. Stimulation of these areas of the brain may aid in the management of some of the uncontrolled symptoms of chronic, severe, treatment resistant OCD. Unlike surgical procedures for chronic, severe, treatment resistant OCD that may be destructive, Reclaim™ DBS Therapy for OCD is reversible and adjustable.

- **Document current findings and status of the patient**

*Describe the patient's current status including diagnosis, complaints and level of impairment. Detail functional impairments and state how quality of life, activities of daily living, caregiver, employment, etc. are affected.*

- **Document chronological medical history**

*Document the patient's history of interventional efforts noting procedures, medications and/or therapies that have been previously rendered. Note the outcome of each. A timeline may be useful.*

- **Recommend Reclaim™ DBS therapy for OCD**

*Note the probable benefits of the specific system. State how this therapy is an appropriate intervention at this point in the patient's care. Note therapeutic goals, anticipated outcomes, risks of performing the procedure, risks of not performing the procedure, and possible complications.*

- **Describe the Implant Procedure**

*Describe the surgery itself, listing the Current Procedural Terminology (CPT) codes (CPT) anticipated. Note the follow-up care associated with the therapy. You could add this as an attachment rather than in the body of the letter itself.*

I am requesting confirmation that this therapy is considered a covered benefit based on medical necessity and that associated professional fees for the surgery and follow-up will be covered. I request authorization for all costs associated with the implant procedures, including physician professional fees.

The procedure has been scheduled at [name of facility] on [date].

Thank you for taking the time to review this information and for your coverage consideration. Please contact me if you have any further questions regarding this request.

Sincerely,

[name of physician], M.D.

Enclosures:

[list enclosures]

Reclaim™ Deep Brain Stimulation Therapy for Obsessive Compulsive Disorder: Product labeling must be reviewed prior to use for detailed disclosure of risks.

**Indications:** The Medtronic Reclaim DBS Therapy is indicated for bilateral stimulation of the anterior limb of the internal capsule, AIC, as an adjunct to medications and as an alternative to anterior capsulotomy for treatment of chronic, severe, treatment-resistant obsessive compulsive disorder (OCD) in adult patients who have failed at least three selective serotonin reuptake inhibitors (SSRIs).

**Contraindications:** Contraindications include patients who are unable to properly operate the neurostimulator, and patients who will be exposed to MRI or diathermy. MRI and diathermy (e.g., shortwave diathermy, microwave diathermy or therapeutic ultrasound diathermy) are contraindicated because the energy can be transferred through the implanted System (or any of the separate implanted components), which can cause tissue damage and can result in severe injury or death. Diathermy can damage parts of the neurostimulation system. Transcranial Magnetic Stimulation (TMS) is contraindicated for patients with an implanted DBS System.

**Warnings/precautions/adverse events:**

Electroconvulsive Therapy (ECT) – The safety of ECT in patients who have an implanted deep brain stimulation (DBS) system has not been established. Induced electrical currents may interfere with the intended stimulation or damage the neurostimulation system components resulting in loss of therapeutic effect, clinically significant undesirable stimulation effects, additional surgery for system explantation and replacement, or neurological injury.

There is a potential risk of tissue damage using stimulation parameter settings of high amplitudes and wide pulse widths. Extreme care should be used with lead implantation in patients with a heightened risk of intracranial hemorrhage. Do not place the lead-extension connector in the soft tissues of the neck. Placement in this location has been associated with an increased incidence of lead fracture. Theft detectors and security screening devices may cause stimulation to switch ON or OFF, and may cause some patients to experience a momentary increase in perceived stimulation. Severe burns could result if the neurostimulator case is ruptured or pierced. The safety of somatic psychiatric therapies using equipment that generates electromagnetic interference (e.g., vagus nerve stimulation) has not been established. The Reclaim DBS System may be affected by or adversely affect medical equipment such as cardiac pacemakers or therapies, cardioverter/ defibrillators, external defibrillators, ultrasonic equipment, electrocautery, or radiation therapy. Patients should be monitored for at least 30 minutes after a

programming session, for side effects, including: autonomic effects (e.g., facial flushing, facial muscle contractions, or increased heart rate), hypomania, increased disease symptoms, sensations such as tingling, smell, or taste. In addition, during treatment, patients should be monitored closely for increased depression, anxiety, suicidality, and worsening of obsessive-compulsive symptoms. The safety and probable benefit of this therapy has not been established for patients with: Tourette's syndrome, OCD with a subclassification of hoarding, previous surgical ablation (e.g., capsulotomy), dementia, coagulopathies or who are on anticoagulant therapy, neurological disorders, and other serious medical illness including cardiovascular disease, renal or hepatic failure, and diabetes mellitus. In addition, the safety and probable benefit has not been established for these patients: those whose diagnosis of OCD is documented to be less than 5 years duration or whose YBOCS score is less than 30, who have not completed a minimum of 3 adequate trials of first and/or second line medications with augmentation, who have not attempted to complete an adequate trial of cognitive behavior therapy (CBT), who are pregnant, under the age of 18 years, and who do not have comorbid depression and anxiety. Physicians should carefully consider the potential risks of implanting the Reclaim DBS System in patients with comorbid psychiatric disorders (e.g., bipolar, body dysmorphic, psychotic) as the Reclaim DBS System may aggravate the symptoms. Additionally, the abrupt cessation of stimulation for any reason should be avoided as it may cause a return or worsening (i.e., "rebound" effect) of disease symptoms. Serious adverse events related to the therapy, device, or procedure can include: suicidality/increased depression, increased OCD/fluctuating results, intracranial hemorrhage, lead/extension failure, aggression/violent behavior, accident proneness, irritability, death, hypomania, infection, pyelonephritis, and post-operative seizure. Adverse events related to the therapy, device, or procedure can include: coma, paralysis, pain or discomfort at incision/implant sites, general post-op discomfort, GI symptom (post op), increased anxiety, insomnia, cognitive disturbance (clouding), induced muscle contraction, restlessness, stimulation induced paresthesia, device migration, shocking or jolting stimulation, induced sensation of taste/smell, weight gain, increased fatigue, upper respiratory infection, headaches, dizziness, dry mouth, itching at surgical site(s), nausea, sedation, and weight loss.

**Humanitarian Device:** Authorized by Federal (U.S.A) law for use as an adjunct to medications and as alternative to anterior capsulotomy for treatment of chronic, severe, treatment-resistant obsessive compulsive disorder (OCD) in adult patients who have failed at least three selective serotonin reuptake inhibitors (SSRIs). The effectiveness of this device for this use has not been demonstrated.

USA Rx Only  
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