

Focused Ultrasound Frequently Asked Questions

For patients with essential tremor

What is focused ultrasound?

Focused ultrasound (FUS) is an incisionless treatment for essential tremor patients who have not been helped by medications. It is based on magnetic resonance-guided focused ultrasound (MRgFUS) technology, which uses sound waves to treat deep targets in the brain, precisely guided by MRI.

How long has this procedure been approved by the Food and Drug Administration?

The Food and Drug Administration (FDA) approved the Exablate Neuro procedure for treating unilateral (one-sided) essential tremor at the end of 2016, and for staged treatment of the patient's other side affected by essential tremor in 2022.

Where is this procedure done in Kentucky?

Norton Neuroscience Institute is the first and only institution in Kentucky that performs this procedure, which is done at Norton Brownsboro Hospital.

Is this treatment effective for hand tremors?

The treatment is FDA-approved to treat hand tremor.

If I have tremors in both hands, do I need two treatments for each hand?

Patients with tremors in both hands should discuss treatment options with their provider. This treatment is FDA-approved for one side at a time, with at least nine months between treatments for eligible patients who are without significant side effects from the first treatment.

Why is the treatment limited to age 22 and older?

The age limitation is based on the FDA approval, which is based on the clinical study that was performed and its criteria.

If the thalamus is in the center of the brain, why doesn't this treatment affect the rest of the brain?

The ultrasound waves pass through the rest of the brain. Only where they converge in the thalamus does the temperature rise, heating and creating a lesion that helps disrupt the pathways causing the tremor.



CANDIDACY PROCESS

Do I need to have a diagnosis before visiting Norton Neuroscience Institute?

No, you will meet our functional neurosurgeon to discuss surgical treatment options and may need to meet with our movement disorders neurologist if you have not been diagnosed or medically optimized.

Should I try medications first?

In order to be a candidate for the incisionless treatment, you must have a confirmed diagnosis of essential tremor that does not respond to least two standard-of-care medications. Your physician will assist with individualized assessment of your case.

If I am found to be suitable for treatment, how soon can the treatment be done?

This will be different for every patient. Call our nurse navigator at **(502) 671-9489** to discuss your options.

ABOUT INSURANCE COVERAGE

In which states is there Medicare coverage for the treatment for essential tremor?

The MRgFUS treatment for medication-refractory essential tremor is a Medicare covered benefit in all 50 states.

Is focused ultrasound covered under Medicare Part A, Medicare Part B, or a supplemental Medicare plan?

MRgFUS for treatment of essential tremor is covered under Medicare Part B.

Do private health insurance plans cover the treatment?

Aetna and many Blue Cross Blue Shield Association plans cover MRgFUS treatment for medication-refractory essential tremor. For up-to-date information on insurance coverage, visit **USA.Essential-Tremor.com/Insurance-Coverage**.

In general, it's best to contact your health plan's member services department by calling the phone number listed on the back of your insurance card. Ask whether or not MR-guided focused ultrasound for treating essential tremor is a covered benefit in an outpatient setting based on your health plan.

Will there be an out-of-pocket expense if the majority of the treatment is covered by insurance?

Your insurance plan can best answer this for you, as each plan is different.

BEFORE THE TREATMENT

Do I need to get any imaging scans done before the treatment?

Yes, you will need to get a specialized CT scan, which helps determine if you are a candidate. You also will need a specialized MRI scan for surgical planning. These must be done at Norton Healthcare facilities.

Why do I need a CT scan?

Everyone's skull is different, and a CT scan is done to determine whether the density of your skull is suitable for the incisionless treatment. Certain skull shapes and thickness may make it impossible for ultrasound waves to reach the temperature at the target required for treatment.

How many times will I meet with my treating surgeon?

You will meet with the surgeon at least once before treatment, on treatment day and at least once at a postoperative appointment. The treating team also will discuss any additional follow-up visits needed, as well as information that will be relayed back to your referring physician.

Why do I need to have my head shaved?

This is necessary for two reasons:

- Ultrasound waves do not travel well through air. In this treatment, water is used (like a gel used when having an abdominal ultrasound) as a conductive medium. The smooth-shaven scalp and a silicone cap enable a tight interface with the ultrasound transducer.
- Air bubbles could get trapped in the hair, blocking the ultrasound waves and absorbing energy, which could potentially lead to skin burns.

DURING THE TREATMENT

Why do I need to have a frame put on?

The frame is a standard device that helps ensure your head does not move during the treatment.

Does my entire body need to be put inside the MRI scanner?

No, from about your mid-torso up will be placed inside the scanner.

Will I be in the MRI scanner for the entire treatment?

No, the treatment bed will move in and out of the MRI scanner. After each application of energy, you will be asked to do various tasks, such as draw a spiral, so that your tremor can be assessed.

Why do I have to be awake?

During the treatment, you will be asked to do different tasks, such as drawing, writing or talking. This neurologic exam is critical to inform the surgeon about your tremor and identify and address any potential side effects that you may experience during the treatment. Therefore, you cannot be sedated before or during the treatment, including during the MRI scans done as part of the treatment.

How long do I need to stay for the treatment, during and after?

The treatment time is, on average, 2.5 hours. The treatment is performed on an outpatient basis, meaning you will return home after.

How long is the effect of the treatment expected to last?

The most recent data shows hand tremor improvement of study subjects was mostly maintained at least three years. There is the possibility that your tremor may return months or even years after the treatment, or that the tremor may not improve at all. And while the treatment may improve your tremor, it is important to understand that it does not treat the underlying disease nor prevent its progression.

What side effects can I expect during and after the treatment?

You should have a detailed conversation with your physician regarding complications, also known as adverse events, that you may experience.

Exablate Prime manufacturer Insightec-sponsored clinical studies have shown that the most common adverse events experienced after treatment of the first side included:

- Imbalance/gait disturbance (26% of subjects)
- Numbness/tingling (33% of subjects)
- Headache/head pain (51% of subjects)

Most of these events were classified as mild or moderate, and 48% of all adverse events resolved on their own within 30 days. Complications that persisted at three years were all mild or moderate and included:

- Numbness/tingling (9% of subjects)
- Imbalance (4% of subjects)
- Unsteadiness (4% of subjects)
- Gait disturbance (2% of subjects)
- Musculoskeletal weakness (2% of subjects)

AFTER THE TREATMENT

How soon can I return to work after the treatment?

How soon you can return to work depends on the type of work that you do and how you feel. Consult with your physician.

What do I need to do once I am home?

The treatment team will provide you with instructions related to your post-treatment recovery. You will return for a post-treatment MRI the next day.

