

Departmental Policy

POLICY NO.: 200.02.101P

POLICY TITLE: Transcranial Magnetic Stimulation (TMS)

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SUMMARY & PURPOSE: Transcranial Magnetic Stimulation (TMS) Therapy is a specialized somatic treatment available for the management of major depressive episodes (acute symptoms and provision of prophylactic maintenance care) in adult patients. The purpose of this policy is to provide faculty and staff at Herbert Wertheim (HWCOM) with the guidelines for the delivery of care for patients that will receive TMS therapy.

SCOPE/APPLICABILITY: This policy applies only to the HWCOM Clinical Location: FIU Health Modesto Maidique ("MMC"), where HWCOM faculty and staff provide TMS therapy to patients. TMS therapy will not be offered at these locations: FIU Health Broward, Green Family Foundation NeighborhoodHELP Mobile Health Centers, Household visits and the Linda Fenner 3D Mobile Mammography Center.

POLICY: HWCOM will comply with the standards of care for all patients that receive TMS therapy. Specific TMS practices will be integrated into the assessment, planning, prioritizing, delivery, and documentation of patient care as outlined in this policy.

DEFINITIONS:

Adverse Incident:

Is an event that causes, or has the potential to cause, an unexpected or unwanted effect involving the safety of a patient *whether* an injury has occurred. Examples of an adverse incident for TMS include but are not limited to: Consent not signed by the patient, transfer to higher level of care, and allegation from either the patient or a family member that an injury has occurred.

Refer to Administrative Policy: *Incident Report Policy No.:* **200.03.100A**

AED:

An Automated External Defibrillator (**AED**) is a portable device that checks the heart rhythm and can send an electric shock if necessary to the heart to try to restore a normal rhythm. AED's are used to treat sudden cardiac arrest.

Medical Necessity Criteria for TMS Therapy:

Criteria for TMS therapy include but it is not limited to:

- Confirmed diagnosis of severe major depressive disorder. Treat the symptoms of major depressive disorder, without inducing seizure, in patients who have failed at least one antidepressant medication.

(Reference: 21 CFR 882.5805; accessed at:

<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=882.5805>)

AND one or more of the following:

- Demonstrated resistance to treatment with psychopharmacologic agents as evidenced by lack of clinically significant response to four trials of such agents, in the current depressive episode, from at least two different agent classes
- Inability to tolerate psychopharmacologic agents
- History of response to TMS in a previous depressive episodes; (evidenced by a greater than 50% improvement in a standard rating scale for depressive symptoms); or
- Is currently receiving or is a candidate for and has declined ECT and TMS is considered less invasive treatment option.

A patient can elect TMS treatment when one or more provisions of the medical necessity described in this policy is not met. The TMS Psychiatrist must agree that proceeding with TMS treatment is beneficial. In such instances, patients will need to complete financial responsibility form; For Medicare patients, specifically, the Advance Beneficiary Notice form completion is required.

Electroconvulsive Therapy or ECT:

Electroconvulsive therapy (ECT or “electroshock”) is a psychiatric procedure that is used to treat depression and other mental disorder.

Emergency Equipment:

AED, ambu-bag with mask, oxygen, suction, blood pressure machine, pulse oximeter.

HWCOTM TMS Psychiatric Physician:

A HWCOTM psychiatrist with established TMS credentials who is responsible for the safe delivery of care and provides standardized and appropriate treatment of TMS therapy. Appropriate TMS credentials require the completion of an authorized TMS training course.

Medical Clearance for TMS Therapy:

The primary physician, any specialist consultant, and TMS Psychiatric Physician who find the patient within a reasonable degree of medical certainty to be healthy enough to participate in TMS treatment may deem the patient medically clear. Medical clearance is not intended to indicate the absence of ongoing medical issues that may require further diagnostic assessment, monitoring or treatment, nor does it guarantee that there are no undiagnosed medical conditions.

Patient Identifiers:

All patients are asked to provide their unique Patient Identifiers when receiving TMS at FIU Health MMC. The following are approved Patient Identifiers for HWCOCM to ask patients:

- Patient's full name
- Date of Birth

A third Patient Identifier can be utilized if there are two patients with the same name. In this case, the patients Medical Record Identification number can be used. In the Centricity Electronic Medical Record (EMR), the Patient Identification Number serves this purpose. The third identifier is necessary in instances of a patient name alert because two (or more patients) have the same name, names close to being spelled the same, and or pronounced the same.

Informed Consent:

The HWCOCM TMS Psychiatrist will review the risks, benefits and alternatives with the patient in the patients' preferred language.

"Preferred" Language Consent:

The consent for TMS therapy is read and signed in the patient's preferred language. This language is the one most comfortable for the patient to understand, read, and provide written consent after discussing the risks, benefits and alternatives with the physician. The consent can be offered in (English, Spanish, and Creole). If the patient's preferred language is not available, the Official Language Line Interpreter Services will be contacted for official translation in the patient's preferred language and or dialect.

Referring Clinician:

A licensed physician, nurse prescriber or therapist who refers a patient to HWCOCM for TMS therapy.

TMS Clinical Operator:

A trained and qualified individual supervised by the TMS HWCOCM Psychiatric Physician to deliver, or assist in the delivery of, TMS therapy treatments. This individual is trained in the use of TMS devices at the HWCOCM FIU Health MMC Clinical location. Additional training is required in basic CPR, first aid, basic management of a generalized seizure and pre and post general clinical condition screen. In addition, this individual has knowledge of safety precautions associated with TMS therapy.

TMS Therapy Team: For the purposes of this policy, refer to the following individuals:

- Referring Clinician
- HWCOCM TMS Psychiatric Physician
- TMS Clinical Operator

Roles and Responsibilities:**HWCOCM TMS Psychiatrist Role and Responsibilities:**

- Determines if a patient meets the criteria to receive TMS Therapy
- A TMS Psychiatric Physician must document in the EMR (example: evaluation note on medical record) adequate justification as to why TMS is prescribed for the patient.
- Completes the safety-screening tool of patients referred for TMS Therapy. Reviews the history, physical exam, labs for the last year and consults with patient's primary physician or other physician that knows the patient and deems that patient has been medically

cleared to begin TMS Therapy.

- Determines a patient's motor threshold, treatment coil location, coil position, treatment power level, and treatment parameters that will be utilized for a patient's TMS therapy sessions. These items will be documented in the EMR.
- Supervises the qualified TMS Clinical Operator who administers each TMS Therapy session.
- TMS psychiatrist must be at FIU HEALTH MMC during all TMS Treatments providing direct supervision, for the entire duration of each treatment and available by phone for immediate response in case of an emergency or concerns.
- Provides serial evaluations of the patients receiving treatments through daily communication with the TMS Clinical Operator to monitor progress, side effects, and document in the EMR.
- Provides additional office visit evaluations, as needed, for patients receiving TMS therapy.
- Makes all clinical decisions about TMS treatment parameters.
- TMS Psychiatrist must meet face to face with the patient when there is a change in the individual's mental status and/or other significant change in clinical status.

Referring Clinician Role and Responsibilities

1. Maintains primary responsibility for prescribing psychotropic medications and/or providing psychotherapy to the patient prior, throughout and after the acute course of TMS therapy.
2. Works collaboratively with the HWCOTM TMS Psychiatric Physician while a patient is undergoing TMS treatments.

TMS Clinical Operator Role and Responsibilities:

1. Provides patients with education and information (via phone or mail) about the TMS therapy.
2. Positions the patient appropriately in the TMS device prior to initiation of the TMS treatment.³ Operates the computer software associated with the TMS device and operates other computer programs utilized to support the TMS therapy clinical care and services.
3. Administers TMS treatment sessions, under the supervision and guidance of the HWCOTM TMS Psychiatric Physician, by following the established parameters set by the HWCOTM TMS Psychiatric Physician.
4. Completes a pre and post session screen and general clinical condition before and after the patient receives TMS treatments.
5. Monitors the patient during the TMS therapy session. The TMS Clinical Operator must remain in the room and observe the patient's physical status for potential adverse incidents throughout the entire TMS treatment session. See definition of an adverse incident listed above.

Report any adverse incident through the Clarity Incident reporting system.

Refer to the Administrative Policy: *Incident Report Policy: 200.03.100A*

6. Contacts the HWCOTM TMS Psychiatric Physician onsite, providing direct supervision for feedback and instructions, to address any questions or concerns raised by the patient in the clinical assessment prior to starting TMS treatment.
7. Make routine TMS adjustments to the device as required and consistent with the manufacturer labeling recommendations and proper use (example: ensure there is contact between patients head and the treatment coil) during the TMS treatment session.
8. The TMS Operator will follow the pre-determined stimulation dose or treatment coil position parameters prescribed by the HWCOTM TMS Psychiatric Physician. The TMS operator will not independently adjust the parameters set by the HWCOTM TMS Psychiatric Physician.

9. Provides the HWCOTM TMS Psychiatric Physician with the daily report of the patient clinical status (including overall progress, side effects, medication changes, or other new clinical data) for each patient receiving TMS therapy during the day.
10. Administers and Collects a self-report assessment form.
11. The TMS Clinical Operator can interrupt treatment or terminate treatment (example: patient expresses urgency to move position) and can stop or pause TMS therapy treatments as indicated by the HWCOTM TMS Psychiatric Physician.

PROCEDURE:

1. TMS Therapy may only be performed by a trained clinical operator under the supervision of a HWCOTM TMS Psychiatric Physician.
2. The HWCOTM TMS Psychiatric Physician completes an evaluation of the patient's emotional and physical condition and documents in the EMR medical necessity for the administration of TMS therapy.
3. All patients referred for TMS will be informed, by their HWCOTM TMS Psychiatric Physician about TMS therapy, the indications, risks, benefits of the procedures, and alternatives to the procedure. The patient will be given the opportunity to ask questions, discuss other alternatives and has the right to refuse TMS therapy. Informed consent must be obtained by the HWCOTM TMS Psychiatric Physician and documented in the EMR. The consent will be in writing in the patient's "preferred" language (The language that the patient understands). The consent form will be signed prior to commencement of new TMS therapy treatment and once a year for continued treatment.
4. Medical Clearance of Patient for TMS therapy:
 - 4.1 Required documentation of patient's general health and appropriateness to begin TMS therapy includes a history, physical exam, and standard laboratory tests performed within the past year. This medical information may be provided by the Primary Care Physician or by any other healthcare provider that is familiar with the patient's care and is able to provide required information to medically clear the patient to begin the TMS treatment.
 - 4.2 The HWCOTM TMS Psychiatric Physician will review the history, physical, and lab values provided and decide if the patient is a candidate to begin a trial of TMS.
 - 4.3 The medical clearance to begin a trial of TMS will be documented in the electronic medical record (EMR) by the HWCOTM TMS Psychiatric Physician prior to beginning a trial of TMS.
 - 4.4 In the event of a significant change in the patient's medical status, as assessed by either the patient's primary care physician, referring practitioner or the HWCOTM TMS Psychiatric Physician, TMS treatment will be re-evaluated and a decision will be made whether to continue with treatment. This re-evaluation will be documented in the EMR.
 - 4.5 Documentation of medical review must be done:
 - 4.5.1.1 Prior to the start of TMS.
 - 4.5.1.2 In the event of a significant change in the patient's medical status, as assessed by either the primary care physician or psychiatrist providing the TMS.
5. **TMS Delivery Procedures:**
 - 5.1 Each TMS treatment must include documentation of the current diagnosis and mental status by the TMS Psychiatric Physician with attention to the components of the mental status that relate to the indication and potential risks of TMS. The risks are outlined in the informed consent.
 - 5.2 TMS Motor Threshold assessment and determination of the coil placement is done by a TMS Psychiatric Physician. TMS treatment sessions can be administered by a TMS

Psychiatric Physician, or by a trained TMS Clinical Operator under the supervision of a TMS Psychiatric Physician.

- 5.3 The TMS Psychiatric Physician must be at the FIU Health MMC location during all TMS treatments, for the entire duration of each treatment, and available by phone and/or pager for immediate response in case of urgent matters or an emergency.
- 5.4 There must be communication between the TMS Clinical Operator and the supervising HWCOT TMS Psychiatric Physician, to provide clinical updates and review patient progress. This will occur daily when TMS treatments are being administered. The TMS physician makes all clinical decisions about TMS treatment parameters.

6. Care of TMS Patient:

- 6.1 Concurrent and continued use of psychotropic medications (prescribed by the patient's outpatient psychiatric medication provider) during TMS is generally determined before initiating an acute course of TMS treatment. Changes to ongoing pharmacotherapy indicated during course of daily TMS therapy may be recommended by the treating TMS Psychiatric Physician but should not be initiated without collaboration with the patient's regular outpatient prescriber.

Safety Precautions During TMS:

- All FIU Health clinical staff will be able to respond to any medical emergency. Every staff member certified in Basic Life Support (BLS) is responsible for being ready, initiating BLS if necessary and bring emergency equipment necessary to the emergency and as requested by the physician. Refer to Administrative Policy: *Response to Medical Emergencies – 911 No.:* **200.02.100A**
- First responder will ask for "Help". Anyone can assist in calling 911 (EMS) followed by the University Security if on MMC, call 305-348-2727.
- For transfers to higher level of care or any unusual adverse incident an incident report will be completed through the Clarity system. Link: <https://events.healthcaresafetyzone.com/EventsModuleWeb/Default.aspx?cs=7eefdf11-4184-41f0-bd9b-9695c86716a0&groupaccessid=0d36cd8b-cdef-4401-9243-0ddd6ee4b311>
- Procedures for TMS therapy treatments are listed in the TMS Procedure Manual. Information specifically pertaining to the specific TMS device is also kept in a User's Manual, located in the TMS Suite.
- Prior to each TMS treatment, two patient identifiers will be utilized to maintain patient safety and correct patient identification. The two patient identifiers are full name and date of birth (MONTH/DAY/YEAR). A third Patient Identifier, the medical record identification number can be utilized if there are two patients with the same name. These patient identifiers are utilized to confirm appropriate delivery of TMS therapy to the correct patient and to the correct side of the head. The EMR documentation will reflect that this process occurred at each TMS therapy visit. Refer to Administrative Policy: *Patient Identifiers No.:* **200.021.02A**
- A patient receiving TMS therapy must always be directly observed during a treatment session either by a HWCOT TMS-trained Physician or by a trained TMS Clinical Operator in the room with the patient.
- The patient will never be left unattended in the room while TMS is being administered.

SUPPORTING/ REFERENCE DOCUMENTATION:

- Joint Commission on Accreditation of Health Care Organizations, 2013
- Keel JC, Smith MJ, Wasserman EM. A safety-screening questionnaire for transcranial magnetic stimulation. *Clinical Neurophysiology*. 2001; 112:720.
- Florida Statue 458.351 Reports of adverse incidents in office practice setting, 2016
- Perera, T. George, M.S., Grammar, G., Janiack, P. G., Pascual-Leone, A., & Wirecki, T.S. (2016). The clinical TMS society consensus review and treatment recommendations for TMS therapy for major depressive disorder. *Brain stimulation*, 9(3), 336-346

RELATED POLICIES, PROCEDURES AND ASSOCIATED FORM:

- HWCOC Administrative Policy: *Response to Medical Emergencies – 911 No.:* **200.02.100A**
- HWCOC Administrative Policy: *Incident Reporting No.:* **200.03.100A**
- HWCOC Administrative Policy: *Patient Identifiers No.:* **200.02102A**