FACT SHEET: Medi-Cal Coverage of Transcranial Magnetic Stimulation (TMS)

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Transcranial magnetic stimulation (TMS) is an evidence-based device and procedure used in the treatment of major depresisve disorder (MDD). Despite its effectiveness and widespread use, questions have remained for a long time regarding Medi-Cal coverage for the service. In this fact sheet, we summarize the history and evidence of TMS as well as the coverage status among Medicare, commercial plans in California, and Medicaid programs in other states. We then describe the coverage status of TMS in Medi-Cal, the mechanisms under which Medi-Cal provides coverage for the service, and provide recommendations for the Department of Health Care Services (DHCS) to enforce coverage of and access to this important mental health benefit.

Background

What is TMS and what does the evidence say about its effectiveness?

Developed in 1985, TMS is a non-invasive form of brain stimulation therapy that has been extensively studied and applied as a treatment for depression, psychosis, anxiety, and other mental disorders. TMS is a simple procedure that does not require anesthesia and is performed in an outpatient or inpatient setting by a psychiatrist or an TMS technician under the supervision of a psychiatrist.[1] During an TMS session, a magnet connected to an electric stimulator is placed near the head of the person receiving the treatment. This magnet produces small currents in targeted regions of the brain via electromagnetic induction. When applied repeatedly, the intervention is known as repetitive TMS (rTMS) and it can progressively change brain activity.[2] Low-frequency stimulation reduces, and high-frequency

[1] National Institute of Mental Health, Brain Stimulation Therapies, available at: https://www.nimh.nih.gov/health/topics/brain-stimulation-therapies/brain-stimulation-therapies.shtml.
[2] *Id.*

stimulation increases, activity in underlying brain tissue.[3] Generally, a full course of rTMS consists of 20 daily treatments sessions lasting between 30 and 60 minutes each.

While TMS has been tested in humans since the 1980's, the evidence supporting the effectiveness of the procedure remained mixed until the results of the first large clinical trial were published in 2010. That study, which was funded by the National Institute of Mental Health (NIMH), showed that 14% of patients with major depressive disorder (MDD) achieved remission with TMS, compared to only 5% among patients receiving an inactive or sham treatment. Remission climbed to 30% during a second phase where all patients received TMS.[4] Based on this evidence, in 2008, the FDA first approved the use of the TMS device from Neurostar Advanced Therapy as safe and effective treatment for MDD for patients who do not respond to at least one antidepressant medication in the current depression episode.[5] This device was subsequently approved for treatment in adolescents and youth aged 15 to 21 in

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[3] The noninvasive and targeted nature of rTMS contrasts with electroconvulsive therapy (ECT), an invasive procedure in which electrical stimulation is delivered to the brain in a generalized form. Some experts believe that, by focusing on a specific site in the brain, rTMS reduces the side effects associated with ECT. *Supra* note 1.

[4] M.S. George et al., *Daily Left Prefrontal Transcranial Magnetic Stimulation Therapy for Major Depressive Disorder: A Sham-Controlled Randomized Trial*, 67 ARCH. GEN. PSYCHIATRY 507 (2010). Other studies have shown the effectiveness of rTMS in treating MDD, including some that have found rTMS to be more effective than ECT. *See* for example J.P. O'Reardon et al., *Efficacy and Safety of Transcranial Magnetic Stimulation in the Acute Treatment of Major Depression: A Multisite Randomized Controlled Trial*, 62 BIOL PSYCHIATRY 1208 (2007) (finding that TMS was effective in treating major depression with minimal side effects reported); Aditya Somani & Sujita Kumar Kar, *Efficacy of Repetitive Transcranial Magnetic Stimulation in Treatment-Resistant Depression: The Evidence Thus Far*, 32 GEN PSYCHIATRY e100074 (2019) (finding that for patients with treatment-resistant depression, rTMS appears to provide significant benefits in short-term treatment studies); Róbert György Vida et al., *Efficacy of Repetitive Transcranial Magnetic Stimulation (rTMS) Adjunctive Therapy for Major Depressive Disorder (MDD) After Two Antidepressant Treatment Failures: Meta-Analysis of Randomized Sham-Controlled Trials*, 23 BMC PSYCHIATRY 545 (2023) (finding that rTMS is significantly more effective than sham rTMS in TRD in response and remission outcomes and may be beneficial as an adjunctive treatment in patients with MDD after two treatment failures).

[5] The FDA has classified rTMS devices under Class II (higher risk devices that require greater regulatory controls to provide reasonable assurance of the device's safety and effectiveness). For additional information on FDA approval of TMS devices, *see* FDA, Repetitive Transcranial Magnetic Stimulation (rTMS) Systems – Class II Special Controls Guidance for Industry and FDA Staff (2011), https://www.fda.gov/medical-devices/guidance-documents-medical-devices-and-radiation-emitting-products/repetitive-transcranial-magnetic-stimulation-rtms-systems-class-ii-special-controls-guidance.

2024.[6] For patients with less severe MDD, the procedure may also be recommended as a less invasive treatment option to electroconvulsive therapy (ECT).

Coverage of TMS in Medicare, commercial plans, and Medicaid programs in other states

Major public and private insurers across the country now provide coverage for TMS when medically necessary for the treatment of MDD. For example, Medicare covers TMS for patients with severe forms of MDD who meet the following criteria:[7]

- The patient has a confirmed diagnosis of severe MDD as defined by the current DSM or recurrent episode; **and**
- One or more of the following:
    - Resistance to treatment with psychopharmacologic agents as evidenced by a lack of a clinically significant response to 2 trials of psychopharmacologic agents in the current depressive episode from at least 2 different agent classes; or
    - Inability to tolerate psychopharmacologic agents as evidenced by 2 trials of psychopharmacologic agents from at least 2 different agent classes, with distinct side effects; or
    - History of response to TMS in a previous depressive episode; or
    - If patient is currently receiving ECT, TMS may be considered reasonable and necessary as a less invasive treatment option; **and**
- A trial of an evidence-based psychotherapy known to be effective in the treatment of MDD of an adequate frequency and duration without significant improvement in depressive symptoms as documented by standardized rating scales that reliably measure depressive symptoms; **and**
- The order for treatment (or retreatment) is written by a psychiatrist who has examined the patient and reviewed the record. The physician will have experience in administering TMS therapy. The treatment shall be given under direct supervision of this physician (physician present in the area, but does not necessarily personally provide the treatment).

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[6] *See https://ir.neuronetics.com/news-releases/news-release-details/neurostarr-advanced-therapy-receives-fda-clearance-first-line*.

[7] CMS, Repetitive Transcranial Magnetic Stimulation (rTMS) in Adults, https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdid=34869&ver=38&keywordtype=starts&keyword=Transcranial%20Magnetic%20Stimulation&bc=0.

In California, several private health plans offered through Covered California, including Anthem Blue Cross, Blue Shield of California, and L.A. Care Health Plan, provide coverage for TMS.[8] These plans follow medical necessity guidelines that are similar to the Medicare's guidelines. For example, under Blue Shield's Medical Policy, TMS is generally considered medically necessary for use in a non-pregnant adult (ages 18 to 64) who meets the following criteria:

- Has a confirmed diagnosis of severe MDD (single or recurrent episode); **and**
- **One or more** of the following:
    - Resistance to treatment as evidenced by a lack of a clinically significant response
    - Inability to tolerate psychopharmacologic agents
    - History of positive response to TMS in a previous depressive episode
    - Is a candidate for ECT, but ECT would not be clinically superior to TMS; **and**
- Failure of an adequate trial of a psychotherapy known to be effective in the treatment of major depressive disorder as documented by standardized rating scales.[9]

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[8] While most plans make no distinction between outpatient and inpatient TMS, some private plans restrict coverage to TMS administered in an outpatient setting. For example, L.A. Care Health Plan provides coverage only for outpatient TMS under the category of *Outpatient and Other Mental Health and Substance Use Disorder Treatment*. L.A. Care Covered, Silver 70 HMO Summary of Benefits, available at: https://lacare.org/sites/default/files/la1167j_lacc_silver_70_eoc_en_2023.pdf. *See also* Update to the L.A Care Covered, Evidence of Coverage (Member Handbook) (2016), http://www.lacare.org/sites/default/files/mental-health-changes-2016-eoc-lacc.pdf, and L.A. Care Covered, A Helpful Guide to Your Health Care Benefits (2024), https://www.lacare.org/sites/default/files/la1167_lacc_eoc_silver_73_hmo_2024.pdf. For Anthem Blue Cross's TMS medical policy, *see* Anthem Blue Cross, Medical Policy on Transcranial Magnetic Stimulation (2021), https://providers.anthem.com/docs/gpp/california-provider/CA_CAID_PU_MCGCareGuidelines25thEdition.pdf?v=202105111637. For Blue Shield of California's medical policy on rTMS, *see* Blue Shield of California, Medical Policy on Transcranial Magnetic Stimulation as a Treatment of Depression and Other Psychiatric/Neurologic Disorders (2023), https://www.blueshieldca.com/bsca/bsc/public/common/PortalComponents/provider/StreamDocumentServlet?fileName=PRV_Transcranial_TX_Depression_Psyc_Disorders.pdf.

[9] In addition, none of the following conditions may be present:

(1) Seizure disorder or any history of seizure (except those induced by ECT or isolated febrile seizures in infancy without subsequent treatment or recurrence)

(2) Presence of acute or chronic psychotic symptoms or disorders (such as schizophrenia, schizophreniform or schizoaffective disorder) in the current depressive episode

Several behavioral health plans in California also provide coverage for medically necessary TMS for patients with more severe forms of MDD. For example, TMS is a covered service for beneficiaries of Magellan Healthcare who meet certain requirements for severity of need and for intensity and quality of service, including the requirement that a treating psychiatrist orders the service after the patient's symptoms have proven to be treatment-resistant to both medication management and psychotherapy.[10]

Medicaid programs in various states also provide coverage for TMS when medically necessary. Since 2012, Vermont's Medicaid program covers TMS for beneficiaries who meet a set of medical necessity criteria that resembles some of the guidelines followed by private health care plans.[11] Similarly, Iowa, Montana, and Wyoming cover TMS as a behavioral service for beneficiaries who have failed to respond to at least four medication trials from at least two antidepressant medication classes, are currently on an antidepressant, and have declined ECT or have a concurrent illness preventing safe administration of ECT.[12] Medicaid in Missouri and Ohio covers TMS when an inability to tolerate psychopharmacologic agents has been evidenced by two trials of psychopharmacologic agents from at least two different agent

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(3) Neurological conditions that include epilepsy, cerebrovascular disease, dementia, increased intracranial pressure, having a history of repetitive or severe head trauma, or with primary or secondary tumors in the central nervous system
(4) Presence of an implanted magnetic-sensitive medical device located less than or equal to 30 centimeters from the TMS magnetic coil or other implanted metal items, including but not limited to a cochlear implant, implanted cardioverter defibrillator, pacemaker, vagus nerve stimulator, or metal aneurysm clips or coils, staples, or stents

See Blue Shield of California, Medical Policy on Transcranial Magnetic Stimulation 1, *supra* note 8.

[10] Magellan Healthcare Inc., *2022-2023 Magellan Healthcare Guidelines* 24–32 (2022), https://www.magellanprovider.com/media/45694/mcg.pdf.

[11] Dep't Vt. Health Access, *Transcranial Magnetic Stimulation Clinical Practice Guidelines* (2020), https://humanservices.vermont.gov/sites/ahsnew/files/documents/MedicaidPolicy/GCRProposedPolicies/20-078-TMS-Guidance.pdf.

[12] For information on coverage in Iowa, see Iowa Dep't Hum. Servs., *Repetitive Transcranial Magnetic Stimulation* (2024), https://hhs.iowa.gov/media/9679/download?inline=. For information on coverage in Montana, see Mont. Dep't Pub. Health & Hum. Servs., Medicaid Services Provider Manual for Substance Use Disorder and Adult Mental Health – Transcranial Magnetic Stimulation (TMS) (2022), https://dphhs.mt.gov/assets/BHDD/MedicaidManual/475TMS.pdf. For information on coverage in Wyoming, *see* Wyo. Dep't Pub. Health, *CMS 1500 Provider Manual* (2022).

classes or if the patient has a history of good response to TMS.[13] In addition, Washington covers TMS under the following conditions: limited to 30 visits in a seven-week period followed by six taper treatments; must be ordered and performed by a psychiatrist or a P-ARNP; and must be performed in outpatient settings only.[14]

Coverage of TMS in Medi-Cal

TMS is a covered benefit in Medi-Cal based on the following three prongs for which we provide further details below: 1) TMS is not an experimental or investigate services, which would allow Med-Cal to exclude the service from coverage; 2) TMS is no longer listed as a non-benefit in Medi-Cal as it had been in the past; and 3) TMS fits the description of a Medi-Cal category of benefits, which allows DHCS to cover the benefit withoutthe need to submit a state plan amendment (SPA) to the Centers for Medicare and Medicaid Services (CMS).

TMS is not an experimental or investigative service

Pursuant to Cal. Code Regs. Tit. 22, § 51303, experimental and/or investigational services are not covered under Medi-Cal even if they fit within a covered category.[15] Experimental services are defined as "drugs, equipment, procedures or services that are in a testing phase undergoing laboratory and/or animal studies prior to testing in humans."[16] Investigational services are "drugs, equipment, procedures or services for which laboratory and animal studies have been completed and for which human studies are in progress but:

- Testing is not complete; and
- The efficacy and safety of such services in human subjects are not yet established; and
- The service is not in wide usage."[17]

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[13] For information on coverage in Missouri, see Mo. Dep't Soc. Servs., *Provider Bulletin, Volume 44, Number 48* (2022), https://mydss.mo.gov/media/pdf/transcranial-magnetic-stimulation-major-depressive-disorder-revised; For information on coverage in Ohio, see CareSource, *Medical Policy Statement – Transcranial Magnetic Stimulation* (2023), https://www.caresource.com/documents/medicaid-oh-policy-medical-mm-0223-20230101/.
[14] Wash. State Health Care Auth., *Mental Health Services Billing Guide* (2023) 49–50, https://www.hca.wa.gov/assets/billers-and-providers/mental-health-svcs-bg-20230101.pdf.
[15] Cal. Code Regs. tit. 22, § 51303(g)–(h).
[16] Cal. Code Regs. tit. 22, § 51056.1(a).
[17] Cal. Code Regs. tit. 22, § 51056.1(b).

According to the regulations, "the determination that a service is experimental or investigational is based on:

- Reference to relevant federal regulations, such as those contained in Title 42, Code of Federal Regulations, Chapter IV (Health Care Financing Administration) and Title 21, Code of Federal Regulations, Chapter I (Food and Drug Administration);
- Consultation with provider organizations, academic and professional specialists pertinent to the specific service; or
- Reference to current medical literature."

TMS is not an experimental or investigative service as defined in the regulations. The service is not currently in a testing phase undergoing laboratory or animal studies. In fact, experiments with TMS on humans have been documented since the 1980's. TMS is also not an investigational service under California law. While the procedure is continuously undergoing human testing to evaluate its effectiveness in treating other conditions, experimentation regarding the procedure's effect on MDD is well-established, as demonstrated by FDA's approval of TMS devices. Moreover, TMS is already widely used and prescribed for the treatment of MDD, as shown by the fact that many private and public insurers across the country provide coverage for TMS. Current medical literature, including the Practice Guidelines for the Treatment of Major Depression Disorder published by the American Psychiatric Association (APA) in 2010, which describes the uses and benefits of TMS, further confirms the procedure's status as a non-experimental and non-investigational service for the treatment of MDD.[18]

TMS is not included in the Medi-Cal TAR and Non-Benefit List

Prior to July 2024, DHCS included the planning, delivery, and management of TMS in its Medi-Cal TAR and Non-Benefit List.[19] However, in guidance updated in 2022, DHCS clarified that reimbursement for non-benefits may be available when the service is found to be medically necessary and after approval of a treatment authorization request (TAR) has been obtained.[20] Moreover, DHCS has taken the position that inclusion of TMS as a non-benefit does not immediately mean the service is a non-benefit of Medi-Cal. Rather, the non-benefit status

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[18] American Psychiatric Association, Practice Guidelines for the Treatment of Major Depression Disorder, 3rd edition, available at: http://psychiatryonline.org/pb/assets/raw/sitewide/practice_guidelines/guidelines/mdd.pdf.
[19] *See* Cal. Dep't Health Care Servs., *TAR and Non-Benefit List: Introduction to the List*, https://mcweb.apps.prd.cammis.medi-cal.ca.gov/assets/C9688358-EFF1-4BFE-AE82-097B6A5ED942/tarandnon.pdf?access_token=6UyVkRRfByXTZEWIh8j8QaYylPyP5ULO.
[20] *Id.*

means that the CPT code is not directly billable to DHCS' medical Fiscal Intermediary (FI), but it may still be a Medi-Cal benefit billed either through Short Doyle as specialty mental health service (SMHS) or provided through another delivery mechanism. In fact, TMS is expressly a billable SMHS pursuant to the Specialty Mental Health Billing Manual.[21]

Despite DHCS' clarification that TMS was a billable service, Managed care plans (MCPs) across California repeatedly used TMS' status as a non-benefit as justification to deny coverage of TMS for beneficiaries with MDD. These decisions were also upheld during appeals and in state fair hearings under the reasoning that MCP denials were appropriate given the fact that the service was a non-benefit listed in the TAR and Non-Benefit List. The decisions did not consider DHCS' clarification that even for non-benefits, medical necessity should be assessed before denying coverage. In response to these actions, DHCS changed the non-benefit status of TMS effective August 1, 2024. Pursuant to the revised policy, TMS is now a standard Medi-Cal benefit; however, a TAR is always required before coverage is approved and only beneficiaries over 15 are eligible for the benefit.[22]

TMS meets the definition of Specialty Mental Health Services (SHMS)

Under California law, Medi-Cal plans are required to cover all medically necessary services that have been included in the Medicaid State Plan.[23] California law defines medically necessary

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[21] Cal. Dep't Health Care Servs., *Specialty Mental Health Services Medi-Cal Billing Manual, Version 1.2*, https://www.dhcs.ca.gov/provgovpart/Documents/SMHS-Billing-Manual-Revised-8-22.pdf.

[22] *See* Cal. Dep't Health Care Servs., Policy Update for CPT Codes 90867, 90868. 90869, https://mcweb.apps.prd.cammis.medi-cal.ca.gov/news/32938.

[23] Cal. Welf. & Inst. Code § 14059 ("Health care provided under this chapter may include diagnostic, preventive, corrective, and curative services and supplies essential thereto, provided by qualified medical and related personnel for conditions that cause suffering, endanger life, result in illness or infirmity, interfere with capacity for normal activity including employment, or for conditions which may develop into some significant handicap"); Cal. Code Regs. Tit. 22, § 51303 ("Health care services […] which are reasonable and necessary to protect life, to prevent significant illness or significant disability, or to alleviate severe pain through the diagnosis or treatment of disease, illness or injury are covered by the Medi-Cal program […]"); Cal. Code Regs. Tit. 28, § 1300.67 ("The basic health care services required to be provided by a health care service plan to its enrollees shall include, where medically necessary, subject to any copayment, deductible, or limitation of which the Director may approve: physician services […], inpatient hospital services […], ambulatory care services

services for adults as those services that are "reasonable and necessary to protect life, to prevent significant illness or significant disability, or to alleviate severe pain."[24] Medical necessity for beneficiaries under 21 is defined according to the federal Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) benefit and its corresponding medical necessity criteria.[25] The EPSDT criteria establishes that services are medically necessary when needed to correct or ameliorate a physical or behavioral health condition.[26] At the same time, the California Legislature has determined the scope of Medi-Cal benefits to include "mental health services included in the essential health benefits adopted by the state."[27] In California, the provision of Medi-Cal mental health benefits is divided between services provided within a primary care provider's scope of practice, which are covered by MCPs, and SMHS, which are covered by county mental health plans (MHPs).

DHCS regulations define SMHS as extending to Rehabilitative Mental Health Services; Psychiatric Inpatient Hospital Services; Targeted Case Management, Psychiatrist Services; Psychologist Services; EPSDT Specialty Mental Health Services; and Psychiatric Nursing Facility Services.[28] The rule includes the following services as rehabilitative mental health services:[29]

- Mental health services
- Medication-support services
- Day treatment intensive
- Day rehabilitation
- Crisis intervention
- Crisis stabilization
- Adult residential treatment
- Crisis residential treatment services
- Psychiatric health facility services

The regulations define mental health services as "individual or group therapies and interventions that are designed to provide reduction of mental disability and restoration, improvement or maintenance of functioning consistent with the goals of learning,

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[…]"). *See also Cowan v. Myers*, 187 Cal.App.3d 968 (1987) (finding that provisions of California law limiting Medi-Cal benefits to medically necessary services are not inconsistent with the federal Medicaid Act).
[24] Cal. Welf. & Inst. Code § 14059.5(a).
[25] Cal. Welf. & Inst. Code § 14059.5(b)(1).
[26] 42 U.S.C. § 1396d(r)(5).
[27] Cal. Welf. & Inst. Code § 14132.03(a)(1).
[28] Cal. Code Regs. tit 9, § 1810.247.
[29] *Id.*

development, independent living and enhanced self-sufficiency and that are not provided as a component of adult residential services, crisis residential treatment services, crisis intervention, crisis stabilization, day rehabilitation, or day treatment intensive."[30]

California's Medicaid State Plan includes similar language. Under the state plan, Medi-Cal is required to cover "rehabilitative mental health services" as long as the services are medically necessary. Rehabilitative services are defined as "services recommended by a physician or other licensed mental health professional within the scope of his or her practice under State law, for the maximum reduction of mental or emotional disability, and restoration, improvement, and/or preservation of a beneficiary's functional level."[31] Furthermore, the state plan provides the same definition of mental health services as the regulations (individual, group, or family-based interventions designed to provide reduction of mental disability).[32]

The definition of mental health in both Cal. Code Regs. tit. 9, § 1810.227 and the state plan is broad enough to encompass TMS. The service is an individual therapy designed to provide reduction of mental disability, in this case MDD, and is not a component of residential or crisis treatment. Therefore, TMS could be considered a SMHS for purpose of Medi-Cal coverage.

Medi-Cal beneficiaries would still need to prove that they meet the criteria to access SMHS. The access criteria for an adult seeking SMHS is met when:[33]

- The beneficiary has one or both of the following:
    - Significant impairment, where impairment is defined as distress, disability, or dysfunction in social, occupational, or other important activities.
    - A reasonable probability of significant deterioration in an important area of life functioning,

AND

- The beneficiary's condition is due to either of the following:
    - A diagnosed mental health disorder, according to the criteria of the Diagnostic and statistical manual of Mental Disorders and the International Statistical Classification of Diseases and Related Health Problems

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[30] Cal. Code Regs. tit. 9, § 1810.227.
[31] Supplement 3 to Attachment 3.1-A of the State Plan, available at http://www.dhcs.ca.gov/formsandpubs/laws/Documents/Supplement_3_to_Attachment_3.1-A.pdf.
[32] *Id.*
[33] Cal. Welf. & Inst. Code § 14184.402(c). Cal. Dep't Health Care Servs., Behavioral Health Information Notice No. 21-073 (2021), https://www.dhcs.ca.gov/Documents/BHIN-21-073-Criteria-for-Beneficiary-to-Specialty-MHS-Medical-Necessity-and-Other-Coverage-Req.pdf.

- A suspected mental disorder that has not yet been diagnosed.

MDD, which TMS is recommended for, is considered a mood disorder. MDD also contributes to significant impairment in an important area of life functioning and, if untreated, may lead to significant deterioration in life functioning. As such, patients seeking coverage for TMS to treat their depression condition are likely to meet the criteria to access SMHS. Importantly, recent policy changes that apply to the access criteria have established that a diagnosis is not required for coverage; rather, a beneficiary with a *suspected* MDD may be eligible for TMS if other prongs of the SMHS access criteria for adults are met.

For individuals under 21, the access criteria is met when either of the following applies:[34]

- The beneficiary has a condition placing them at high risk for a mental health disorder due to experience of trauma evidenced by any of the following: scoring in the high-risk range under a trauma screening tool approved by DHCS, involvement in the child welfare system, juvenile justice involvement, or experiencing homelessness.

OR

- The beneficiary meets both of the following requirements:
  - The beneficiary has at least one of the following:
    - A significant impairment
    - A reasonable probability of significant deterioration in an important area of life functioning
    - A reasonable probability of not progressing developmentally as appropriate.
    - A need for specialty mental health services, regardless of presence of impairment, that are not included within the mental health benefits that a Medi-Cal managed care plan is required to provide.

  AND

  - The beneficiary's condition as described in subparagraph (2) above is due to one of the following:
    - A diagnosed mental health disorder, according to the criteria of the current editions of the Diagnostic and Statistical Manual of Mental Disorders and the International Statistical Classification of Diseases and Related Health Problems.
    - A suspected mental health disorder that has not yet been diagnosed.

[34] Cal. Welf. & Inst. Code § 14184.402(d). Cal. Dep't Health Care Servs., BHIN 21-073 (2021), *supra* note 33.

- Significant trauma placing the beneficiary at risk of a future mental health condition, based on the assessment of a licensed mental health professional.

The SMHS access criteria for individuals under 21 is designed to be less restrictive than the access criteria for adults in order to comply with the EPSDT requirements. Therefore, beneficiaries under 21 with a suspected or diagnosed MDD that may benefit from TMS according to their providers are likely to meet both the access and medical necessity criteria for SMHS. According to both federal and state guidance, mental health services do not need to be curative or restorative to ameliorate a mental health condition. DHCS guidance states "[s]ervices that sustain, support, improve, or make more tolerable a mental health condition are considered to ameliorate the mental health condition are thus medically necessary and covered as EPSDT services."[35]

Along the same lines, the EPSDT requirements bar California from limiting coverage of a service to only a subset of the population of individuals under 21, unless medical necessity would not apply in the case of a certain age range. In the case of TMS, the FDA has approved the devices only for adolescents aged 15 or older, which is likely why DHCS' recent policy limits availability of TMS to beneficiaries who are at least 15 years old. In some circumstances, however, providers may prescribe a procedure or device outside of its FDA-approved labeling (known as off-label use). In those situations, when medical necessity and access criteria are met, EPSDT rules require coverage irrespective of the determination made by the state Medicaid agency. These decisions must also determine that TMS is clinically appropriate for the minor in question. Clinical appropriateness, however, should be evaluated on a case-by-case basis and state policy cannot categorically exclude coverage of the service for an entire subset of the population under 21 without running afoul of EPSDT requirements.

Conclusion

DHCS has taken several actions that confirm Medi-Cal's coverage of TMS, including clarifying that non-benefits may still be covered when medical necessity is met, informing that TMS may be covered as a SMHS, and most recently removing TMS from the TAR and Non-Benefit List altogether. DHCS has also indicated that provider bulletins with more information about Medi-Cal coverage and availability of TMS is forthcoming.[36] In addition to the provider bulletin,

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[35] *Id.*

[36] *See* Cal. Dep't Health Care Servs., Policy Update for CPT Codes 90867, 90868. 90869, *supra* note 22.

DHCS should issue guidance to MCPs (via an All-Plan Letter) and MHPs (via a Behavioral Health Information Notice) explaining that TMS is considered a SMHS and, therefore, MHPs are primarily responsible for provision of the service. Under DHCS' No Wrong Door, both plans have the responsibility to assess medical necessity and access criteria and the MCPs should refer the beneficiary to the MHP, as appropriate and through a warm handoff approach, rather than outright denying coverage.[37]

Additional guidance should also further clarify the applicable medical necessity criteria and the access criteria that plans should use for this benefit. While DHCS could adopt the criteria that Medicare and commercial plans in California have adopted for TMS coverage, the controlling medical necessity criteria for Medi-Cal beneficiaries under 21 is the EPSDT medical necessity criteria, which requires states to provide access to all Medicaid coverable benefits that are necessary to correct or ameliorate a physical or behavioral health condition even if the prescribed use is considered off-label. This means that DHCS may establish access criteria that resembles typical TMS criteria, but it must not conflict with the EPSDT medical necessity criteria. Finally, since TMS is not an experimental service, as a covered Medi-Cal benefit, it cannot be limited to children over a certain age under EPSDT, as DHCS outlined in the recent policy update removing TMS from the Non-Benefit list where the agency described TMS as eligible for beneficiaries 15 years or older. DHCS should therefore delete that limitation as contrary to EPSDT, and clarify to plans that the EPSDT medical necessity criteria controls for beneficiaries under 21.

[37] Cal. Dep't Health Care Servs., Behavioral Health Information Notice No. 22-011 (2022), https://www.dhcs.ca.gov/Documents/BHIN-22-011-No-Wrong-Door-for-Mental-Health-Services-Policy.pdf; Cal. Dep't Health Care Servs., All Plan Letter No. 22-005 (2022), https://www.dhcs.ca.gov/formsandpubs/Documents/MMCDAPLsandPolicyLetters/APL2022/APL22-005.pdf.