Repetitive Transcranial Magnetic Stimulation for Treatment-Resistant Depression:

Mismatch of Evidence and Insurance Coverage Policies in the United States

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Major depressive disorder (MDD) is common and highly disabling. In the United States, the estimated 12-month prevalence of MDD is 8.9 million adults, of which one third (2.76 million) meet criteria for treatment-resistant depression (TRD).[1] The most common definition of TRD is a minimum of 2 antidepressant medication failures of different classes at an adequate dosage and duration.[2–4] Patients who develop TRD experience diminishing returns with each additional antidepressant medication trial, which highlights the need for alternative treatments at this critical point in the course of their depressive illness.[3] There is significant burden associated with untreated TRD,[5,6] as it is more disabling compared to MDD.[7] This disease burden extends to medical comorbidities as well.[8,9] The amount of time one is depressed, which is far lengthier in TRD, also predicts future disability.[10] Patients with TRD experience large declines in quality of life and social functioning.[11] Evidence also consistently shows the high lethality of TRD, with its strong association to suicidality.[11,12] It is therefore imperative to make effective treatments available for patients diagnosed with TRD. While there is minimal evidence to guide treatment algorithms for patients with TRD, we do believe that current practices of prior authorization by insurance companies specifically overly restrict access to repetitive transcranial magnetic stimulation (rTMS), which is a treatment with proven effectiveness for TRD. In this commentary, we explore this case of overrestriction of access to rTMS in the United States through review of both the clinical evidence and the relevant economic policy.

Thanks to the diligent and innovative work of many researchers in the field, there are effective treatment options available for patients with TRD. The most effective and time-tested treatment for this patient population is electroconvulsive therapy (ECT). However, stigma, the risk of adverse cognitive effects, and side effect burden limit the acceptability of this treatment,[13,14] leading to the use of ECT in less than 1% of patients with TRD.[15] Intravenous (IV) ketamine and intranasal esketamine both demonstrate efficacy in TRD, although there is scant evidence for maintenance IV ketamine, and both treatments are limited by the requirement of anesthesia or nurse monitoring.[16] One effective, safe, and tolerable alternative that has demonstrated real world effectiveness, and has become widespread in clinics across the United States, is rTMS.[17] Multiple national guidelines and government agencies advocate for the use of rTMS to treat depression in patients with TRD who have failed just 1–2 antidepressant trials.[18–21] The defining qualities of rTMS treatment make it a potential first-line treatment when pharmacotherapy has failed or is not an option: it is safe and tolerable, leads to minimal side effects, is easily delivered in an outpatient setting, and, while less efficacious than ECT, demonstrates real world response and remission rates conservatively estimated as approximately 60% and 30%, respectively.[22,23] Additionally, a network meta-analysis revealed superior remission rates for rTMS compared to standard pharmacologic strategies at 4–6 week outcomes.[24] The use of rTMS as a treatment for TRD is growing in acceptability, and future advances in the field are poised to broaden and enhance its role in treating MDD and other neuropsychiatric conditions.[25–28] Given the above evidence and overall attractiveness of this treatment, it is surprising that many insurance companies remain overly cautious and hesitant in granting access to this treatment, some requiring class action lawsuits to motivate coverage for patients.[29] Future studies investigating the place of rTMS within the TRD treatment algorithm will likely help solidify its use earlier in the course of illness.

There is evidence to suggest that many insurance companies overly restrict rTMS access for patients with TRD in the United States (see Supplementary Table 1 for details). Such overrestrictiveness through the prior

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authorization process includes requirements such as high disease severity, high number of failed antidepressant trials, and failed augmentation strategies and psychotherapy. With regard to high disease severity, the vast majority of existing evidence actually supports the use of rTMS in moderate and severe TRD rather than just severe illness.[18,30] Two of the pivotal rTMS trials[31,32] enrolled participants with an average moderate severity of depression, as measured by the 17-item and 24-item Hamilton Depression Rating Scales. This is in contrast to the requirement of moderate-severe or severe depression by many insurance companies (see Supplementary Table 1), for which there is no consistent method of measurement used by the industry. Multiple studies also show enhanced rTMS efficacy in patients with less treatment resistance, which contrasts with insurance companies' demand of over 4 failed medication trials in many cases (Supplementary Table 1).[33,34] In fact, the pivotal rTMS studies that led to FDA approval included only a minimum of 1–2 failed trials.[23,31,32,35,36] Also, in a key network meta-analysis on rTMS in MDD that reviewed 81 trials and demonstrated the superiority of multiple forms of rTMS compared to sham, only 2 trials required failure of 3 or more medication trials, and none required 4 failed trials.[37] Although effective in patients who have more than 3 failed medication trials, rTMS is most effective in patients with less treatment resistance.[18,34,38] It is important to note here, though, that the standard for a failed pharmacotherapy trial can be more rigorous in the context of clinical trials than in regular clinical care. Beyond failed pharmacotherapy trials, there is no evidence to support the rationale for requiring failed psychotherapy prior to a trial of rTMS, and evidence does exist demonstrating that rTMS treatment can potentially lead to a reduction in the need for psychotherapy.[39] Overall, while the above body of evidence clearly supports the use of rTMS as a treatment for TRD after failure of at most 2 antidepressant trials, the majority of insurance company health plans require severe depressive symptoms, at least 4 antidepressant medication trials from 2 different classes, and a course of psychotherapy before rTMS is considered for authorization. It is laudable that rTMS is available for patients with TRD with high disease severity and higher levels of treatment resistance, but access should not be restricted for patients with less disease severity and treatment resistance, for which the evidence shows rTMS is most effective.

The Clinical TMS Society (CTMSS) coverage guidance states that adults 18 years or older with a diagnosis of moderate or severe MDD with at least 1 failed antidepressant trial at an adequate dose and 6–8 week duration, or 2 not tolerated antidepressant trials at shorter duration, should be offered rTMS treatment.[21,40] As a caveat, it is important to note that there is no consensus definition of a not tolerated antidepressant trial. The CTMSS guidance is not only rooted in the evidence, but also makes sense economically. Insurers are increasingly turning to incremental cost-effectiveness when examining new technologies or therapies for coverage. Incremental cost-effectiveness is commonly evaluated over the lifetime of a patient and examines the incremental cost of a new technology or therapy (eg, rTMS) versus standard of care (eg, pharmacotherapy), aggregating the incremental benefit as measured via quality of life (QoL). Aggregated QoL assessments measured over the life of a patient are termed *quality-adjusted life-years* (QALYs). In the US, the incremental cost-effectiveness ratio (ICER) is deemed cost-effective, and of good value, when the ICER is < $50,000/QALY gained.[41] A recent analysis examining cost-effectiveness of rTMS after only 1 failed pharmacotherapy trial demonstrated that initiation of rTMS in younger (mid 20s) and older (mid 50s) patients yielded an incremental cost per QALY less than $50,000.[42] Another study demonstrated that rTMS leads to higher QALYs and lower cost in TRD at both 3 and 5 years when compared to antidepressant treatment alone.[43] This was shown even with conservative estimates of 37.5% response and 21.5% remission for rTMS. Another interesting coverage policy point is that there are at least 2 Medicare local carriers, Novitas Solutions (policy number L34998)[44] and Noridian Healthcare Solutions (policy number L37086),[45] that do cover the use of rTMS after treatment failure of at least 1 psychopharmacologic agent. Why other Medicare carriers and private insurers do not cover the use of rTMS after 1 trial is concerning, and it creates an access issue to a proven therapy.

Specialty society guidelines, upon which insurers generally rely to make coverage determinations, should be updated as it relates to the use of rTMS in MDD. The American Psychiatric Association (APA) clinical practice guidelines for MDD were last updated in 2010. The conclusion in these guidelines states, "Evidence for TMS is currently insufficient to support its use in the initial treatment of major depressive disorder."[46] In 2010, rTMS was being actively evaluated in clinical trials as to its clinical application and efficacy. It is now a proven therapy. The APA MDD clinical practice guidelines should be updated, as insurers commonly seek out the positions of specialty societies on various therapies when making coverage policies. Organizations such as the UK's National Institute for Health and Care Excellence (NICE) support the use of rTMS in MDD in patients who have not responded to antidepressant medication or for whom antidepressants are not suitable. The NICE guidelines do not provide a specific number of failed medication trials, though.[47] An update of this guideline in accordance with the CTMSS guidance would also be helpful for potential patients. Broader coverage and enhanced access for rTMS treatment will reduce morbidity and mortality for patients with TRD, improve cost-effectiveness of depression treatment, and relieve pressure on our burdened health care system. Health insurance plans should consider a revision of rTMS coverage policies accordingly. Advocacy and education initiatives directed at insurance companies by academic experts will help push this important agenda forward. Future studies that prospectively and comprehensively assess treatment algorithms for TRD may also help to highlight this rTMS coverage policy mismatch and lead to treatment optimization in TRD.

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See supplementary material for this commentary at PSYCHIATRIST.COM.

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Supplementary Material

Title: Repetitive Transcranial Magnetic Stimulation for Treatment-Resistant Depression: Mismatch of Evidence and Insurance Coverage Policies in the United States

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List of Supplementary Material

1. Table 1 — Insurance Requirements by Plan for Approval of an Initial 6-Week Course of rTMS for MDD

Disclaimer

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Supplementary Table 1. Insurance Requirements by Plan for Approval of an Initial 6-week Course of rTMS for MDD

Insurance Plans	Estimated Number of Members/ State Operations	Depression Severity Requirement (1) Not specified (NS); Moderate (M); Severe (S); Moderate or Severe (M-S)	Number of Failed Psychopharmacologic Agents Requirement (2) (Antidepressants, Augmentation trials)[1]	Number of Antidepressant Trials Not Tolerated Requirement (3)	Failed Psychotherapy Requirement (4)	Prior Authorization Requirement	Guideline for Treatment After Failure of One Medication Trial
Clinical TMS Society Guidelines	--	M-S	1 (1,0)	2	No	--	1st Line
FDA Clearance	--	MDD (no severity specified)	1 or more	NS	--	--	1st Line
Traditional Medicare Enrollment (2021)	36 million						
First Coast Service Options L34522 Updated 12/11/22	FL, Puerto Rico, US Virgin Islands	S	1 (1,0)	1	No	No	1st Line
Novitas 34998 Updated 12/11/22	AR, CO, DE, DC, MD, NJ, NM, OK, PA, LA, TX	S	1 (1,0)	1	No	No	1st Line
Noridian L37086 Updated 12/1/2019	AK, AZ, CA, HI, ID, ND, NV, MT, OR, SD, UT, WA, WY, American Samoa, Guam, Northern Mariana Islands	S	1 (1,0)	2	Yes	No	1st Line
Palmetto GBA L4869 Updated 6/9/22	AL, GA, NC, TN, SC, VA, WV	S	2 (2,1)	2	Yes	No	2nd Line
Wisconsin Physicians Service Government Health Administrators L34641 Updated 10/17/2022	IA, KS, MO, NE, IN, MI	S	2 (2,0)	2	Yes	No	2nd Line
CGS Administrators, LLC L36569 Updated 1/5/2023	KY, OH	S	2 (2,0)	2	Yes	No	2nd Line
National Government Services Inc L33398 Updated 10/1/2020	IL, MN, WI, CT, NY, ME, MA, NH, RI, VT	NS	4 (4,2)	4	Yes	No	4th Line
Commercial Insurance Plans							
Aetna	39 million/ All 50 States	S	2 (2,1)	2	Yes	Yes	2nd-3rd Line
Cigna	17M/ AZ, CA, CO, CT, GA, MO, NC, SC, TN, TX MD, FL	M-S	2 (2,0)	2	Yes	Yes	2nd Line
United Health Care/Optum	49.5 million/ All 50 States	S	4 (4,0)	4	Yes	Yes	4th Line
Humana	20 million/ AZ, CO, FL	S	4 (4,0)	4	Yes	Yes	4th Line
Centene (Magellan)	FL, LA, NW, VI, WY, PN	S	4 (4,0)	2	Yes	Yes	4th line
Centene (Health Net)	CA	M-S	4 (4,2)	4	Yes	Yes	4th Line
Tufts	MA	NS	4 (2,2)	4	Yes	Yes	3rd-4th Line

Blue Cross Blue Shield (BCBS) Association							
Heath Care Service Corporation	Il, MN, NW, OK, TX	M-S	2 (2,0)	NS	Yes	Yes	2nd Line
Anthem	42 million/ CA, CO, CT, GA, IN, KY, ME, MI, NV, NH, NY, OH	NS	2 (2,0)	4	No	Yes	2nd Line
Premera Blue Cross Blue Shield of Alaska	2.6 million/ AK, WA	M-S	2 (2,1)	2	No	Yes	2nd Line
Blue Shield of California	CA	S	2 (2,0)	2	Yes	Yes	2nd Line
Care First Blue Cross Blue Shield	DC, MD, VA	NS	2 (2,0)	NS	No	Yes	2nd Line
Blue Cross Blue Shield MN	MN	S	3 (3,1)	4	Yes	Yes	3rd Line
Providence	AK, CA, MN, NM, OR, TX, WA	S	3 (3,0)	3	Yes	Yes	3rd-line
High Mark Blue Cross Blue Shield	DE, PN, WV	S	4 (2,2)	4	Yes	Yes	2nd -4th Line
Multiple Blue Cross and Blue Shield Plans, Blue KC, Florida Blue, Scan Health Plan, High Mark Blue Cross, Blue Shield	AL, AR, KS, LA, MI, FL, MO, WY, VT, ID, NC, DE, PN, WV,	S	4 (2,2)	4	Yes	Yes	2nd -4th Line
Regence Blue Cross Blue Shield	ID, OR, UT, WA	NS	3 (3,0)	3	Yes	Yes	3rd Line
Blue Cross Blue Shield HA, MA, Excellus,	HA, MA, NY	S	4 (4,0)	3	Yes	Yes	4th Line
Blue Shield Blue Cross Federal Program		S	4 (2,2)	4	Yes	No	2nd-4th Line

[1]Some policies specify that medication trials must involve combined antidepressant treatment, or medications from at least two different classes prescribed as separate trials, or failure of a trial that involves an antidepressant agent plus an augmenting agent.

How to interpret the above table: We reviewed insurance TMS coverage policies publicly available on the web from 2/1/2023- 2/7/2023. Coverage for TMS services is based on **(1)** a confirmed diagnosis of MDD with either moderate or severe symptoms documented on a validated rating scale, **(2)** Resistance to treatment with psychopharmacological agents as demonstrated by a lack of clinically significant response (<50% reduction in symptoms) **or (3)** Inability to tolerate psychopharmacological agents **and (4)** lack of response to evidence-based psychotherapy as documented by standardized rating scales that reliably measure depressive symptoms. Policies shaded green are consistent with FDA clearance and CTMSS guidelines, and they consider TMS 1st line treatment after failing one pharmacological treatment for MDD. Policies in yellow are moderately restrictive of TMS treatment compared to FDA clearance and CTMSS guidelines; they consider TMS after two pharmacological trials (i.e., TMS is 2nd Line after one drug failure). Policies in red are overly restrictive compared to the FDA clearance and CTMSS guidelines, and they require multiple pharmacological agents and a high level of treatment resistance before approving TMS.