

TOPICAL WEBINAR FOR APA MEMBERS

An Educational Resource from Big Health

Digital Therapeutics in Clinical Care: What Providers Need to Know

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ATTENDANCE

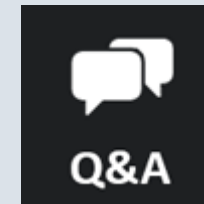
- No CE credit will be offered for this webinar.
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- You must attend for 45 minutes to receive the certificate.

RECORDING

- A recording of this presentation will be emailed to everyone in 2 weeks' time.
- The recording will include the presentation slides.

HAVE A QUESTION?

- You are on mute. Communicate using the **Q&A box** in the webinar screen. Attendees can view and upvote on submitted questions in the Q&A box to help presenters identify popular topics.
- Presentation slides will be posted in the **chat box** of your webinar screen.





Dani Bradley



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Disclosures and conflicts of interest

DB is employed by Big Health Inc. and has stock options.

ALH is employed by Big Health Inc, is a shareholder and has stock options.

Digital interventions can **close gaps and address unmet needs** in mental health care

Improve accessibility

Alleviate common barriers like: geographic location, mobility issues, stigma, schedule availability, language needs.

Early intervention and prevention

Empower individuals and providers to recognize symptoms early and access support before issues escalate.

Personalized support

Interventions that cater to individual needs, preferences, and circumstances, enhancing engagement and adherence.

Continuity of care & support

Continuous support, monitoring, and resources beyond traditional therapy sessions and fill gaps in care between appointments.

Rapid increase in available digital interventions...but not all are created equal

- Conflation of evidence-based digital treatments and wellness apps
- Limited clinical evidence for many commercially available, and widely used wellness programs, with some even making misleading claims and harming users¹

Evidence-based	vs.	Evidence-informed
<u>Program has randomized controlled trials validating its clinical efficacy and safety</u>		<u>Program has no direct clinical trial evidence, relies on broader literature for CBT or digital CBT</u>
		No evidence of efficacy and safety; often making unsubstantiated claims

1. Torus, J., Firth, J., & Goldberg, S. (2024). Digital Mental Health's Unstable Dichotomy: Wellness and Health. *JAMA Psychiatry*, 81(6): 539-540.
2. Espie, C.A., & Henry, A.L., (2022). Designing and Delivering a DTx Clinical Research Program: No Need to Re-invent the Wheel. In A. Sverdllov & J. VanDam (Eds.), *Digital Therapeutics: Scientific, Statistical, Clinical, and Regulatory Development Aspects*.

Evidence standards for digital treatments

- Evidence-based digital therapeutics need to be differentiated from evidence-informed apps
- There is no need for “digital exceptionalism” - the same scrutiny should apply to all treatments that will end up in the hands of patients.^{1,2}

WHAT criteria ³	Demonstrated by...
W: The therapeutic has to WORK	Treatment efficacy needs to be supported by adequately powered randomized control trials (RCTs) to demonstrate level 1 evidence of change that is attributable to the digital intervention. The trial and its primary and secondary outcomes should be pre-registered, and those data should be published following peer-review.
H: The therapeutic has to HELP	Statistically significant between-group effects of the digital intervention over a control condition are important. However, RCT(s) need to demonstrate clinically meaningful differences or clinical remission endpoints relating to the target therapeutic condition, as assessed by clinically accepted and standardized pre-registered measures.
A: The therapeutic has to be ACCESSIBLE	A digital intervention has to use high quality technology to deliver a reliable and acceptable patient experience within the target population. There needs to be evidence that the digital therapeutic is capable of scaling safely and effectively to population-level distribution in the real world.
T: The therapeutic has to be TRUSTED	The digital intervention needs to adhere to clinical governance and risk management standards for software as a medical device and privacy and data security certifications, and reflect national and international clinical guidelines for information storage and data transfer.

1. Espie & Henry (2022). *Digital Therapeutics*

2. Espie et al (2018). *The Lancet*

3. Espie, Torous & Brennan. (2022). *Health Affairs Forefront*.

Differentiating digital mental health treatments (DMHT) from wellness products

Differentiating DMHTs from wellness apps

	DMHTs	Wellness apps
REGULATORY OVERSIGHT	FDA-regulated as medical devices	Not regulated; cannot claim to be CBT or a treatment, or manage symptoms
EVIDENCE	Vetted in clinical trials for safety, efficacy, and outcomes	May not have clinical validation
DATA SECURITY + PRIVACY	Must be compliant with HIPAA and other medical regulations	May not meet healthcare data standards due to lack of oversight
CARE INTEGRATION	Integrated into patient care plans + monitored by providers	No provider oversight or formal care integration
REIMBURSEMENT	Reimbursable as an incident-to provider service (code G0552)	Not reimbursable

Digital Mental Health Treatments (DMHTs)

- **DMHTs (Digital Mental Health Treatments)** are a new treatment class defined by Centers for Medicare & Medicaid Services (CMS).
 - Must be **FDA-cleared under 21 CFR 882.5801**.
 - FDA review assesses clinical evidence, software quality, and cybersecurity.
 - Approval requires meeting **quality, security, and clinical efficacy** standards
- DMHTs include both **patient-facing interventions** and **provider dashboards** for insights/feedback.
- Can be prescribed by both **traditional and non-traditional licensed prescribers** (e.g., psychologists, LCSWs, LMFTs, LPCs).

Current DMHT landscape

To date, 7 programs meet the DMHT criteria, and are eligible for reimbursement under the DMHT G-codes

SleepioRx

Insomnia disorder
(18+)

DaylightRx

GAD (22+)

Rejoyn

MDD (22+)

MamaLift Plus

Postpartum
depression (22+)

Somryst

Insomnia disorder
(22+)

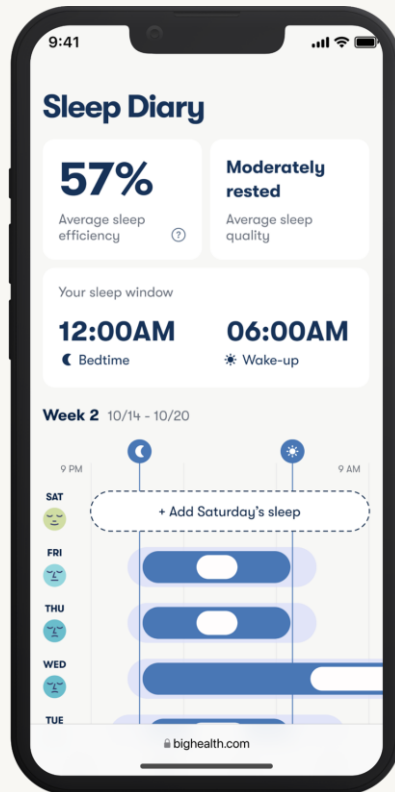
reSET

Substance use
disorder (18+)

reSET-O

Opioid use disorder
(18+)

Big Health Rx Product Portfolio: SleepioRx and DaylightRx



SleepioRx: The only FDA-cleared digital treatment delivering first-line CBT-I for adults 18 and older.

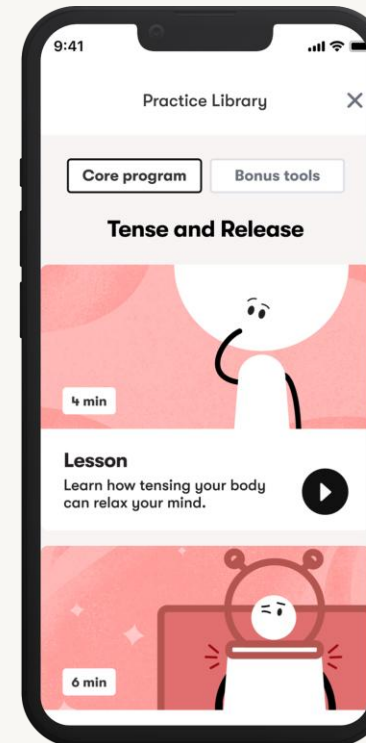
- **76%** experience clinically meaningful improvement¹
- Evaluated in **17 RCTs**
- Used by **over 500k** people²

SleepioRx is a digital therapeutic intended for the treatment of chronic insomnia/insomnia disorder as an adjunct to usual care in patients aged 18 and older. SleepioRx is a prescription device delivering Cognitive Behavioral Therapy for Insomnia (CBT-I) and can be made available on the order of a licensed healthcare provider. Patients should read the indications for use.

1. Changes up to these levels have been demonstrated across studies, including:

- Espie et al. (2012). *Sleep* 35(6), 769-781.
- Tarnai et al. (2025). *Aging and Mental Health*, 1-7.
- Prather et al. (2025). *JMIR Mental Health*, 12, e84323.

2. Internal Data. (Jan 2026).



DaylightRx: The only FDA-cleared digital treatment delivering first-line CBT for GAD in adults 22 and older.

- **71%** experience clinically meaningful improvement³
- Evaluated in **3 RCTs**
- Used by **over 110k** people⁴

DaylightRx is a prescription device delivering Cognitive Behavioral Therapy and can be made available on the order of a licensed healthcare provider. DaylightRx is a digital therapeutic intended to treat generalized anxiety disorder (GAD) by improving a patient's GAD symptoms as an adjunct to usual care in patients aged 22 years and older. Patients should read the instructions for use for full information.

3. Changes up to these levels have been demonstrated across studies, including:

- Carl et al. (2020). *Depression & Anxiety*
- Parsons et al. (2025). *JAMA Network Open*

2. Internal Data. (Jan 2026).

How to integrate DMHTs into clinical practice

But will DMHTs replace psychologists?

COACHING

Will AI Replace Coaches and Psychologists?

Prepare for massive disruption.

Posted March 5, 2021

Is robot therapy the future?

Will robots replace therapists?

Sit back, relax, and tell the algorithm what's on your mind

Machines can do most of a psychologist's job. The industry must prepare for disruption

Published: February 8, 2021 7.05pm GMT



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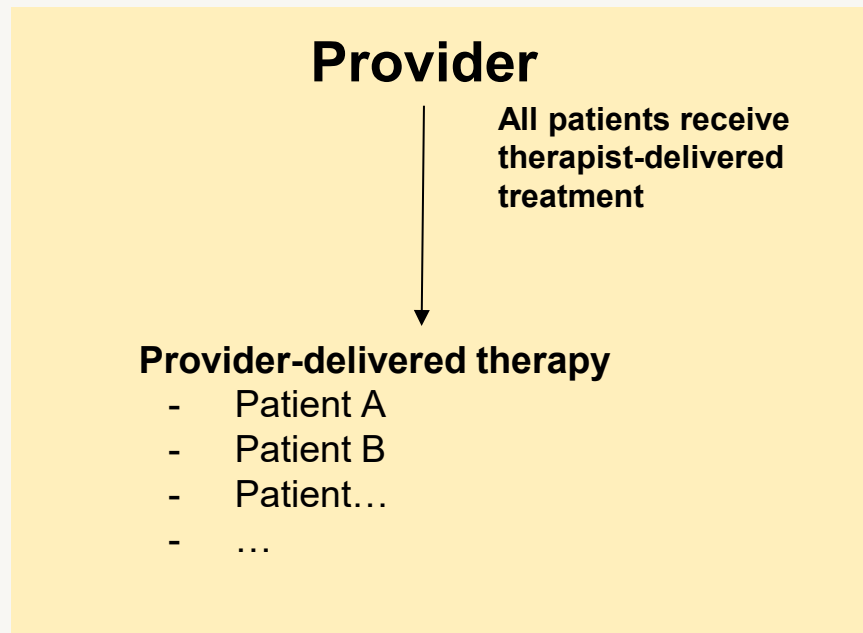
Projecting the future impact of advanced technologies: Will a robot take my job?

No, but DMHTs can help expand providers capabilities

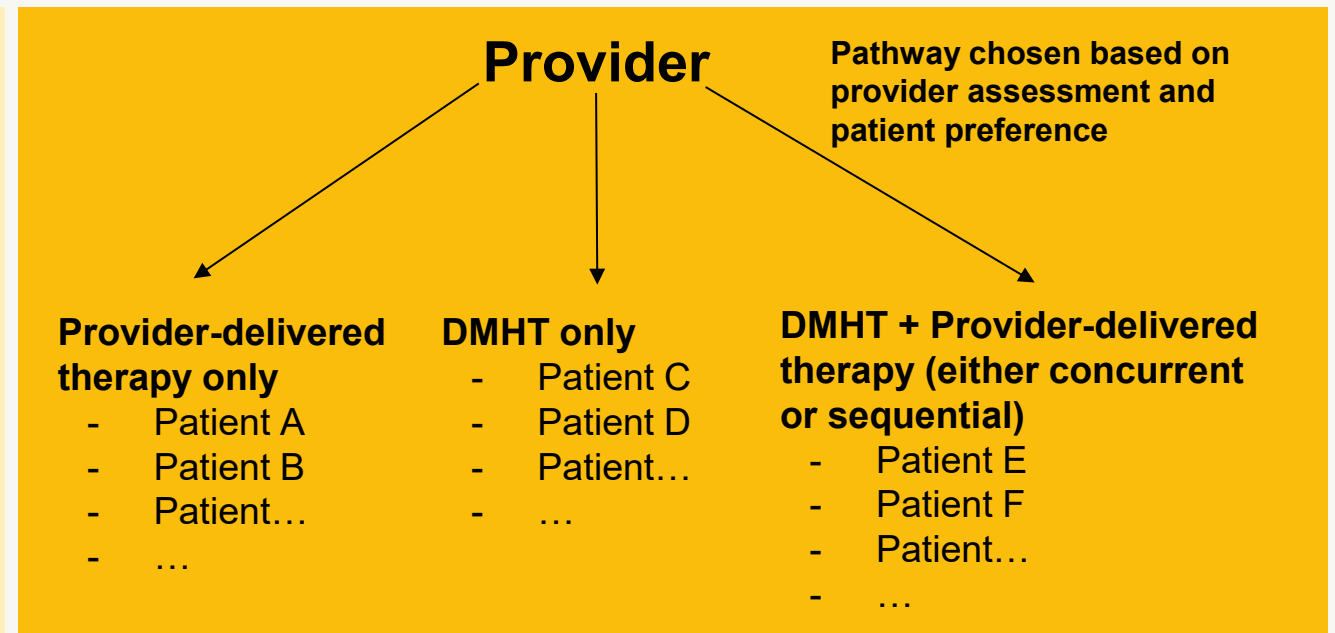
DMHTs and integration with traditional psychological practice

- DMHTs can help providers expand their clinical practice and offer an additional service

Traditional practice



DMHT enabled practice



Clinical use cases for DMHTs for psychologists

First line care	Offer DMHT to provide first-line treatment per clinical guidelines
Waitlist support	Offer DMHT as a support tool for patients on a waitlist
Therapy reinforcement	Offer DMHT to reinforce therapy skills and support practice of CBT between sessions
Comorbid condition treatment	Offer DMHT to address a comorbid patient complaint (e.g., insomnia) while clinician focuses on the primary condition in face-to-face sessions (e.g., depression or anxiety)
Maintenance support	Offer DMHT ahead of treatment termination as a tool to maintain CBT skills

CASE STUDY: Health System

Henry Ford Health: Improving care by integrating digital treatments into a US health system

Challenge

- 5 month wait to see a licensed clinician trained in CBT-I
- Medications with serious risks & side effects
- Limited other options for HCPs to offer patients with insomnia

Solution

SleepioRx was implemented as first-line insomnia care in Internal Medicine and Sleep Medicine clinics.

Adoption

4,400+ orders across early adopting HFH Sleep & Internal Medicine Providers

1. Henry Ford Health Epic order flow data (September 2025). 2. Improvement defined as at least a 25% improvement on the SCI-2 pre-to-post SleepioRx from the last observed SCI-2 score.

1. Out of the total number of Sleepio orders placed by providers.
2. Limited to patients with symptoms of insomnia at baseline (defined as SCI-2 ≤ 7 at baseline)

ACCESS TO SLEEPIORX AT HENRY FORD HEALTH

1 day
Time to care

Average access time from order to treatment initiation

60%
Order-to-sign ups

Percent of patients who enrolled in SleepioRx¹

79%
Improvement rate

Percent of patients who saw improvements in insomnia symptoms²

“ Our patients are better off with digital CBT. It provides them with access to an evidence-based treatment option that aligns with clinical guidelines. Overall, it’s been a very helpful intervention.”

— BOARD-CERTIFIED SLEEP SPECIALIST,
HENRY FORD HEALTH

CASE STUDY: Private Neuropsychology Practice

Integrating digital treatments into a private neuropsychology practice

The Challenge

A medium-sized private neuropsychology practice frequently encountered patients presenting with insomnia alongside other mental health and cognitive complaints

- One provider specialized in CBT-I, but did not have bandwidth to see all patients
- Many other providers, although trained in CBT-I, had no means of offering it alongside other interventions
- Reluctance to use pharmacology interventions given cognitive and neurological profile of many patients

The Solution

The clinic integrated SleepioRx into their workflows and all providers were trained to use it with patients. LICSW hired and trained to conduct SleepioRx onboarding and intake visits.

The Impact

1 hr

Time to care

Average access time from HCP order to program initiation

90%

Enrollment rate

Percent of patients who enrolled in SleepioRx¹

92%

Improvement rate

Percent of patients who saw improvement in symptoms²

Implementation is a collaborative process

Implementation

- **Set Up Workflows:** Deciding on ordering process (e.g., specific ordering portal or EHR integration), and data transfer back to provider
- **Confirm Billing Processes:** Identify billing processes for using G0552

Launch

Train providers on:

- Patient identification and diagnosis
- How to explain the DMHT to patients
- How to order the DMHT
- How to use patient data to support engagement

Post-launch

- **Ongoing support:** Drop-in sessions to answer questions and provide support
- **Learn and adjust:** Refine workflows based on feedback for ordering, data feedback loop, and billing
- **Track results:** Review data to assess impact and refine as needed

Integration into private practice

Private practices can often adopt DMHTs quickly, benefitting both patients and the practice

Tips to get started

Identify decision makers

Highlight clinical and
business value of
DMHTs

Set up ordering workflows

Ordering portal or
EHR integration

Set up billing workflows

Inform billing team
about G0552 and
claim requirements

Navigating integration within health systems

Health systems can be complex to navigate when integrating new treatments like DMHTs, especially for psychologists who are unfamiliar with procurement and device integration.

Tips to get started

Identify an internal champion to lead the effort - you or a senior colleague

Map key decision-makers, such as clinic medical directors and procurement teams

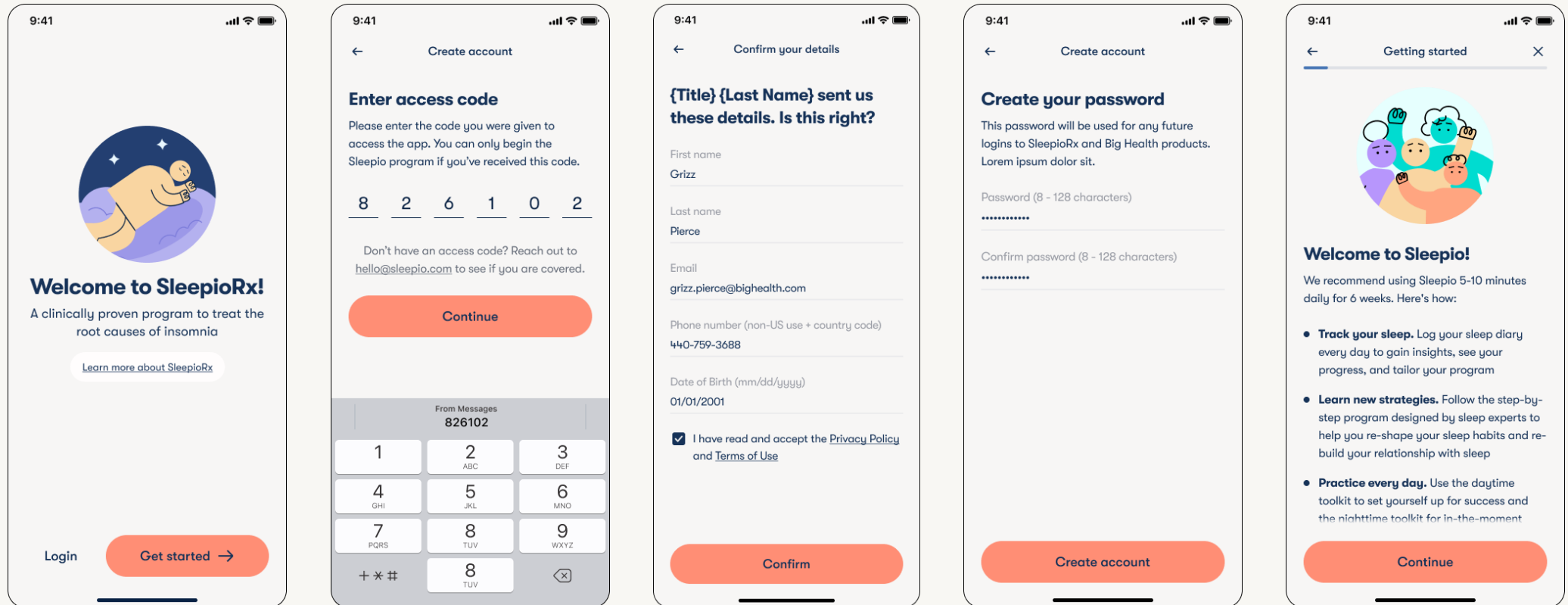
Engage contracting, billing and coding teams early on to streamline operations

Coordinate with IT/operations teams if EHR integration is needed

Collaborate with clinicians to build support and demonstrate demand

Parallel process tasks to speed-up implementation

Patient Activation Experience example - SleepioRx



Treatment activation occurs during a visit to allow the patient to get started immediately

How are DMHTs reimbursed and who can be reimbursed?

These statements are in no way intended to imply or suggest any claims regarding SleepioRx beyond its FDA cleared indications and should in no way be considered a guarantee of coverage or reimbursement for any product or service.

These statements are intended to provide information to practitioners, they do not seek to maximize payment, and should not be mistaken for official payer guidance.

CMS codes specifically for digital mental health treatments (DMHTs)

Code	Description
G0552	Supply of digital mental health treatment device and initial education and onboarding, per course of treatment that augments a behavioral therapy plan.
G0553	First 20 minutes of monthly treatment management services directly related to the patient’s therapeutic use of the digital mental health treatment (DMHT) device that augments a behavioral therapy plan, physician/other qualified health care professional time reviewing information related to the use of the DMHT device, including patient observations and patient specific inputs in a calendar month and requiring at least one interactive communication with the patient/caregiver during the calendar month.
G0554	Each additional 20 minutes of monthly treatment management services directly related to the patient’s therapeutic use of the digital mental health treatment (DMHT) device that augments a behavioral therapy plan, physician/other qualified health care professional time reviewing information related to the use of the DMHT device, including patient observations and patient specific inputs in a calendar month and requiring at least one interactive communication with the patient/caregiver during the calendar month. (List separately in addition to HCPCS code G0553).

G0552 is billed once for 12 months access to the treatment.
G0553/G0554 are bundled and billed monthly, with 1 synchronous interaction required per month.

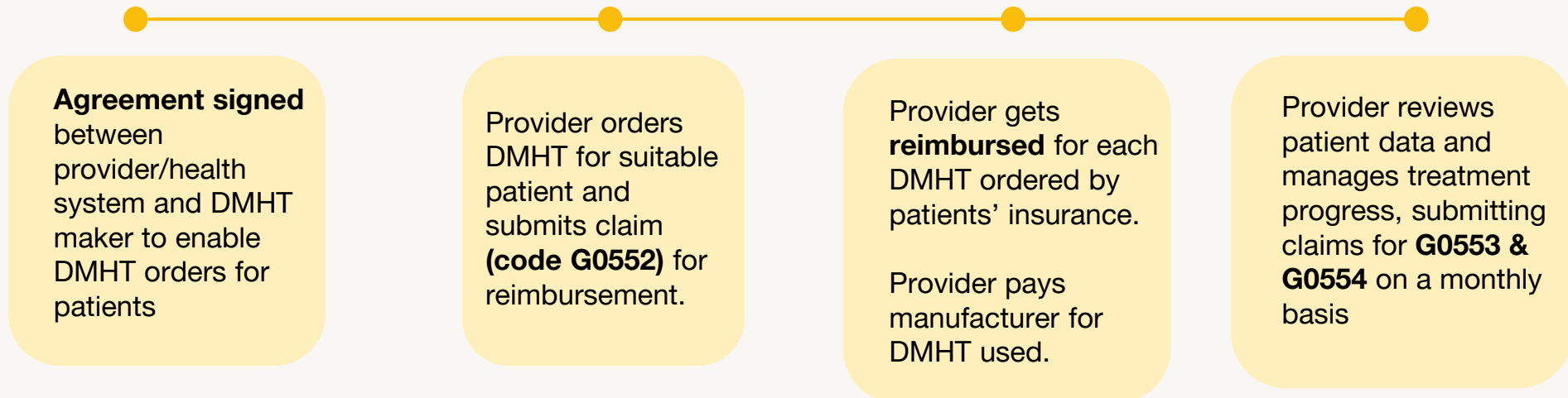
CMS reimbursement requirements for DMHTs

Reimbursement requires the following:

- Relevant ICD-10 diagnosis code
- The billing practitioner orders the DMHT for the patient
- The billing practitioner incurs the cost of the DMHT
- Provision of the DMHT is incident to the billing practitioner's professional services in association with an ongoing behavioral health plan of care

Billing and **provider reimbursement** for DMHTs

HOW IT WORKS



AUDIENCE Q&A

FINAL THOUGHTS

- A recording will be emailed to you in 2 weeks. It will include the presentation slides.
- Take our survey immediately after the webinar has concluded.

THANK YOU!

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