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Medicare Advantage Policy Manual **Policy ID:** M-MED 175.02

Digital Therapeutic Products for Substance Use Disorders

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IMPORTANT REMINDER

The Medicare Advantage Medical Policy manual is not intended to override the member Evidence of Coverage (EOC), which defines the insured's benefits, nor is it intended to dictate how providers are to practice medicine. Physicians and other health care providers are expected to exercise their medical judgment in providing the most appropriate care for the individual member, including care that may be both medically reasonable and necessary.

The Medicare Advantage medical policies are designed to provide guidance regarding the decision-making process for the coverage or non-coverage of services or procedures in accordance with the member EOC and Centers of Medicare and Medicaid Services (CMS) policies and manuals, along with general CMS rules and regulations. In the event of a conflict, applicable CMS policy or EOC language will take precedence over the Medicare Advantage Medical Policy. In the absence of a specific CMS coverage determination for a requested service, item or procedure, the health plan may apply CMS regulations, as well as their Medical Policy Manual or other applicable utilization management vendor criteria developed with an objective, evidence-based process using scientific evidence, current generally accepted standards of medical practice, and authoritative clinical practice guidelines.

Some services or items may appear to be medically indicated for an individual but may be a direct exclusion of Medicare or the member's benefit plan. Medicare and member EOCs exclude from coverage, among other things, services or procedures considered to be investigational (experimental) or cosmetic, as well as services or items considered not medically reasonable and necessary under Title XVIII of the Social Security Act, §1862(a)(1)(A). In some cases, providers may bill members for these non-covered services or procedures. Providers are encouraged to inform members in advance when they may be financially responsible for the cost of non-covered or excluded services. Members, their appointed representative, or a treating provider can request coverage of a service or item by submitting a pre-service organization determination prior to services being rendered.

DESCRIPTION

Digital health products are technologies, platforms, and systems that engage consumers for lifestyle, wellness, and health-related purposes. A digital therapeutic product is a specific type of digital health product that is practitioner-prescribed software that delivers evidence-based therapeutic intervention directly to a patient to prevent, manage, or treat a medical disorder or disease. Digital therapeutic products have been proposed to supplement or replace individual or group therapy and/or to deliver cognitive-behavioral therapy for the treatment of substance use disorders.

MEDICARE ADVANTAGE POLICY CRITERIA

CMS Coverage Manuals*	Medicare Managed Care Manual Chapter 4 - Benefits and Beneficiary Protections, See Section 10.2 in the following link: MCM Chapter 4 Medicare coverage and payment is contingent upon a determination that: • A service is in a covered benefit category; • A service is not specifically excluded from Medicare coverage by the Act; and • The item or service is "reasonable and necessary" for the diagnosis or treatment of an illness or injury, to improve functioning of a malformed body member, or is a covered preventive service.

NOTE: If a procedure or device lacks scientific evidence regarding safety and efficacy because it is investigational or experimental, the service is noncovered as not reasonable and necessary to treat illness or injury. (*Medicare IOM Pub. No. 100-04, Ch. 23, §30 A*). According to Title XVIII of the Social Security Act, §1862(a)(1)(A), only medically reasonable and necessary services are covered by Medicare. In the absence of a NCD, LCD, or other coverage guideline, CMS guidelines allow a Medicare Advantage Organization (MAO) to make coverage determinations, applying an ***objective, evidence-based process, based on authoritative evidence***. (*Medicare IOM Pub. No. 100-16, Ch. 4, §90.5*). The Medicare Advantage Medical Policy - Medicine Policy No. M-149 - provides further details regarding the plan's evidence-assessment process (see Cross References).

POLICY GUIDELINES

MEDICARE AND MEDICAL NECESSITY

According to Medicare guidelines, Medicare coverage is contingent upon the services meeting certain requirements to determine medical necessity. In order to be considered a covered service, Medicare requires that the service in question:

• Fall within a defined medicare benefit category,[2,5]

• Not be excluded from coverage by statute, regulation, national coverage determination, (NCD), or local coverage determination (LCD),[2]

• Be considered medically necessary, as required per the social security act, §1862(a)(1)(a). This means the service must be considered reasonable and necessary in the diagnosis or treatment of an illness or injury, or to rule out or

confirm a suspected diagnosis because the patient has a sign and/or symptoms.[1,4] This also means services that are determined to be **not** medically necessary for any reason (including lack of safety and efficacy because it is an investigational service) are non-covered.[6]

• Be ordered by a physician who is treating the beneficiary,[7,8]

• Provide data that would be directly used in the management of a beneficiary's specific medical problem.[7,8]

REGULATORY STATUS

In 2017, reSET® (Pear Therapeutics), received De Novo marketing clearance from the FDA to provide CBT as an adjunct to contingency management, for patients with SUD who are enrolled in outpatient treatment under the supervision of a clinician (DEN160018). This was the first prescription digital therapeutic to be approved by the FDA. reSET® is indicated as a 12-week (90 days) prescription-only treatment intended to increase abstinence from a patient's substances of abuse during treatment and increase retention in the outpatient treatment. FDA product code: PWE

In 2018, reSET-O® (Pear Therapeutics) was cleared for marketing by the FDA through the 510(k) pathway as a prescription-only digital therapeutic to "increase retention of patients with opioid use disorder (OUD) in outpatient treatment by providing cognitive behavioral therapy, as an adjunct to outpatient treatment that includes transmucosal buprenorphine and contingency management" (K173681). FDA determined that this device was substantially equivalent to existing devices. The predicate device was reSET.

Vorvida® and Modia® (Orexo) provide support for individuals with problematic drinking and OUD. These digital technologies have not received marketing clearance by U.S. Food and Drug Administration and are not reviewed here.

Note, the fact a new service or procedure has been issued a CPT/HCPCS code or is FDA approved for a specific indication does not make the procedure medically reasonable and necessary.

CROSS REFERENCES

Investigational (Experimental) Services, New and Emerging Medical Technologies and Procedures, and Other Non-Covered Services, Medicine, Policy No. M-149

REFERENCES

1. Social Security Act §1862 (ssa.gov)
2. Medicare Managed Care Manual, Chapter 4, §10.2

3. Medicare Benefit Policy Manual, Ch. 15 – Covered Medical and Other Health Services Using the following link: Medicare Benefit Policy Manual
4. Medicare Benefit Policy Manual, Chapter 16 - General Exclusions from Coverage, See Section §20 - Services Not Reasonable and Necessary in the following link: Medicare Benefit Policy Manual
5. Medicare Coverage Determination Process
6. Medicare Claims Processing Manual, Chapter 23 - Fee Schedule Administration and Coding Requirements, §30 - Services Paid Under the Medicare Physician's Fee Schedule, Subsection A
7. 42 CFR § 410.32(a)
8. Medicare Benefit Policy Manual, Ch. 15 – Covered Medical and Other Health Services, §80.1 - Clinical Laboratory Services

CODING

NOTE: Not all digital health products will have a specific code. These are examples of codes that may be relevant.

Codes	Number	Description
CPT	98978	Remote therapeutic monitoring (eg, therapy adherence, therapy response); device(s) supply with scheduled (eg, daily) recording(s) and/or programmed alert(s) transmission to monitor cognitive behavioral therapy, each 30 days
	99199	Unlisted special service, procedure or report
HCPCS	A9291	Prescription digital behavioral therapy, fda cleared, per course of treatment
	E1399	Durable medical equipment, miscellaneous
	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 data generated from the dmht device from 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

***IMPORTANT NOTE:** Medicare Advantage medical policies use the most current Medicare references available at the time the policy was developed. Links to Medicare references will take viewers to external websites outside of the health plan's web control as these sites are not maintained by the health plan.*