

Policy: MP367

Section: Medical Policy

Subject: Prescription Digital Therapeutics

Applicable line of business:

Commercial	x	Medicaid	x
Medicare	x	ACA	x
CHIP	x		

I. Policy: Prescription Digital Therapeutics

II. Purpose/Objective: To provide a policy of coverage regarding Prescription Digital Therapeutics

III. Responsibility:

- A. Medical Directors
- B. Medical Management

IV. Required Definitions

1. Attachment – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. Exhibit – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. Devised – the date the policy was implemented.
4. Revised – the date of every revision to the policy, including typographical and grammatical changes.
5. Reviewed – the date documenting the annual review if the policy has no revisions necessary.

Commercial

Geisinger Health Plan may refer collectively to health care coverage sponsors Geisinger Health Plan, Geisinger Quality Options, Inc., and Geisinger Indemnity Insurance Company, unless otherwise noted. Geisinger Health Plan is part of Geisinger, an integrated health care delivery and coverage organization.

Medicare

Geisinger Gold Medicare Advantage HMO, PPO, and HMO D-SNP plans are offered by Geisinger Health Plan/Geisinger Indemnity Insurance Company, health plans with a Medicare contract. Continued enrollment in Geisinger Gold depends on contract renewal. Geisinger Health Plan/Geisinger Indemnity Insurance Company are part of Geisinger, an integrated health care delivery and coverage organization.

CHIP

Geisinger Health Plan Kids (GHP Kids) is a Children's Health Insurance Program (CHIP) offered by Geisinger Health Plan in conjunction with the Pennsylvania Department of Human Services (DHS). Geisinger Health Plan is part of Geisinger, an integrated health care delivery and coverage organization.

Medicaid

Geisinger Health Plan Family (GHP Family) is a Medical Assistance (Medicaid) insurance program offered by Geisinger Health Plan in conjunction with the Pennsylvania Department of Human Services (DHS). Geisinger Health Plan is part of Geisinger, an integrated health care delivery and coverage organization.

V. Additional Definitions

Medical Necessity or Medically Necessary means Covered Services rendered by a Health Care Provider that the Plan determines are:

- a. appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- b. provided for the diagnosis, and the direct care and treatment of the Member's condition, illness disease or injury;
- c. in accordance with current standards of good medical treatment practiced by the general medical community.
- d. not primarily for the convenience of the Member, or the Member's Health Care Provider; and
- e. the most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

Medicaid Business Segment

Medically Necessary — A service, item, procedure, or level of care that is necessary for the proper treatment or management of an illness, injury, or disability is one that:

- Will, or is reasonably expected to, prevent the onset of an illness, condition, injury or disability.
- Will, or is reasonably expected to, reduce or ameliorate the physical, mental or developmental effects of an illness, condition, injury or disability.
- Will assist the Member to achieve or maintain maximum functional capacity in performing daily activities, taking into account both the functional capacity of the Member and those functional capacities that are appropriate for Members of the same age.

DESCRIPTION:

Prescription digital therapeutics (PDTs) are software applications that are prescribed by a licensed healthcare practitioner legally authorized to prescribe medications and devices. They are used on a mobile device such as a mobile phone, tablet, smartwatch, or laptop computer. The goal of prescription digital therapeutics is to evaluate, diagnose, manage symptoms, or treat an illness, injury, or disease.

MEDICAID BUSINESS SEGMENT

The PA DHS has determined that reSet, reSet-o, and Somyst may be considered for coverage under narrow clinical circumstances through the Program Exception process. **Note:** reSet and reSet-o may have limited availability or be unavailable due to manufacturing circumstances beyond the control of Geisinger Health Plan and/or the PA Dept. of Human Services.

[MCS-07-2022-003.pdf \(pa.gov\)](#)

[MCS-06-2021-005.pdf \(pa.gov\)](#)

EXCLUSIONS:

Unless otherwise specified, the Plan does **NOT** provide coverage for Prescription Digital Therapeutics, including but not limited to Freespira, reSET, reSET-o, Insulia, BlueStar, NightWare, CanvasDx, Somryst, d-NAV System, EndeavorRX, and Parallel to evaluate, diagnose, manage symptoms, or treat an illness, injury, or disease because this technology is considered **unproven**. The Geisinger Technology Assessment Committee evaluated this technology and concluded that there is insufficient evidence in the peer-reviewed published medical literature to establish the effectiveness of these digital applications on health outcomes when compared to established tests or technologies.

Direct to consumer non-prescription digital software applications (with the exception of FDA approved or cleared* mobile apps for contraception based on fertility awareness covered per state or federal mandates) used on a mobile device such as a mobile phone, tablet, smartwatch, smart rings (eg, Oura Ring) or laptop computer are considered to be not medically necessary and are **NOT COVERED**. There is insufficient evidence in the peer-reviewed published medical literature to establish the effectiveness of these digital applications on health outcomes when compared to established tests or technologies.

*NOTE: Natural Cycles is currently the only FDA-cleared fertility app (**A9293**)

The Plan does **NOT** provide coverage for direct to consumer devices to monitor personal biometrics, including but not limited to smart rings (eg, the Oura Ring), smart watches, or the monthly fees associated with their use. These devices are considered to be **Unproven** and are **NOT COVERED**. There is insufficient evidence in the peer-reviewed published medical literature to establish the effectiveness of these biometric collecting devices on health outcomes.

Note: A complete description of the process by which a given technology or service is evaluated and determined to be experimental, investigational or unproven is outlined in MP 15 - Experimental Investigational or Unproven Services or Treatment.

Medicaid Business Segment:

Any requests for services, that do not meet criteria set in the PARP, may be evaluated on a case by case basis.

CODING ASSOCIATED WITH:

The following codes are included below for informational purposes and may not be all inclusive. Inclusion of a procedure or device code(s) does not constitute or imply coverage nor does it imply or guarantee provider reimbursement. Coverage is determined by the member specific benefit plan document and any applicable laws regarding coverage of specific services. Please note that per Medicare coverage rules, only specific CPT/HCPCS Codes may be covered for the Medicare Business Segment. Please consult the CMS website at www.cms.gov or the local Medicare Administrative Carrier (MAC) for more information on Medicare coverage and coding requirements.

- 0687T Treatment of amblyopia using an online digital program; device supply, educational set-up, and initial session
- 0688T Treatment of amblyopia using an online digital program; assessment of patient performance and program data by physician or other qualified health care professional, with report, per calendar month
- 0702T Remote therapeutic monitoring of a standardized online digital cognitive behavioral therapy program ordered by a physician or other qualified health care professional; supply and technical support, per 30 days
- 0703T Remote therapeutic monitoring of a standardized online digital cognitive behavioral therapy program ordered by a physician or other qualified health care professional; management services by physician or other qualified health care professional, per calendar month
- 99199 Unlisted special service, procedure or report [when specified as a digital health management software application]
- A9291 Prescription digital behavioral therapy, FDA cleared, per course of treatment
- A9292 Prescription digital visual therapy, software-only, FDA cleared, per course of treatment
- A9293 Fertility cycle (contraception & conception) tracking software application, FDA cleared, per month, includes accessories (e.g., thermometer)
- E1399 Durable medical equip
- T1505 Electronic medication compliance management device, includes all components and accessories, not otherwise classified

Current Procedural Terminology (CPT®) © American Medical Association: Chicago, IL

LINE OF BUSINESS:

Eligibility and contract specific benefits, limitations and/or exclusions will apply. Coverage statements found in the line of business specific benefit document will supersede this policy. For Medicare, applicable LCD's and NCD's will supersede this policy. For PA Medicaid Business segment, this policy applies as written.

REFERENCES:

Geisinger Health Plan Technology Assessment Committee. Prescription Digital Therapeutics. Nov. 2022

Vedaa O, Kallestad H, Scott J. et al. Effects of digital cognitive behavioural therapy for insomnia on insomnia severity: a large-scale randomized controlled trial. *Lancet Digit Health*. 2020; 2(8) e.397-e406

Hagatun, S, Vedaa, Ø, Nordgreen, T, et al. The short-term efficacy of an unguided internet-based cognitive-behavioral therapy for insomnia: A randomized controlled trial with a six-month nonrandomized follow-up. *Behav Sleep Med*. 2019;17(2):137-155

Ritterband LM, Thorndike FP, and Ingersoll Karen S. Effect of a web-based cognitive behavior therapy for insomnia intervention with 1-year follow-up. *JAMA Psychiatry*. 2017; 74(1):68-75

Shaffer, KM, Hedeker, D, Morin, CM, et al. Intra-individual variability in sleep schedule: Effects of an internet-based cognitive behavioral therapy for insomnia program and its relation with symptom remission. *Sleep*. 2020; 43(12).

Garcia LM, Birkhead BJ, Krishnamurthy P. et al. An 8-week self-administered at-home behavioral skills-based virtual reality program for chronic low back pain: Double-blind, randomized, placebo-controlled trial conducted during COVID-19. *J Med Internet Res*. 2021; 23(2): e26292

Garcia LM, Birkhead BJ, Krishnamurthy et al. Three-month follow-up results of a double-blind, randomized placebo-controlled trial of 8-week self-administered at-home behavioral skills-based virtual reality (VR) for chronic low back pain. *J Pain*. 2022; 23(5): 822-84

Kollins SH, DeLoss DJ, Cañada E, et al. A novel digital intervention for actively reducing severity of paediatric ADHD (STARS-ADHD: a randomized controlled trial. *The Lancet Digit Health*. 2020 2(4): e168-e178.

Quinn CC, Clough SS, Minor JM, et al. WellDoc mobile diabetes management randomized controlled trial: change in clinical and behavioral outcomes and patient and physician satisfaction. *Diabetes Technol Ther*. 2008; 10(3):160-168

Bergenstal RM, Johnson M, Passi R, et al. Automated insulin dosing guidance to optimize insulin management in patients with type 2 diabetes: a multicentre, randomized controlled trial. *Lancet* 2019; 393(10176): 1138-1148.

Charpentier G, Benhamou PY, Dardari D, et al. The Diabeo software enabling individualized insulin dose adjustments combined with telemedicine support improves HbA1c in poorly controlled type 1 diabetic patients: a 6-month, randomized, open-label, parallel-group, multicenter trial (TeleDiab 1 study). *Diabetes Care*. 2011;34(3):533-539

Franc S, Jobert M, Daoudi A, et al. Efficacy of two telemonitoring systems to improve glycaemic control during basal insulin initiation in patients with type 2 diabetes: The TeleDiab-2 randomized controlled trial. *Diabetes Obes Metab*. 2019; 21(10):2327-2332.

Franc S, Hanaire H, Benhamou PY et al, Diabeo system combining a mobile app software with and without telemonitoring versus standard care: a randomized controlled trial in diabetes patients poorly controlled with a basal-bolus insulin regimen. *Diabetes Technol Ther*. 2020; 22(12): 904-911.

Rosenblatt P, McKinney J, Rosenberg RA, et al. Evaluation of an accelerometer-based digital health system for the treatment of female urinary incontinence: a pilot study. *Neurourol Urodyn*. 2019; 38 (7): 1944-1952

Weinstein MM, Collins S Quiroz L, et al. Multicenter randomized controlled trial of pelvic floor muscle training with a motion based digital therapeutic device versus pelvic floor muscle training alone for treatment of stress-predominant urinary incontinence. *Female Pelvic Med Reconstr Surg*. 2022; 28(1): 1-6

Kaplan A, Mannarino AP et al. Evaluating the impact of Freespira on panic disorder patients' health outcomes and healthcare costs within the Allegheny Health Network. *Appl Psychophysiol Biofeedback*. 2020;45(3):175-181.

Tolin DF, McGrath PB, Hale LR, et al. A multisite benchmarking trial of capnometry guided respiratory intervention for panic disorder in naturalistic treatment settings. *Appl Psychophysiol Biofeedback*. 2017;42(1):51-58

Abbas H, Garberson F, Glover E, Wall DP. Machine learning approach for early detection of autism by combining questionnaire and home video screening. *J Am Med Inform Assoc*. 2018; 25(8):1000-1007.

Abbas H, Garberson F, Liu-Mayo S, et al. Multi-modular AI approach to streamline autism diagnosis in young children. *Sci Rep*. 2020; 10(1):5014.

Kanne SM, Carpenter LA, Warren Z. Screening in toddlers and preschoolers at risk for autism spectrum disorder: evaluating a novel mobile-health screening tool. *Autism Res*. 2018;11(7):1038-1049.

Campbell AN, Nunes EV, Matthews AG, et al. Internet-delivered treatment for substance abuse: A multisite randomized controlled trial [published correction appears in *Am J Psychiatry*. 2014 Dec 1;171(12):1338]. *Am J Psychiatry*. 2014;171(6):683-690

Christensen DR, Landes RD, Jackson L, et al. Adding an internet-delivered treatment to an efficacious treatment package for opioid dependence. *J Consult Clin Psychol*. 2014; 82(6):964-972.

Institute for Clinical and Economic Review (ICER). Digital health technologies as an adjunct to medication assisted therapy for opioid use disorder. December 11, 2020.

Maricich YA, Bickel WK, Marsch LA, Gatchalian K, Botbyl J, Luderer HF. Safety and efficacy of a prescription digital therapeutic as an adjunct to buprenorphine for treatment of opioid use disorder. *Curr Med Res Opin*. 2021 Feb;37(2):167-173.

Maricich YA, Xiong X, Gerwien R, et al. Real-world evidence for a prescription digital therapeutic to treat opioid use disorder. *Curr Med Res Opin.* 2020b. Dec 7.

Velez FF, Colman S, Kauffman L, et al. Real-world reduction in healthcare resource utilization following treatment of opioid use disorder with reSET-O, a novel prescription digital therapeutic. *Expert Rev Pharmacoecon Outcomes Res.* 2020 Nov 4.

Grunberger G, Sherr J, Allende M, et al. American Association of Clinical Endocrinology clinical practice guideline: The use of advanced technology in the management of persons with diabetes mellitus. *Endocr Pract.* 2021;27(6):505-537.

Draznin B, Aroda VR, Bakris G, American Diabetes Association (ADA), et al. Diabetes technology: Standards of medical care in diabetes 2022. *Diabetes Care.* 2022;45(Supplement_1):S97-S112

Davies MJ, D'Alessio DA, Fradkin J, et al. Management of hyperglycaemia in type 2 diabetes, 2018. A consensus report by the American Diabetes Association (ADA) and the European Association for the Study of Diabetes (EASD) [published correction appears in *Diabetologia.* May 2019;62(5):873]. *Diabetologia.* 2018;61(12):2461-2498

Agarwal P, Mukerji G, Desveaux L, et al. Mobile app for improved self-management of type 2 diabetes: Multicenter pragmatic randomized controlled trial. *JMIR Mhealth Uhealth.* 2019;7(1):e10321

Everitt, HA, Landau, S, O'Reilly, G, Sibelli, A, Hughes, S, Windgassen, S, Holland, R, Little, P, et al. Assessing telephone-delivered cognitive-behavioural therapy (CBT) and web-delivered CBT versus treatment as usual in irritable bowel syndrome (ACTIB): a multicentre randomised trial. *Gut.* 2019;68(9):1613-1623

Everitt, HA, Landau, S, O'Reilly, G, Sibelli, A, Hughes, S, Windgassen, S, Holland, R, Little, P, et al. Cognitive behavioural therapy for irritable bowel syndrome: 24-month follow-up of participants in the ACTIB randomised trial. *Lancet Gastroenterol Hepatol.* 2019;4(11):863-872

ECRI reSET-O Prescription Digital Therapeutic (Pear Therapeutics, Inc.) for Opioid Use Disorder 7/2020

ECRI reSET Prescription Digital Therapeutic (Pear Therapeutics, Inc.) for Substance Use Disorder 7/2020

ECRI Somryst Prescription Digital Therapeutic (Pear Therapeutics, Inc.) for Treating Chronic Insomnia 10/2020

ECRI Freespira Digital Therapeutic (Palo Alto Health Sciences) for Treating Panic Disorder 11/2020

ECRI Insulia Digital Therapeutic (Voluntis SA) for Aiding Management of Type 2 Diabetes 9/2022

ECRI BlueStar Rx Digital Therapeutic (WellDoc, Inc.) for Aiding Diabetes Management 9/2022

ECRI EndeavorRx (Akili Interactive Labs, Inc.) Interactive Cognitive Training Software for Treating Attention-deficit/Hyperactivity Disorder in Children 7/2020

ECRI Mahana IBS (Mahana Therapeutics, Inc.) for Aiding Management of Irritable Bowel Syndrome 8/2022

PA Dept. of Human Services. Managed Care Operations Memorandum Technology Assessment Group MCOPS MEMO # 07/2022-003

Wyganski-Jaffe T, Kushner BJ, Moshkovitz A., et al. An eye-tracking based dichoptic home treatment for amblyopia: a multicenter randomized clinical trial. *Ophthalmology.* 2022; Oct 25: S0161-6420(22)00835-1.

Weinstein MM, Collins S Quiroz L, et al. Multicenter randomized controlled trial of pelvic floor muscle training with a motion-based digital therapeutic device versus pelvic floor muscle training alone for treatment of stress-predominant urinary incontinence. *Female Pelvic Med Reconstr Surg.* 2022; 28(1): 1-6.

Svensson T, Madhawa K, et al. Validity and reliability of the Oura Ring Generation 3 (Gen3) with Oura sleep staging algorithm 2.0 (OSSA 2.0) when compared to multi-night ambulatory polysomnography: A validation study of 96 participants and 421,045 epochs. *Sleep Medicine* 2024;115:251-263.

deZambotti M, Rposas L, et al. The Sleep of the Ring: Comparison of the OURASleep Tracker Against Polysomnography. *Behav Sleep Med.* 2017 Mar 21;17(2):124–136.

Cao R, Azimi I, et al. Accuracy Assessment of Oura Ring Nocturnal Heart Rate and Heart Rate Variability in Comparison With Electrocardiography in Time and Frequency Domains: Comprehensive Analysis. J Med Internet Res. 2022 Jan 18;24(1):e27487

This policy will be revised as necessary and reviewed no less than annually.

Devised: 12/22

Revised: 12/23 (add exclusion for non-Rx digital apps); 12/24 (add smart ring exclusion)

Reviewed:

CMS UM Oversight Committee Approval: 12/23, 02/25

Geisinger Health Plan may refer collectively to health care coverage sponsors Geisinger Health Plan, Geisinger Quality Options, Inc., and Geisinger Indemnity Insurance Company, unless otherwise noted. Geisinger Health Plan is part of Geisinger, an integrated health care delivery and coverage organization.

Coverage for experimental or investigational treatments, services and procedures is specifically excluded under the member's certificate with Geisinger Health Plan. Unproven services outside of an approved clinical trial are also specifically excluded under the member's certificate with Geisinger Health Plan. This policy does not expand coverage to services or items specifically excluded from coverage in the member's certificate with Geisinger Health Plan. Additional information can be found in MP015 Experimental, Investigational or Unproven Services.

Prior authorization and/or pre-certification requirements for services or items may apply. Pre-certification lists may be found in the member's contract specific benefit document. Prior authorization requirements can be found at <https://www.geisinger.org/health-plan/providers/ghp-clinical-policies>

Please be advised that the use of the logos, service marks or names of Geisinger Health Plan, Geisinger Quality Options, Inc. and Geisinger Indemnity Insurance Company on a marketing, press releases or any communication piece regarding the contents of this medical policy is strictly prohibited without the prior written consent of Geisinger Health Plan. Additionally, the above medical policy does not confer any endorsement by Geisinger Health Plan, Geisinger Quality Options, Inc. and Geisinger Indemnity Insurance Company regarding the medical service, medical device or medical lab test described under this medical policy.