Digital Therapeutics as a Medical Benefit: Emergence of Published Policies by Managed Care Organizations

Song Lee, PharmD, MBA[1]; Smit Patel[2]; Jane Ha[3]; Benjamin Parcher, PharmD, MS[1]

[1]Xcenda, L.L.C., Palm Harbor, FL, USA;[2] The Ohio State University, Columbus, OH;[3] Butler University, Indianapolis, IN

BACKGROUND

- Digital therapeutics (DTx) are software-based interventions that deliver a clinical mechanism of action, either alone or in combination with other standard-of-care treatments to improve outcomes.[1]
- DTx products can collect patient data to help healthcare providers deliver personalized care for better outcomes.[1]
- Due to the nascent marketplace, there is a rising debate for an appropriate reimbursement model that aligns with and captures the full value of DTx products.[2]
- Although the pharmacy benefit has been recommended for DTx coverage, published medical policies can offer a detailed glimpse into the qualifications and evaluation methods for a DTx product for medical necessity.[1]

OBJECTIVE

- To identify current DTx products with published medical policies by managed care organizations (MCOs) in the US in order to elucidate trends for coverage determination and status.

METHODS

STUDY DESIGN

- A search was conducted on Canary Insights (Lakewood, CO) on June 5, 2020 of companies that were members of the Digital Therapeutics Alliance (DTA) and have products on the market, as well as pending regulatory review.
- Key search terms consisted of the product name and company name.
  - Only relevant policies, as defined by correct disease state of DTx product, were included.
  - Policies mentioning the product name or company in passing were **not** included as part of the in-depth analysis.
- Policies were segmented by parent policy vs derivative policy to be analyzed across key parameters assessing total policy count, unique payers, state and national plan coverage, and percentage covering the DTx product.
- Additional policy details, such as coverage rationale, if available, and coverage requirements were also analyzed.

DATA SOURCE

- Canary Insights provides coverage and reimbursement information on over 200 payers and related healthcare sites, including Medicare, Medicaid, and hundreds of commercial insurance companies.[3]

RESULTS

- A total of 37 DTx companies were identified as members of the DTA with products on the market or pending regulatory review.
- Of the 37 DTx companies, 7 were found to have a published policy on at least one of their DTx products.
- There were 112 total policies analyzed, with 22 parent policies identified.
- 43% of the companies showed coverage from a single unique payer; 73% of the policies were state-specific vs 27% that were national; 4% of all policies provided coverage if certain requirements were met within the payer organization.
- Within the covered policies found, four policies indicated that the DTx product may be considered medically necessary for specified patient populations, while one was managed under the pharmacy benefit with a prior authorization requirement and had specific policies already available.

Figure 1. Identified and Investigated DTx Companies

Identified DTx Companies

DTx Companies, 7

Total DTA Members, 37

DTx Companies

Key: DTA – Digital Therapeutics Alliance; DTx – digital therapeutics.

Table 1. DTx Policy Coverage Data

Company	Product Name(s)	Parent Policy Count	Total Policy Count	Regional	National
Akili Interactive	EndeavorRx™ (AKL-T01) (Previously named "Project EVO")	2	16	88%	13%
Global Kinetics Corporation	Personal KinetiGraph®	1	6	33%	67%
Palo Alto Health Sciences	Freespira®	13	40	85%	15%
Voluntis	Insulia®	1	15	93%	7%
Voluntis	Diabeo®	1	15	93%	3% (2)
Proteus Digital Health	Abilify MyCite®	1	1	0%	100%
Welldoc	BlueStar®	1	15	93%	7%
Pear Therapeutics, Inc.	Reset-O®	2	4	100%	0%

Table 2. Details of Coverage Criteria Requirements Within 5 Policies for Proteus Health and Palo Alto Health Sciences

Coverage Criteria Requirements

- Approved or cleared by FDA	- Credible scientific evidence permits reasonable conclusions regarding impact of the mobile software application on health outcomes
- Proven to improve a net health outcome or be as beneficial as the established alternative	- Prescribed by a healthcare practitioner
- Documentation supporting mobile software application was ordered for a covered purpose and in accordance with generally accepted standards of medical practice	- Requested mobile software application not primarily for the convenience of the individual, prescribing clinician, caregiver, or other health care provider

Table 3. Specific Covered Criteria Found Within One Policy for Proteus's Product Abilify MyCite

Coverage Criteria Requirements

Patient must be 18 years of age or older	Prescribed by or in consultation with a psychiatrist, AND physician attestation that the patient has a medical necessity for tracking medication ingestion

Patient diagnosed with schizophrenia or major expressive disorder AND the request is for use as an adjunctive treatment OR if the patient has a diagnosis of bipolar I disorder, one of the following criteria is needed for approval:
  - Request is for acute treatment of manic and mixed episodes as monotherapy, OR as an adjunct to lithium or valproate
  - Request is maintenance treatment as monotherapy, OR as an adjunct to lithium or valproate

CONCLUSIONS

- Our analysis indicates that payers are still developing a uniform foundation for their coverage policies of DTx products.
- Additional evidence gathered through direct payer input would provide further insights to elucidate DTx product coverage efforts and perceptions.
- By referencing existing policies, DTx innovators may be able to help guide conversations with payers regarding the coverage of their product.

REFERENCES

1. AMCP Partnership Forum: Digital therapeutics— what are they and where do they fit in pharmacy and medical benefits? *J Manag Care Spec Pharm.* 2020;26(5):674-681. https://www.jmcp.org/doi/pdf/10.18553/jmcp.2020.19418
2. Wang E, et al. DTx Part I: identifying optimal payment models for digital therapeutics. Boston Healthcare Associates. December 2019. https://www.bostonhealthcare.com/dtx-part-i-identifying-optimal-payment-models-for-digital-therapeutics/
3. Canary Insights. https://www.canaryinsights.com/.

AmerisourceBergen®

Presented at: Academy of Managed Care Pharmacy Nexus Virtual; October 19-23, 2020. Funded by Xcenda.

Xcenda
AmerisourceBergen®