National Alliance

New Prescription Digital Therapeutics (PDTs) in Behavioral Healthcare Delivery

September 2, 2021
Speakers

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Prescription Digital Therapeutics (PDTs):
A new therapeutic class that is being integrated into standard of care

PDTs = Software to treat human disease
• Safety and efficacy tested in randomized clinical trials\textsuperscript{1,2}
• Product label authorized by FDA\textsuperscript{3,4,5}
• Pricing and reimbursement pathways designed to reflect health economic value\textsuperscript{6}
• IP, quality, regulatory, and compliance barriers to entry
Prescription Digital Therapeutics (PDTs) are a sub-category within digital health defined by clinical efficacy, FDA market authorization, and reimbursement.

- **DTx (Digital Therapy)**
  - Evidence-based digital treatments
  - Directly impact disease state
  - May or may not be FDA regulated

- **Telemedicine**
  - Video diagnostic consultation
  - Remote health services
  - Support long-distance healthcare

- **Health IT**
  - Electronic health records (EHR)
  - Health information exchange (HIE)
  - Patient portals

- **Remote Monitoring**
  - Collect health data
  - Tracked by healthcare professionals
  - FDA regulation

- **Consumer Apps**
  - Promote wellness
  - No FDA regulation
  - Free / at patient’s cost

- **PDTs (Prescription Digital Therapeutics)**
  - Medical software to treat disease
  - Randomized clinical trials
  - FDA regulation and authorization
PDTs have effectiveness and safety data in the label for market authorization by the FDA

<table>
<thead>
<tr>
<th>Prescription Digital Therapeutics (PDTs)</th>
<th>Traditional Wellness Apps*</th>
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<tbody>
<tr>
<td>✔</td>
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Deliver disease-specific, evidence-based treatment via mobile devices

FDA-regulated software as a medical device (SaMD)

Evaluated and clinically-validated for safety and effectiveness

Receive FDA-marketing authorization

Intended to be used as adjunct to standard outpatient treatment

Label describes indications and intended use, supporting appropriate clinical use

*defined as a health and wellness app that is not regulated
The digital therapeutic industry has exploded in the last several years
6 FDA Authorized Prescription Digital Therapeutics and 8 FDA Breakthrough Designations Granted

- **Otsuka America Pharmaceutical, Inc.** launches development of a new PDT for major depressive disorder
- **Dthera Sciences** receives a Breakthrough Designation for a PDT in Alzheimer’s
- **Nightware, Inc.** launches development of a new PDT for major depressive disorder
- **MedRhythms, Inc.** receives FDA breakthrough designation for chronic stroke Digital Therapeutic
- **Pear Therapeutics, Inc.** releases PEAR-004 to help people living with schizophrenia under the FDA’s Emergency Guidance
- **Nightware, Inc.** receives FDA authorization for the treatment of PTSD driven traumatic nightmares
- **Pear Therapeutics, Inc.** receives 1st ever FDA PDT clearance for reSET in treatment of SUD
- **Dthera Sciences** receives a Breakthrough Designation for a PDT in Alzheimer’s
- **Otsuka America Pharmaceutical, Inc.** launches development of a new PDT for major depressive disorder
- **Nightware, Inc.** launches development of a new PDT for major depressive disorder
- **MedRhythms, Inc.** receives FDA breakthrough designation for chronic stroke Digital Therapeutic
- **Pear Therapeutics, Inc.** receives Breakthrough Designation for reSET-O to treat OUD
- **Cognos, Inc.** receives Breakthrough Designation for PTDs treating autism and ADD
- **Pear Therapeutics, Inc.** receives their 3rd FDA clearance for reSET-O and the treatment of OUD
- **Cognos, Inc.** receives Breakthrough Designation for PTDs treating autism and ADD
- **Pear Therapeutics, Inc.** receives their 2nd FDA clearance for reSET-O and the treatment of OUD
- **FDA grants breakthrough designation to The Learning Corp for Speech Therapy App**
- **Akili Interactive Labs, Inc.** receives the 4th ever FDA clearance to improve attention function
- **Mahana Therapeutics, Inc.** receives FDA authorization for the treatment of IBS symptoms
- **Nightware, Inc.** receives FDA authorization for the treatment of PTSD driven traumatic nightmares

**Timeline:**
- SEP 2017: **Pear Therapeutics, Inc.** receives 1st ever FDA PDT clearance for reSET in treatment of SUD
- AUG 2018: **Dthera Sciences** receives a Breakthrough Designation for a PDT in Alzheimer’s
- JAN 2019: **Otsuka America Pharmaceutical, Inc.** launches development of a new PDT for major depressive disorder
- MAY 2019: **Nightware, Inc.** launches development of a new PDT for major depressive disorder
- APR 2020: **Pear Therapeutics, Inc.** releases PEAR-004 to help people living with schizophrenia under the FDA’s Emergency Guidance
- JUN 2020: **MedRhythms, Inc.** receives FDA breakthrough designation for chronic stroke Digital Therapeutic
- OCT 2020: **AppliedVR, Inc.** receives FDA breakthrough designation for a Digital Therapeutic
- DEC 2020: **Nightware, Inc.** receives FDA authorization for the treatment of PTSD driven traumatic nightmares

**Additional Information:**
- FDA Authorized Prescription Digital Therapeutics
- FDA Breakthrough Designations Granted
- Various companies and their achievements in the digital therapeutic industry

**Sources:**
- FDA Authorized Prescription Digital Therapeutics
- FDA Breakthrough Designations Granted

**Visual Aid:**
- Diagram illustrating the timeline and achievements of various companies in the digital therapeutic industry.

**National Alliance of Healthcare Purchaser Coalitions:**
- Driving Health, Equity and Value

**Pear Therapeutics:**
- Final footer logo and text.
An additional 8 PDTs may be authorized by early 2024 with at least 13 other companies potentially developing product candidates in preparation to submit to FDA for review.

Companies developing candidates for potential FDA submission:

1. AppliedVR, Inc.
2. Happify Health
3. GAIA AG*
4. Big Health
5. Biofourmis, Inc.
6. Propeller Health
7. Apricity Health
8. Yao – The Bard, LLC
9. metaMe Health, Inc.
10. Bold Health Limited
11. Headspace, Inc.
12. Cognito Therapeutics, Inc.
13. Constant Therapy Health
PDTs follow the traditional therapeutics model

- **Prescription**: Patient diagnosed by physician and product is prescribed
- **Payment**: Reimbursed via pharmacy or medical benefit
- **Fulfillment**: Dispensed via a specialty pharmacy/Patient Services Center
- **Use**: Patient uses product according to directions for use
- **Follow-up**: Patient follows up with clinician

**Pharmaceutical** with effectiveness claims to treat disease

**Software** with effectiveness claims to treat disease
About The Hartford

• The Hartford is a leader in property and casualty insurance, group benefits and mutual funds

• With more than 200 years of expertise, The Hartford is widely recognized for its service excellence, sustainability practices, trust and integrity

• Employees: 18,500 with total of 35,000 total members

• Headquarters: Hartford, Conn

• As part of our Stigma-Free program we are educating, advocating, and activating programs that help dispel stigma associated with mental health and addiction in the workplace

• In September 2020, The Hartford became the first employer to add Prescription Digital Therapeutics (PDT) for Substance Use Disorder (SUD) and Opioid Use Disorder (OUD) to a prescription drug plan
We saw that PDTs could be a potential solution
To support SUD and OUD treatment

PDTS Demonstrate Their Value During Covid-19
To reduce potential exposure to COVID-19, the FDA issued temporary authorization of digital health devices for treating psychiatric disorders

The Kennedy Forum, Shatterproof, Pear Therapeutics, And Others Created The Recovery Access Coalition in June, 2020

Aimed at eliminating access barriers for substance use disorder-focused FDA authorized digital therapeutics

“Addiction is a disease that thrives in isolation. Because of social distancing, COVID-19 has already put millions who live in recovery from substance use disorders, including opioid use disorder, at extreme risk. The inability to regularly access traditional forms of care will only compound the problem—thus an urgent need for more remote treatment options.”

Patrick J. Kennedy, founder of the Kennedy Forum
Vetted by internal and external SMEs

All supported adding PDT for SUD / OUD to our formulary
• Recognition of significant gaps in treatment today
• Proven to improve treatment adherence
• Supports overall awareness of this new form of treatment
• Interested in our learnings and outcomes

<table>
<thead>
<tr>
<th>Role</th>
<th>SME</th>
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<tbody>
<tr>
<td>Internal Clinical</td>
<td>• Medical Director</td>
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<td>• Nurse specializing in behavioral health</td>
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<tr>
<td>External Clinical</td>
<td>• Shatterproof Head of Policy and Quality</td>
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<tr>
<td></td>
<td>• OptumRx Chief Pharmacy Officer</td>
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<td></td>
<td>• ConsumerMedical Clinical team</td>
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<td></td>
<td>• Health Transformation Alliance Pharmacist</td>
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<tr>
<td>Internal Digital</td>
<td>• Team member focused on digital solutions</td>
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SME Feedback
“Delighted” that The Hartford is considering covering
Tools provide short-term support during a vulnerable period
Expectation that federal payers will cover since it is FDA approved
Will only be successful if prescribers know to use it
Not a silver bullet, but another tool to support individuals facing addiction
It can only do good, no harm
## The Business Case

“Low Cost, No Down-side, Opportunity to Be a Leading Voice in New Treatment”

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<tr>
<th>Why</th>
<th>Description</th>
<th>Success Measures</th>
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<tr>
<td>Low cost</td>
<td>Minimal downsides:</td>
<td>10% of eligible patients being treated to use PDT over 12 months</td>
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<tr>
<td>Supports abstinence and treatment adherence</td>
<td>• No side effects</td>
<td>Decreased relapses</td>
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<tr>
<td></td>
<td>• Low cost</td>
<td>Reduced average patient spend</td>
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<tr>
<td>Be the catalyst to test, evolve, and promote this new form of treatment</td>
<td>PBMs are slow to evaluate new, non-traditional Rx</td>
<td>Share our experience, including the results (good or bad)</td>
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<td>Plan sponsor advocates are needed</td>
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<td>Will provide additional utilization data to influence the evolution of this treatment space</td>
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<td>Continue to lead in the nation’s conversation about the opioid crisis</td>
<td>Support our members and their families by continuing to discuss SUD and OUD and offer meaningful support</td>
<td>Share our experience with the Benefits community and the business community at large</td>
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The process was easier than expected.

- Added Rx codes to formulary (preferred brand)
  - 11-digit NCPDP Product Identifiers

- Trained PBM call center (and other partners)
Questions for Speakers and Medical Directors

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Upcoming Webinars and Meetings

Mental Health Index: August results
**September 17** | noon-12:30 p.m.

Annual Forum
**November 8-10** | See website for details

All times are Eastern Time

- Registration is open
- Early Bird Rates:
  - Non-Member - $650.00
  - Member Rate - $450.00
- Hotel Discount Rate - $229/per night until October 15, 2021

COVID-19 ANNOUNCEMENT: Based on the current environment and for the health and safety of all our attendees, we will require all attendees to be vaccinated