

INTEGRATING FDA-APPROVED APP-BASED PRESCRIPTION DIGITAL THERAPEUTIC APPS INTO CLINICAL PRACTICE

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Background

Prescription digital therapeutics (PDTx) present an innovative category of professionally endorsed software programs designed for the treatment of various medical disorders.

App-only PDTx provides a distinctive opportunity to deliver approved therapies for physical ailments either alone or alongside the traditional pharmaceuticals.

Objective

To conduct a literature review related to FDA-approved PDTx that are App-based and are exclusively developed for management of physical ailments. Special focus was given on the therapeutic applications, clinical benefits, and incorporation of PDTx in the domain of patient care. 33.11 inches wide × 46.81 inches high

Methodology

Study Design

A targeted narrative review on FDA-cleared App PDTx from 2015 to 2025 was performed, primarily focusing on their role in management of physical health issues. We synthesized data on therapeutic targets, clinical justifications, and administration methods from main regulatory documents and published clinical literature.

Data Sources and Search Strategy

Searches were performed in:

- FDA databases.
- Peer-reviewed literature (PubMed, Scopus, Google Scholar).
- Manufacturer websites and product monographs.

Exclusion Criteria

- Non-FDA-regulated wellness, lifestyle, or fitness applications
- Digital therapeutics not requiring a prescription
- PDTx designed for mental or psychiatric health conditions.
- Apps lacking clinical evidence or regulatory documentation.

Inclusion Criteria

- App-based prescription digital therapeutics delivered via smartphone or tablet applications
- PDTx that may require associated hardware (e.g., VR headsets)
- FDA-approved/cleared PDTx, or those available by prescription.
- PDTx indicated for management of physical health conditions.

Screening and Selection Process

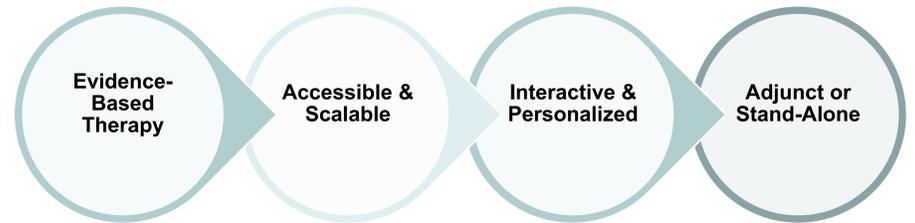
- Records were initially retrieved through database searches.
- After removal of duplicate entries, records remained for screening and eligibility review.

Data Extraction and Analysis

- Extracted data elements [therapeutic targets and indications, mode of administration (e.g., cognitive behavioral therapy, neurostimulation, VR).
- Data were synthesized narratively, emphasizing therapeutic benefits and barriers.

Results

Figure 1. Benefits of PDTx

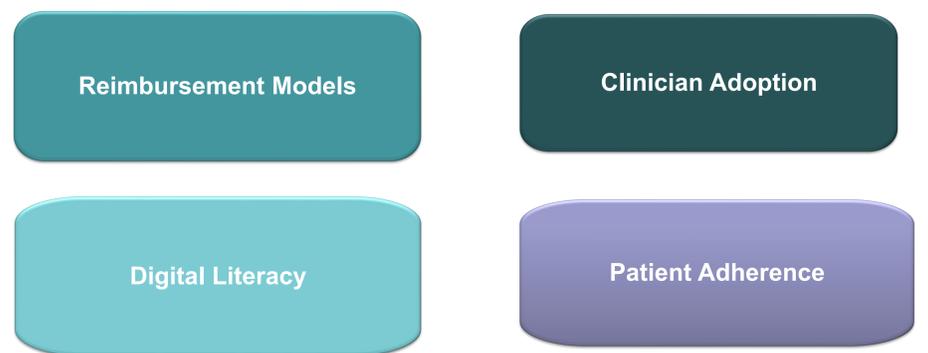


Four FDA-approved App-based PDTx, exclusively used for physical conditions management, were identified and evaluated:

- **EaseVRx** – Chronic back pain
Uses virtual reality-based therapy to reduce pain perception
- **Luminopia One** – Amblyopia
Uses visual neurostimulation to improve visual function
- **Regulora** – IBS-related abdominal discomfort
Uses gut-directed hypnotherapy delivered digitally to manage IBS-related abdominal pain
- **Mahana IBS** – Irritable bowel syndrome
CBT-based mobile app for managing IBS symptoms

Product	Treatment modality	Treatment Duration	Indication	Age range
EaseVRx	Virtual reality-based behavioral therapy program	8-week in-home program	Chronic low back pain	≥ 18 years
Luminopia One	Virtual reality-based visual neurostimulation therapy	12-week program	Amblyopia	4–7 years
Regulora	Digital cognitive behavioral therapy (gut-directed hypnotherapy) delivered via app	12-week program	IBS-related abdominal pain	≥ 22 years
Mahana IBS	Digital cognitive behavioral therapy program delivered via app	~10–12-week program	Irritable Bowel Syndrome	≥ 18 years

Figure 2. PDTx Adoption Barriers



Conclusion

App-based PDTx offer an effective, patient-centric alternative solution to traditional healthcare. However, their successful adoption into practice requires a clear understanding by patients, physicians and pharmacists.

References

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- Docherty JP and Colbert BM (2024). The evolution of psychotherapy: from Freud to prescription digital therapeutics. *Front. Psychiatry* 15:1477543. doi: 10.3389/fpsy.2024.1477543