



PHTI Evaluations of Virtual Solutions for Depression and Anxiety and Opioid Use Disorder

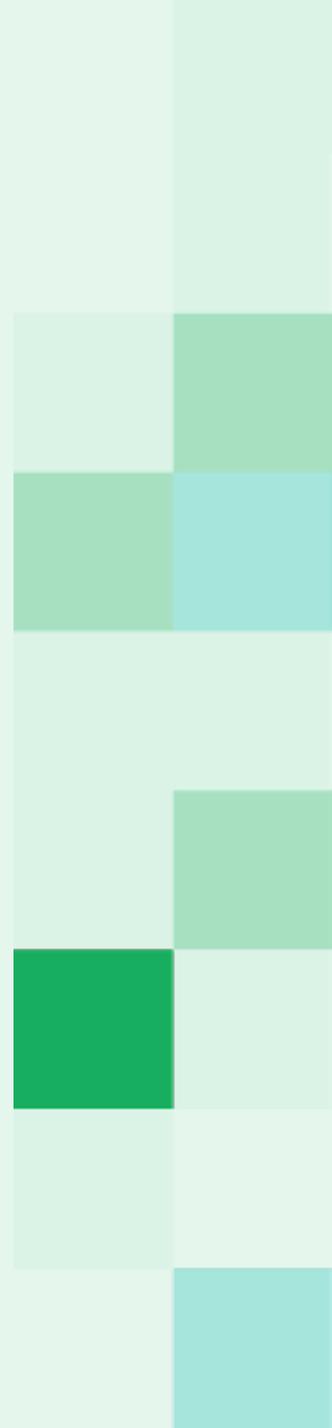
FDA Digital Health Advisory Committee

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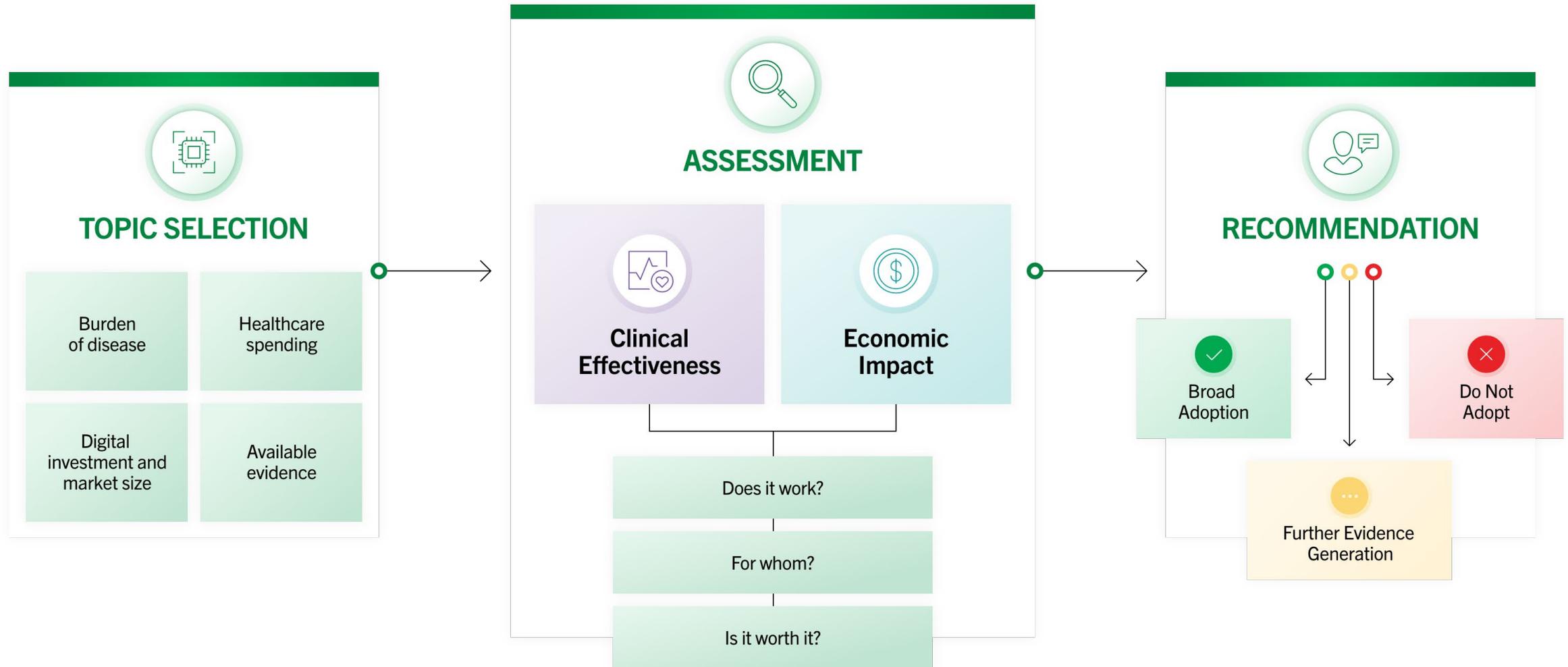
Introduction to PHTI

The **Peterson Health Technology Institute (PHTI)** is an independent non-profit that provides rigorous, evidence-based assessments of digital health technologies to improve health outcomes and lower costs.

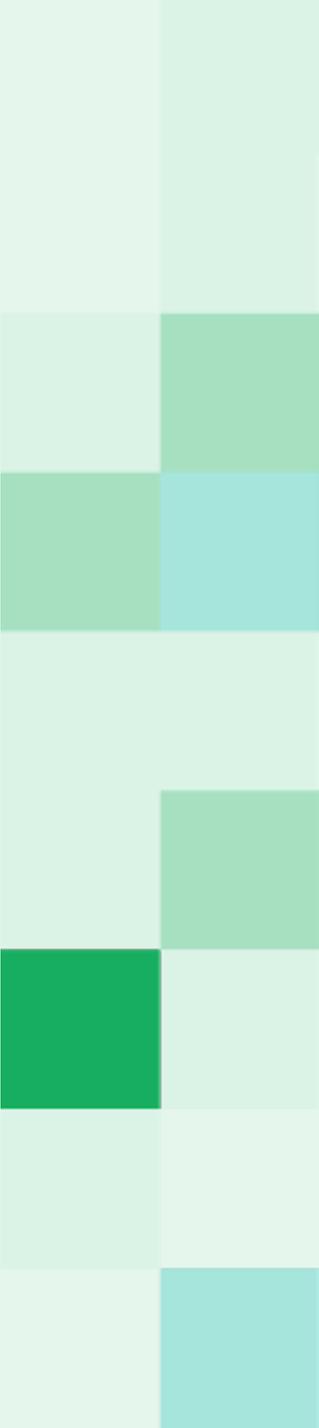
Our evaluations are designed to inform digital health purchasing decisions.



PHTI evaluations aim to accelerate the adoption of high-value digital health solutions that improve health and lower costs



Findings From Evaluation of Virtual Solutions for Depression and Anxiety



Virtual solutions for depression and anxiety aim to expand access to care with digital content, coaching, and therapy services

Self-Guided Solutions

Offer digital content that people can access anytime

Sold to employers or health plans

AbleTo*	Meru Health*
Dario	SilverCloud
Headspace*	Talkspace*
Learn to Live	Teladoc*

Prescription Digital Therapeutics (PDTs)

FDA-cleared digital therapies that require a prescription

Sold to healthcare providers

DaylightRx (for anxiety)
Rejoyn (for depression)

Blended-Care Solutions

Networks of virtual care teams that integrate therapy and digital content

Sold to employers or health plans

AbleTo*	Meru Health*
Brightside	Modern Health
Headspace*	Spring Health
Koa Health	Talkspace*
Lyra	Teladoc*

Note: * Companies offering both self-guided and blended-care solutions.

PHTI reviewed evidence to assess whether solutions deliver clinically-meaningful improvements in symptoms

Primary Outcomes

Clinically-meaningful improvement (5-pt reduction) in depression symptoms, as measured by PHQ-9
Clinically-meaningful improvement (4-pt reduction) in anxiety symptoms, as measured by GAD-7

Additional Outcome Measures

Secondary Outcomes

Psychosocial functioning
Workplace productivity
Adverse events
Crisis events

User Experience

Engagement
Satisfaction and usability

Health Equity

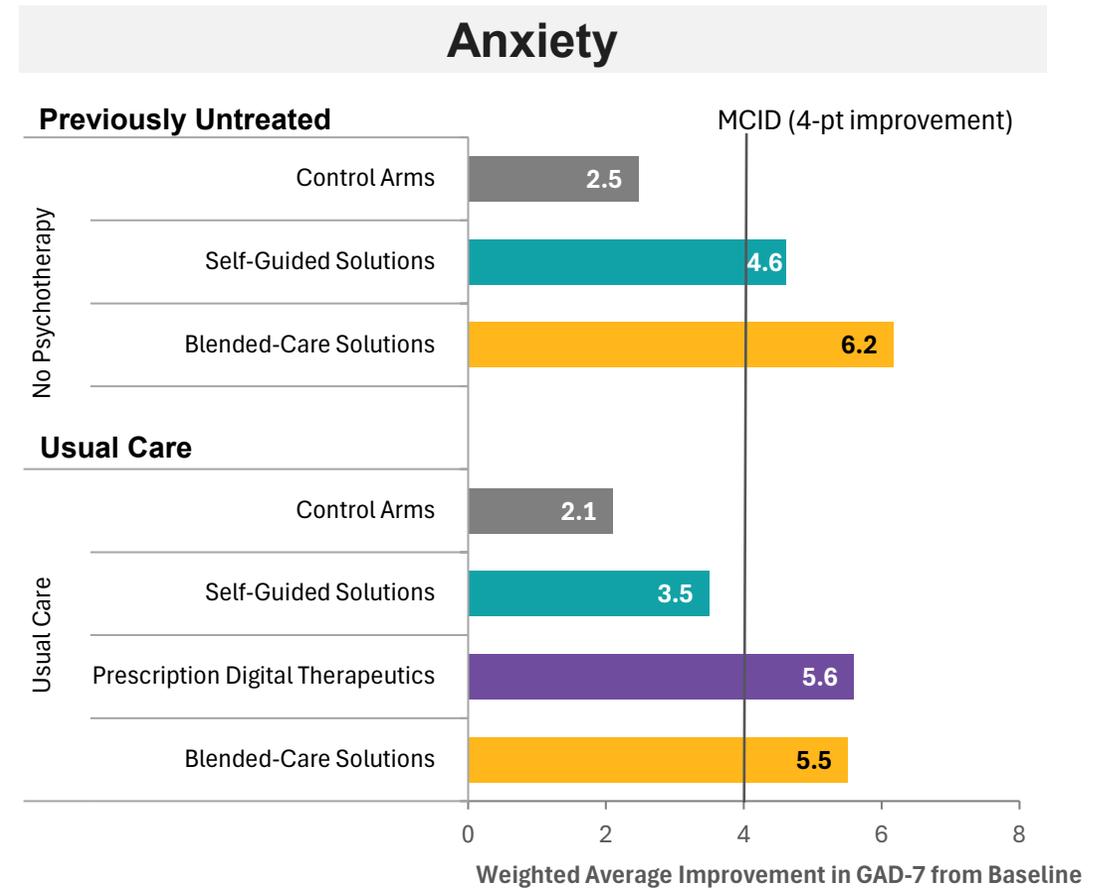
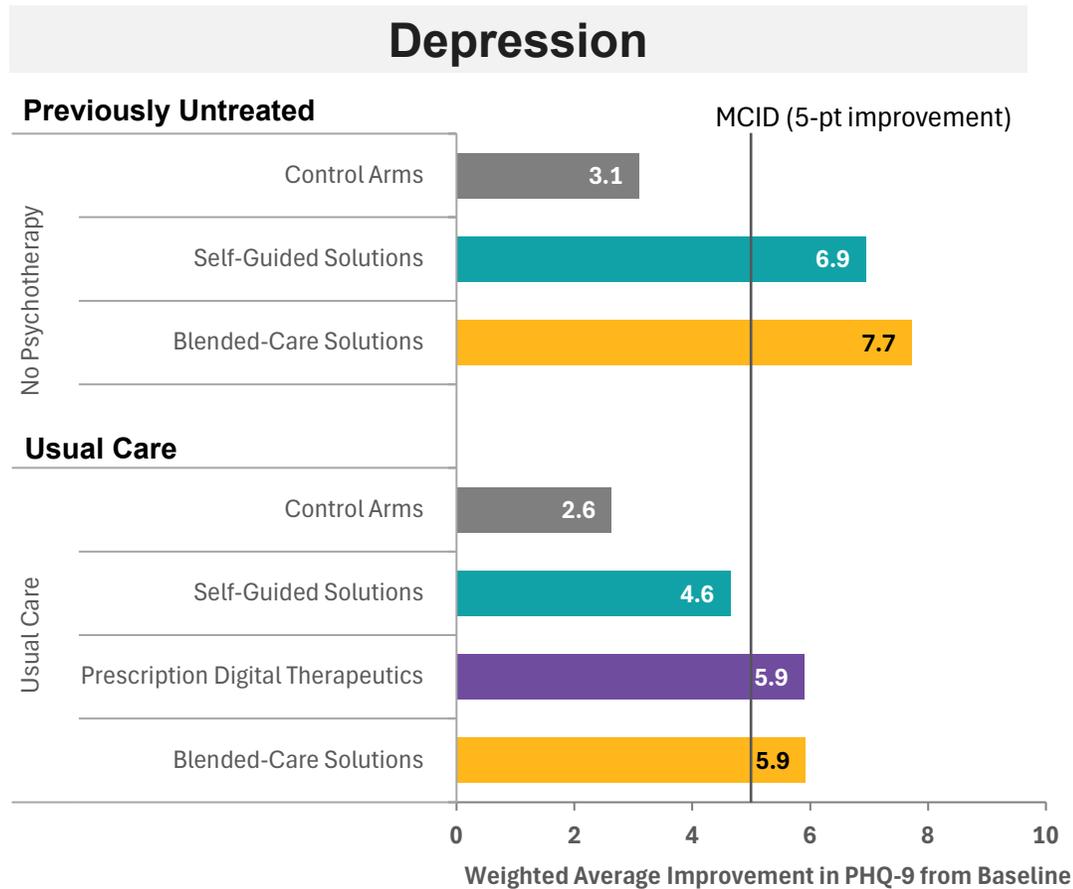
Access and accessibility
Distribution

Evidence Base

Large, well-designed body of literature

Reviewed 5,000+ articles or other evidence
Assessment based on 103 studies
Includes comparative studies, real-world evidence, and company data

Most virtual solutions are clinically effective for depression and anxiety, with PDTs and blended-care having stronger results



Source: PHTI, Virtual Solutions for Depression and Anxiety, May 2025. See PHTI.org for complete report, methods, and recommendations.

Notes: Previously untreated refers to people who were not receiving psychotherapy. Data for control arms is the weighted average of self-guided and blended-care solution control arms.

By improving symptoms, virtual solutions can reduce healthcare utilization—but impact on total cost of care depends on pricing

Estimated Net Change in Healthcare Spending

Self-Guided Solutions	Commercial
Annual Spend Per 1M Members	-\$3.6M
Per Member Per Month	-\$0.30
Prescription Digital Therapeutics	
Annual Spend Per 1M Members	-\$8.7M
Per Member Per Month	-\$0.72
Blended-Care Solutions	
Annual Spend Per 1M Members	+\$25.2M
Per Member Per Month	+\$2.10

Virtual solutions for mental health improve symptoms and expand access, but some tools come with high costs

PHTI RATINGS BY CATEGORY FOR VIRTUAL SOLUTIONS FOR DEPRESSION AND ANXIETY

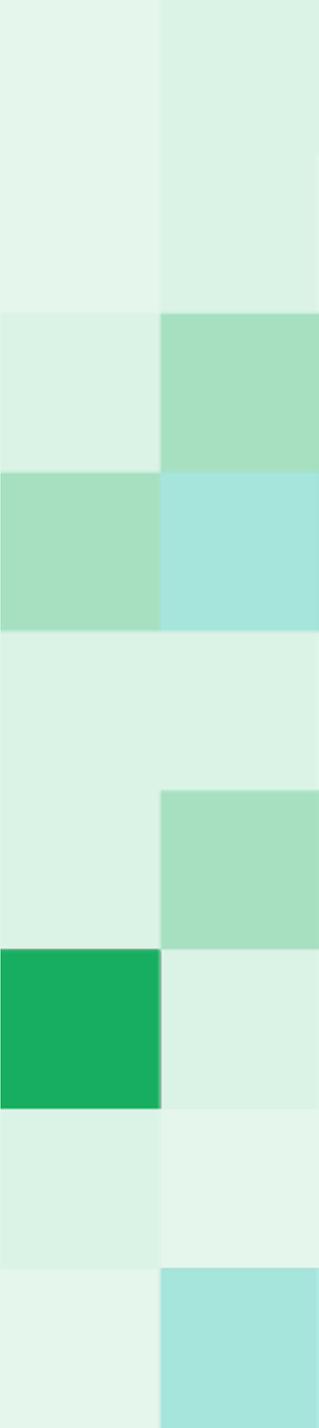
● Positive ● Moderate ● Negative
● Higher Evidence Certainty ○ Lower Evidence Certainty

Category	Clinical Effectiveness ^a	Economic Impact	Summary Rating ^b
Self-Guided Solutions AbleTo,* Dario, Headspace,* Learn to Live, Meru Health,* SilverCloud, Talkspace,* Teladoc*	 Results: Clinically meaningful improvements in depression and anxiety symptoms for people not receiving psychotherapy Evidence Certainty: Higher	 Decreases net health spending for commercial payers	 Evidence supports broader adoption for people not otherwise accessing therapy
Prescription Digital Therapeutics DaylightRx, Rejoyn	 Results: Clinically meaningful improvements for depression and anxiety symptoms as part of usual care Evidence Certainty: Higher	 Decreases net health spending for commercial payers and Medicare at anticipated reimbursement rates	 Evidence supports broader adoption due to improved efficacy of mental health treatment
Blended-Care Solutions AbleTo,* Brightside, Headspace,* Koa Health, Lyra, Meru Health,* Modern Health, Spring Health, Talkspace,* Teladoc*	 Results: Larger, clinically meaningful improvements for depression and anxiety symptoms for all users Evidence Certainty: Lower	 Increases net health spending for payers because savings from users' health improvements do not offset total solution costs	 Positive clinical outcomes and net savings for users would support broader adoption, if prices were lower

Source: PHTI, Virtual Solutions for Depression and Anxiety, May 2025. See [PHTI.org](https://phti.org) for complete report, methods, and recommendations.

Notes: ^a Not all solutions have clinical data that meet the inclusion standards for this report. ^b Summary rating reflects the combination of clinical and economic results. * Companies offering both self-guided and blended-care solutions.

Findings From Evaluation of Virtual Opioid Use Disorder Solutions



Virtual OUD solutions aim to expand access and help patients stay in treatment

Medication-Focused Solutions

Provide virtual MOUD prescribing—primarily buprenorphine—with optional support services, such as therapy, peer support, and contingency management.

Affect Therapeutics	Boulder Care	Pelago
Aware Recovery Care	Eleanor Health	PursueCare
Better Life Partners	Groups Recover Together	Wayspring
Bicycle Health	Ophelia	Workit Health

Digital Wraparound Solutions

Used to enhance MOUD treatment by adding services such as contingency management, peer support, navigation, and educational content.

CHESS Health	Q2i
DynamiCare Health	WEconnect Health

The primary clinical outcome is treatment retention, which reduces overdose risk and helps patients adhere to care

Primary Outcome: Retention on buprenorphine-based treatment

Additional Outcome Measures

- Opioid abstinence and relapse rates
- Safety
- Symptoms of withdrawal
- Engagement and satisfaction
- Health equity

Evidence Base

- Reviewed 4,000+ articles, abstracts, and other evidence
- Assessment based on 43 studies
- Includes comparative studies, real-world evidence, and company data

Virtual OUD solutions showed slightly higher retention on treatment and relatively small changes in healthcare spending

Clinical Effectiveness Results

- **Retention:** Patients using virtual OUD solutions had comparable or slightly higher retention than those receiving usual care
 - On average, patients using virtual solutions were retained in treatment **13 days longer** over six months
- **Access:** No evidence that virtual solutions improve access by caring for more previously untreated patients

Economic Impact

- **Medication-focused solutions:** When used as alternatives to usual care, these solutions result in comparable or slightly lower overall treatment costs
- **Digital wraparound solutions:** When added to usual care, these solutions result in small increases in spending
 - Solution prices outweigh the cost savings from small improvements in retention

Virtual OUD solutions are as effective as usual care, but only slightly improve retention

PHTI RATINGS FOR VIRTUAL OPIOID USE DISORDER SOLUTIONS BY CATEGORY

- Positive ● Moderate ● Negative
- Higher Evidence Certainty ○ Lower Evidence Certainty

Category of Solution	Clinical Effectiveness ^a	Economic Impact	Summary Rating ^b
Medication-Focused Affect Therapeutics, Aware Recovery Care, Better Life Partners, Bicycle Health, Boulder Care, Eleanor Health, Groups Recover Together, Ophelia, Pelago, PursueCare, Wayspring, Workit Health	 Results: Comparable or slightly better treatment retention than usual care Evidence Certainty: Lower	 Comparable or slight decrease in net spending due to avoided healthcare costs from improved treatment retention	 May be substituted for usual care Given only slight improvement in treatment retention, broader adoption should be focused on previously untreated patients
Digital Wraparound CHES Health, DynamiCare Health, Q2i, WEconnect Health	 Results: Slightly better treatment retention when added to usual care Evidence Certainty: Higher	 Increases net spending because the price of the solution exceeds the avoided healthcare costs from improved treatment retention	 Greater improvements in treatment retention are needed to justify broader adoption at current solution prices

Source: PHTI, Virtual Solutions for Opioid Use Disorder, September 2025. See PHTI.org for complete report, methods, and recommendations.

Notes: ^a Not all solutions have clinical data that meet the inclusion standards for this report. ^b Summary rating reflects the combination of clinical and economic results.

Thank you.

