

# Evidence-Based Prescription Digital Therapeutics for Mental Health Care

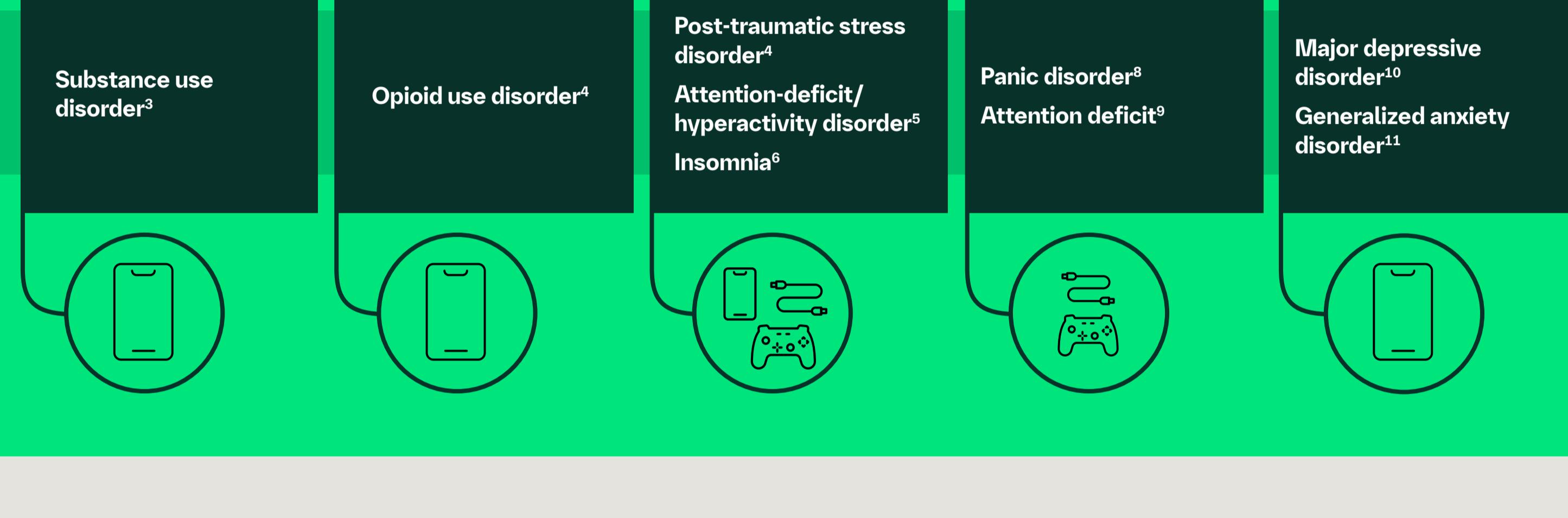


## Prescription Digital Therapeutics Require Clinical Validation and Regulatory Oversight<sup>1,2</sup>

EVIDENCE-BASED	Digital Therapeutic <sup>1,*</sup>	Prescription Digital Therapeutic <sup>2</sup>
REGULATORY OVERSIGHT	Clinical trial data may not be available	Clinical trial data required for safety and effectiveness
HEALTH CARE PROFESSIONAL (HCP) OVERSIGHT	May not have received US Food and Drug Administration (FDA) authorization	Has received FDA authorization
	Not required	Only available with prescription and HCP supervision

\*This information is based on observation in the marketplace.

## Prescription Digital Therapeutics Available for Mental Health Care in the US<sup>3-11</sup>



## Development and Approval of Prescription Digital Therapeutics<sup>12</sup>

Development	Regulatory Review	Payor Coverage	Provider Oversight
Developed using Good Manufacturing Practices	Must pass regulatory clearance	Many are eligible for reimbursement	May be prescribed as a <b>standalone</b> or <b>add-on</b> to other treatments
FDA oversight	Safety and effectiveness	Health insurance	
Clinical trial data	Review of labeled claims	Regional health systems	

## Summary

Prescription digital therapeutics are<sup>13</sup>:

Evidence-based

Software-driven

Approved for a number of mental health conditions

Prescription digital therapeutics are typically regulated as a Class II medical device.<sup>13</sup>

Clinical validation

De Novo or FDA 510(k) pathway to approval

## References

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