Operationalizing the First FDA-Cleared Prescription Digital Therapeutic, reSET®, for Real World Implementation: Initial Pilot Methodology

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Problem Description

• Healthcare resource utilization and costs are higher for patients living with substance use disorder (SUD) than those without SUD, but <50% of patients receive the recommended minimum of 12 weekly face-to-face (FTF) cognitive behavior therapy sessions.1
• The first FDA-cleared prescription digital therapeutic, reSET®, is now available for adjunctive therapy with outpatient FTF SUD treatment.
• Digitalizing SUD treatment stands to improve the state of access and care; however, further elucidation of optimal strategies for delivering reSET® at the point-of-care and evaluating its effectiveness are needed.

Observations

• To facilitate a successful approach to treating SUD patients, this pilot established an interdisciplinary clinical and analytical team, developed a detailed workflow plan (Figure 1), and identified and addressed operational needs including:
  - Specialty Pharmacy integration and reimbursement
  - HUB coordination (support services, for select products)
  - Patient identification criteria
  - Data management and information privacy
  - Development of an HEOR analysis plan inclusive of outcome metrics to assess medium and long-term program impact on the cost of care

Findings

• Introduction of FDA-cleared prescription digital therapeutics, such as reSET®, creates new managed care and patient support opportunities and challenges.
• A well-developed plan is essential for successful integration and assessment of such clinically-validated therapies, including those used in combination with currently available treatment regimens, into payer operations.

Disclosures

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References