Digital Health Industry Regulatory Case Study

From FDA to multiple US market access pathways

About JOGO

JOGO comprises a mobile app and wearable electromyography (EMG) sensors to provide treatments for pain and neuromuscular conditions by tapping into the neuromuscular pathways. JOGO therapy is delivered via the JOGO virtual clinic and through a network of partner providers. Therapeutic areas of interest include: stroke, chronic pain, pelvic health, and movement disorders.

The opportunity

- Neuromuscular re-education focuses on retraining the brain and muscles to work together.
- While developing their new therapy for patients with neuromuscular diseases and disorders, JOGO recognized the value of conducting studies and working with the FDA to receive formal regulatory recognition for their product.
- JOGO's first project, JOGO-GX, underwent a full 18-month review by the FDA and received 510(k) exempt status. Similarly, their second product, JOGO-CLBP, was FDA-reviewed and granted breakthrough device designation.

The challenge

- With the growing impact of neuromuscular conditions, JOGO was keen to treat patients across numerous conditions impacted by these disorders.
- Yet, JOGO faced numerous questions by healthcare providers and payers about how to translate their clinical studies and FDA recognition into downstream patient access and impact.

The approach

- As a first step to pursuing diverse market access pathways, the JOGO team understood that neuromuscular re-education is typically covered as a service.
- Through their team's direct engagement with FDA, a review team member shared insights on how JOGO could consider pairing their products with a clinical service as a virtual provider to serve clinicians and their patients.
- Health systems in the US embraced this approach since they frequently do not have a sufficient number of clinicians on staff to deliver this form of therapy to patients independently.
- By integrating their products into Electronic Health Record (EHR) platforms, JOGO can now retrieve prescriptions directly from health systems to activate and care for patients.

The success

- JOGO-Gx has been deployed in health systems, ambulatory care clinics, and home settings.
- Their two primary commercial models include self-insured company benefits and direct-to-consumer.
- JOGO-related provider services are reimbursed by Medicare and major payers under 4 CPT codes.
- Additionally, providers bill remote therapeutic monitoring (RTM) codes for monitoring patients at home.

FDA was prompt in responding to our queries and has an open-door policy, whereas payers can be a black box for start-ups like us.”

— Siva Nadarajah
Co-founder and President, JOGO