

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 [neuroplasticity of the brain](#) through the established pathway of EMG biofeedback. 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 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**.



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.



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