EndeavorRx® Medical Device Briefing

Introduction

On June 15 2020, the US Food and Drug Administration (FDA) permitted marketing of the game-based digital therapeutic device EndeavorRx®[1] (also known as AKL-T01).[2] The product is indicated to improve attention in 8 to 17 year old patients with inattentive or combined-type ADHD.[2] The device is considered "low risk" according to information submitted to the FDA by the manufacturer.[2] The product's FDA filings refer to it as "a software-as-medical device (SaMD) that resides on the user's mobile device and can be executed at home."[2]

Indications and Patient Populations

As stated above, the device is indicated for use in patients 8 to 17 years of age who have difficulties with attention and a diagnosis of ADHD.[2] Thus, it may be of limited utility in patients of other ages, or in patients whose ADHD predominantly manifests as hyperactivity. The product "should be considered for use as part of a therapeutic program that may include: clinician-directed therapy, medication, and/or educational programs", and "is not intended for use as a standalone therapeutic device."[1]

The device was only tested in individuals with an estimated IQ of at least 80, as assessed by the Kaufmann Brief Intelligence Test.[2] The device may be of limited utility to individuals who have conditions that may limit their ability to interact with the hardware and software, such as motor conditions, visual impairment, or colorblindness.[2]

Use

EndeavorRx is described as a "video game experience" which can be executed on home hardware.[2] The product is available on the Apple App Store and the Google Play Store.[3] The product takes the form of a racing or driving game, where the primary inputs are steering (which is done by tilting the hardware that is running the software) and tapping the hardware's touchscreen.[3] The product's audiovisuals are designed to facilitate engagement, and the product's "adaptive algorithm" continually adjusts the level of difficulty that the patient encounters with the software,[2] in an apparent attempt to attract, retain, and build attention.

The recommended duration of use of the device is 25 minutes a day for 5 days a week for 4 consecutive weeks.[3] Distractions should be minimized while using the device: the manufacturer recommends that the device be used in a quiet room with headphones and without other mobile devices and televisions.[3] Patients should know that the device will be challenging to use.[3]

Adverse Events and Monitoring

According to information submitted to the FDA, no serious adverse events were reported in preapproval trials.[2] Some 10% of participants in preapproval trials may have experienced a treatment-related adverse event, including decreased frustration tolerance and headache.[2] Less common adverse events included dizziness, nausea, aggression, and emotional disorder.[2] Of note, individuals with photosensitivity or other known sensitivities to playing video games (e.g., motion sickness) were excluded from preapproval studies, as were individuals with a history of non-febrile seizures.[2] The manufacturer cautions against use in individuals with photosensitive epilepsy.[2,3] The manufacturer recommends pausing use if a patient experiences "emotional reaction, dizziness, nausea, headache, eye-strain, or joint pain" while using the device.[3] The manufacturer recommends using the device "right before bedtime to avoid risk of potential reduction in sleep quality".[3]

Efficacy

EndeavorRx has been studied in at least three clinical trials: two studies supporting its use in patients aged 8 to 12 and one study supporting its use in patients aged 13 to 17.[3] The first study was a randomized, double-blind, digital controlled study in children aged 8 to 12; participants received either a the device or a comparator device that used a word search exercise.[4] The primary outcome in this study was the change in the Test of Variables of Attention (TOVA) Attention Performance Index (API).[4] Briefly, TOVA API is an electronic assessment of the ability to quickly and correctly respond to visual input on a screen over a period of approximately 20 minutes.[4] In this study, individuals who used the device had a statistically significant improvement of approximately 1 unit on the TOVA-API at day 28.[4] The second study was in a similar population, where the device was used for 1 month, then paused for one month, then used again for one month; of note, this study compared children who were on stimulants to children who were not on stimulants.[5] The primary outcome in this study was the ADHD Impairment Rating Scale (IRS), a parent-rated 1 to 7 visual analog scale; in this study, both the stimulant and no-stimulant cohorts showed an improvement of approximately 0.5 to 0.7 points on the IRS by day 28.[5] The study of adolescents with ADHD was a single-arm open-label study of individuals aged 13 to 17, with a reported improvement of approximately 2.6 on the TOVA attention comparison score after 4 weeks of treatment.[2]

As all of these scores are either parent-reported (IRS) or normalized by demographic characteristics (TOVA), it may be difficult to estimate the magnitude of "real world" benefit to the patient's cognitive or behavioral symptoms.

Costs

At the time of writing, the cost for EndeavorRx is $99 per 30 days; the cost of treatment may be FSA/HAS eligible.[6] As this product is a medical device and not a prescription medication, prior authorization and billing may need to occur through the patient's medical benefits, as if the product were a piece of durable medical equipment.

References

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