August Pharmacy Newsletter

FDA APPROVES FIRST TRIPLE REUPTAKE INHIBITOR FOR ATTENTION DEFICIT-HYPERACTIVITY DISORDER (ADHD)

On July 24, 2026, the FDA approved centanafadine (Simtriyo), a first-in-class medication for the treatment of attention-deficit hyperactivity disorder (ADHD). The once-daily extended-release capsule is a norepinephrine, dopamine, and serotonin reuptake inhibitor that functions as a central nervous system stimulant. Simtriyo is indicated for patients aged 6 years and older who weigh at least 20 kg (44 lb.) and is administered once daily.

Centanafadine has inhibitory activity at norepinephrine (NE), dopamine (DA), and serotonin (5-HT) reuptake transporters and is a central nervous system stimulant. The mechanism of action of centanafadine in the treatment of ADHD is unclear; however, its efficacy could be mediated through its activity as a norepinephrine-dopamine-serotonin reuptake inhibitor.

Approval was supported by results from four randomized, double-blind, placebo-controlled phase III trials: two studies in adults and two in pediatric and adolescent populations.

According to the studies, centanafadine showed statistically significant and clinically meaningful improvements in ADHD symptoms as measured by the ADHD Rating Scale-5 in children and adolescents and the Adult ADHD Investigator Symptom Rating Scale in adults. Symptom improvements were observed as early as week 1 of treatment.

The most common adverse reactions were rash and decreased appetite in children ages 6 to 12 years; decreased appetite, nausea, rash, headache, and abdominal pain in teens ages 13 to 17; and headache, decreased appetite, insomnia, nausea, dry mouth, and diarrhea in adults.

Simtriyo’ s drug label carries boxed warnings for a risk of suicidal ideation and behaviors in pediatric patients, as well as for the potential for abuse, misuse, and addiction. As with other stimulant therapies, clinicians should carefully evaluate patient history, monitor for emerging psychiatric symptoms, and reassess treatment risks and benefits throughout therapy.

Additional warnings include risks for patients with serious cardiac disease, increased blood pressure and heart rate, adverse psychiatric reactions, hypersensitivity reactions, long-term growth suppression in children, peripheral vasculopathy, serotonin syndrome, and tics. Given its serotonergic activity, providers should remain vigilant for symptoms of serotonin syndrome.

Centanafadine is not recommended for children under 6 years due to a higher incidence of weight loss. It is contraindicated in patients with known hypersensitivity to centanafadine, those taking or within 14 days of discontinuing a monoamine oxidase inhibitor, and patients with a history of pheochromocytoma.

According to manufacturer Otsuka Pharmaceutical, Simtriyo is expected to become available later in 2026 following Drug Enforcement Administration review and scheduling. The medication's final controlled substance classification has not yet been determined. Controlled substance schedule to be determined after review by the Drug Enforcement Administration.

References:

1. https://www.accessdata.fda.gov/drugsatfda_docs/label/2026/218145s000lbl.pdf

PREFERRED DRUG LIST UPDATES CAN BE FOUND HERE:

ACC-RBHA, DD, ALTCS and DCS CHP	Behavioral Health (Non-Title 19/21)

** Drugs that are not on the formulary will require a PA (prior authorization) request to be submitted**

Reminder for quicker determinations of a Prior Authorization use the ePA link for Our Providers: Please click here to initiate an electronic prior authorization (ePA) request.

This newsletter is brought to you by the Mercy Care Pharmacy Team. For questions, please email Fanny A Musto (MustoF@mercycareaz.org), Jasmine Phillips (PhillipsJ6@aetna.com)