



NeuroPace RNS® System Receives Approval from CMS for New Technology Add-On Payments

Approval Will Provide Substantially Greater Access to the RNS® System

MOUNTAIN VIEW, CA – August 6, 2014 – [NeuroPace, Inc.](http://www.neuropace.com) today announced the Centers for Medicare & Medicaid Services (CMS) has approved New Technology Add-on Payments (NTAP) for the RNS System, the world's only commercially available implantable closed-loop responsive neurostimulator system. The NTAP program recognizes new technologies that provide substantial clinical improvement over existing therapies, and is designed to support timely access to innovative technologies for Medicare beneficiaries.

NeuroPace received premarket approval (PMA) from the U.S. Food and Drug Administration (FDA) for the RNS System in November 2013. It is approved as a treatment for adults with partial onset seizures with one or two seizure onset zones whose seizures have not been controlled with two or more antiepileptic drugs.

"We are grateful CMS recognizes the substantial benefits the RNS System has provided to patients and the need for patients who suffer from uncontrolled seizures to have access to this therapy," said Frank Fischer, CEO at NeuroPace. "Epilepsy centers have moved quickly since PMA approval to make the RNS System available. To date, 35 Comprehensive Epilepsy Centers that meet all the qualifications for the highest level of epilepsy care have completed required training and are able to implant the RNS System."

Approximately 2.3 million adults in the United States have active epilepsy, and one-third live with seizures because existing therapies have not provided seizure control. Many people with uncontrolled seizures have or are eligible for Medicare disability benefits. Approval of the NTAP will significantly improve patient access to this new technology.

As a closed-loop system, the RNS System monitors the brain's own signals, interprets those signals, provides stimulation when needed, and then assesses the brain's response. The breakthrough aspect of the RNS System is its advanced detection and stimulation capabilities. This is unlike all other existing neurostimulation therapies, which continuously or intermittently stimulate the brain without determining the need for treatment or monitoring the response.

The RNS System has been evaluated in three clinical trials, including a prospective, randomized, double-blinded, sham stimulation controlled pivotal study. Results of the clinical trials demonstrate that the substantial clinical improvements experienced by patients over the short- and long-term are durable over many

years of therapy. At this time, some patients have been treated with the RNS System for over ten years, and more than 1,500 patient years of experience with responsive neurostimulation have been accumulated to date.

About the RNS® System

The RNS System is the first closed-loop responsive brain stimulation system. The system is designed to treat partial onset seizures by detecting specific types of electrical activity in the brain through leads containing electrodes that are placed near the patient's seizure focus or foci. When detection thresholds are met, the device delivers small bursts of electrical stimulation intended to reduce the frequency of seizures. Physicians can program the detection and stimulation parameters of the implanted RNS Neurostimulator non-invasively to customize therapy for each individual.

Indication for Use: The RNS® System is an adjunctive therapy in reducing the frequency of seizures in individuals 18 years of age or older with partial onset seizures who have undergone diagnostic testing that localized no more than two epileptogenic foci, are refractory to two or more antiepileptic medications, and currently have frequent and disabling seizures (motor partial seizures, complex partial seizures and / or secondarily generalized seizures). The RNS® System has demonstrated safety and effectiveness in patients who average three or more disabling seizures per month over the three most recent months (with no month with fewer than two seizures), and has not been evaluated in patients with less frequent seizures.

About NeuroPace

[NeuroPace](#) designs, develops, manufactures and markets implantable devices for the treatment of neurological disorders. The company's initial focus is the treatment of epilepsy, a debilitating neurological disorder affecting approximately one percent of the population worldwide. An estimated 30-40 percent of the 65 million people worldwide (including nearly three million Americans) with epilepsy experience uncontrolled seizures. In addition to treating epilepsy, responsive neurostimulation holds the promise of treating several other disabling neurological disorders that negatively impact quality of life for millions of patients throughout the world.

Located in Mountain View, California, NeuroPace is a privately held company.

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