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Summary of the Calendar Year (CY) 2027 Hospital Outpatient Prospective Payment System (OPPS) Final Rule Determination

The Altius System: Neuros Medical, Inc. ("Neuros Medical") developed the Altius Direct Electrical Nerve Stimulation System (the "Altius System"), a first of its kind FDA-approved and Breakthrough Device Designated technology designed to alleviate chronic post-amputation pain. The Altius System utilizes a nerve stimulator that delivers electrical therapy to damaged nerves, preventing pain signals from reaching the brain and alleviating the need for addictive opioids. Clinical studies demonstrated that recipients of this treatment experienced[1,2]:

- 30% reduction in pain within the first 30 minutes of treatment;
- 50% reduction in pain 120 minutes after initiation of treatment;
- persistent relief over the first year of treatment with no observable therapy fatigue; and
- 86% decrease in opioid use, with 42% of patients stopping opioid use completely.

About Transitional Pass-Through (TPT) Payment: In 2026, Neuros Medical applied to the Centers for Medicare & Medicaid Services (CMS) for TPT payment for the Altius System and the TPT application was discussed in the 2027 OPPS Proposed Rule. According to CMS, the "*intent of pass-through payment is to facilitate access for beneficiaries to the advantages of new and truly innovative devices by allowing for adequate payment for these new devices.*" TPT provides separate payment for three years for qualifying medical devices.

Summary of the 2027 OPPS Proposed and Final Rules: In the 2027 OPPS Proposed Rule, CMS invited public comments on whether the Altius® IPG and the Altius® Cuff Electrode Lead components meet the device category criterion to be eligible for TPT payment. Neuros Medical responded to this concern and clarified that the Altius® System represents a distinct technology class. It has a unique mechanism of action (neurostimulation that results in a complete electrical nerve block), a unique electrode design (360° circumferential cuff surgically wrapped around the sciatic nerve or its main branches through a dedicated open surgical implant), and a unique energy delivery profile (high blocking amplitude in a continuous alternating current (5-10k Hz) in 30 minute).

In the OPPS final rule, CMS agreed with Neuros Medical that no other device category describes a neurostimulator system that uses high-frequency alternating current and granted Altius pass-through status effective January 1, 2027. TPT will be in effect for Altius through December 31, 2029.

Neuros Medical's Take: Neuros Medical is delighted with CMS's decision in the OPPS final rule. TPT will help enable Medicare beneficiary access to Altius, which serves an urgent, unmet need for amputees who often suffer severe pain and high rates of opioid abuse and suicidal ideation.

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[1] Kapural, L. et al. "Long-Term Treatment of Chronic Postamputation Pain With Bioelectric Nerve Block: Twelve-Month Results of the Randomized, Double-Blinded, Cross-Over QUEST Study." Neuromodulation: Journal of the International Neuromodulation Society vol. (link)

[2] Soin A., et al., High-frequency electrical nerve block for postamputation pain: a pilot study. Neuromodulation. (link)