

pionic

Request for APC Assignment

Advisory Panel on Hospital Outpatient Payment
August 26, 2024



APC ASSIGNMENT REQUEST

- New Category III CPT codes become effective January 1, 2025 to report concurrent optical and magnetic stimulation therapy
 - XX18T/0906T Concurrent optical and magnetic stimulation therapy, wound assessment and dressing care; first application, total wound(s) surface area less than or equal to 50 sq cm
 - XX37T/0907T each additional application, total wound(s) surface area less than or equal to 50 sq cm (List separately in addition to primary procedure)
- Piomic has an FDA Category B IDE trial (G220277-NCT05758545) approved by CMS for coverage
 - Appropriate payment assignment is needed to bill Medicare during the trial beginning in 2025
 - The proposed APC assignment is not adequate to cover the cost of the device or the hospital's procedure costs
 - Over 50% of enrolled patients are expected to be Medicare beneficiaries
- CMS is proposing to place XX18T/0906T in APC 5051, Level 1 Skin Procedures (\$190)
 - Results in payment that is 68% below estimated hospital costs
- We request that the Panel recommend to CMS to assign XX18T/0906T to APC 5053, Level 3 Skin Procedures
 - Creates alignment with other wound care procedures that have similar resource costs and procedural time
 - Allows for beneficiary access during the IDE trial and into commercialization

COMS® WOUND THERAPY

A novel therapeutic approach

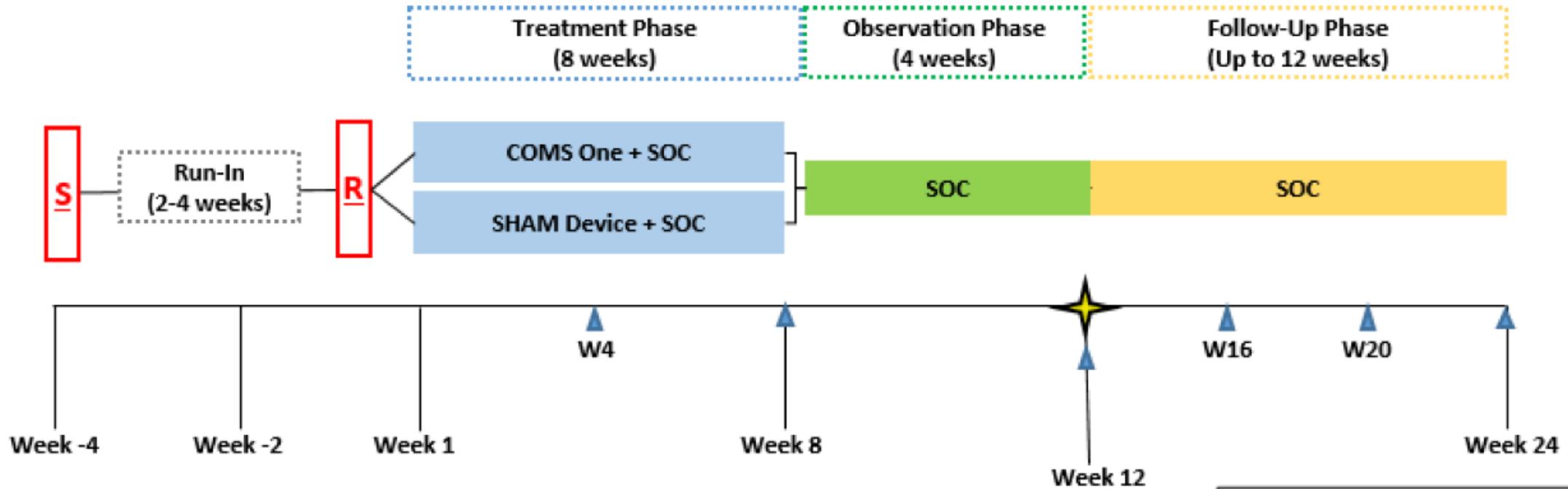


A Novel Physical Stimulation Technology (FDA De Novo) for Chronic Diabetic Foot Ulcers (estimated Q1 2026)

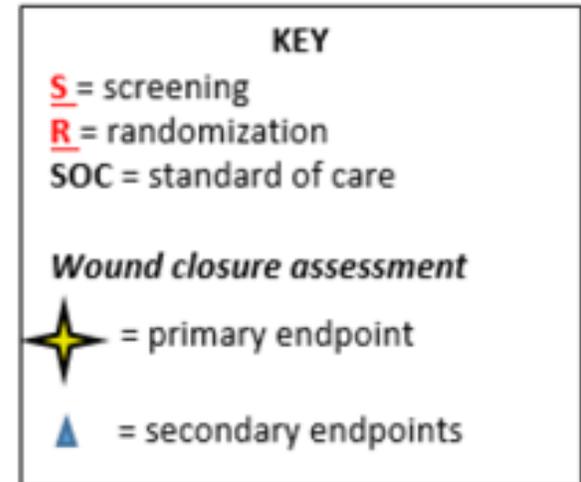
Promising data from open-label trials with up to 3x faster wound healing^{1,2}

Large double-blinded, sham-controlled FDA Category B IDE clinical trial (n=224) with 20 US sites

MAVERICKS FDA CATEGORY B IDE CLINICAL TRIAL



- Among the most extensive clinical investigations ever in wound care
- Designed to demonstrate wound healing superiority vs standard wound care (**COMS One device vs. sham-control**)
- FDA Category B designated study with Medicare coverage approved



COMS PROCEDURE – CLINICAL AND RESOURCE HOMOGENEITY



Procedure time:
35-50 minutes

depending on size and number of wounds treated



Resource Costs: \$627

Estimated to be similar to debridement (11043) and intermediate repair (12044)

Procedural Steps

Wound bed preparation	Remove existing dressings, clean ulcer and periwound area, classify wound, identify areas requiring pressure off-loading, achieve hemostasis, perform comprehensive wound examination (assess wound and periwound skin, measurement and photographs/documentation), perform debridement as necessary
Device application	Position patient and ulcer for treatment, mount the reusable component of the device to the sterile coupler, position and then secure the device directly over the ulcer using a single-use fixation strap
Therapy delivery	Activate the device and monitor the patient for signs of discomfort or device migration
Finalize wound care	Remove the device from the wound, discard disposables, clean periwound if needed and apply new wound dressings

Cost

(assumes avg. 40 min)

Resource Utilization

\$266	Hospital outpatient department treatment room/overhead (@\$400/hr)
\$86	Nursing and other clinical staff (@\$90/hour nursing, \$40/hour clinical staff)
\$40	Supplies (e.g., dressings, sterile drape, gloves, syringes, surgical, peroxide, swabs, etc.)
\$235	COMS disposable costs
\$627 Total	

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Thank You!
PIONIC

APPENDIX: BIBLIOGRAPHY

Clinical References

1. Traber, J., Wild, T., Marotz, J., Berli, M. C., & Franco-Obregón, A. "Concurrent Optical-and Magnetic-Stimulation-Induced Changes on Wound Healing Parameters, Analyzed by Hyperspectral Imaging: An Exploratory Case Series." *Bioengineering* 10.7 (2023): 750.*
2. Reinboldt-Jockenhöfer, F., Traber, J., Liesch, G., Bittner, C., Benecke, U., & Dissemond, J. "Concurrent optical and magnetic stimulation therapy in patients with lower extremity hard-to-heal wounds." *Journal of Wound Care* 31.Sup6 (2022): S12-S21.