

2020 Quick Reference Reimbursement Guidance

S.T. Genesis™ Percutaneous Nerve Field Stimulatory (PNFS) System

S.T. Genesis is an FDA 510(K) Cleared Class 2 Medical Device under the newly granted FDA Product Code PZR: Percutaneous Nerve Stimulator For Opioid Withdrawal – (Code of Federal Regulations 21 - 83 FR 5034, Feb. 5, 2018).

FDA Indications for Use:

S.T. Genesis is a percutaneous nerve field stimulatory (PNFS) system, that can be used as an aid to reduce the symptoms of opioid withdrawal, through application to branches of Cranial Nerves V, VII, IX, and X, and the occipital nerves identified by transillumination.

S.T. Genesis Coding Considerations for Reporting

- The AMA CPT® 2020 Professional Edition and the CMS 2020 Medicare Physicians Fee Schedule do not list a specific CPT Code for a Percutaneous Nerve Field Stimulatory (PNFS) system for the treatment of opioid withdrawal. This is not unusual for products the FDA cleared under a newly granted FDA product code.
- The closest guidance is from the AMA guidelines: For percutaneous electrical stimulation of a cranial nerve using needle[s] or needle electrode[s] [eg, PENS, PNT], use 64999.

Coding Factors for New FDA Product Code (PZR) Granted in 2018

CPT Code Set	Descriptor	Comments
*64999	(Miscellaneous) - <i>Unlisted procedure, nervous system</i>	There are no specific CPT codes for the newly granted FDA Product Code, PNFS procedure or the S.T. Genesis device.

*Please note that miscellaneous codes are paid on a case-by-case basis at the local A/B Medicare Administrative Contractor (MAC) level and will require a letter of medical necessity.

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Professional Services Associated with the Application of the Device

The recommendation for reporting professional services associated with the application of the percutaneous nerve field stimulatory (PNFS) system and patient monitoring, is for the practice to follow their existing practice guidelines and CMS Guidance for reporting E&M Office Visits and E&M Prolonged Services. Listed below are some but not all of the potential CPT® code sets.

Evaluation and Management Services - Office Visits	Medicare Claims Processing Manual Chapter 12 Section 30.6.7 - Payment for Office or Other Outpatient Evaluation and Management	
99201-99205	Evaluation and Management office visits – new patient	Office visit face-to-face time 10-20-30-45 or 60 minutes
99211-99215	Evaluation and Management office visits – existing patient	Office visit face-to-face time 5-10-15-25 or 40 minutes

Evaluation and Management Services – Prolonged Services	Medicare Claims Processing Manual Chapter 12 Section 30.6.15 - Prolonged Services and Standby Services (Codes 99354 - 99360)	
99354	Prolonged service in the office or outpatient setting requiring direct patient contact beyond the usual service	First hour
99355	Prolonged service in the office or outpatient setting requiring direct patient contact beyond the usual service	Each additional 30 minutes
99358	Prolonged evaluation and management service before and/or after direct patient care	First hour
99359	Prolonged evaluation and management service before and/or after direct patient care	Each additional 30 minutes

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AMA Guidelines:

Psychiatry services include diagnostic services, psychotherapy, and other services to an individual, family, or group. Patient condition, characteristics, or situational factors may require services described as being with interactive complexity. Services may be provided to a patient in crisis. Services are provided in all settings of care and psychiatry services codes are reported without regard to setting. Services may be provided by a physician or other qualified healthcare professional. Some psychiatry services may be reported with Evaluation and Management Services (99201-99255, 99281-99285, 99304-99337, 99341-99350) or other services when performed. Evaluation and Management Services (99201-99285, 99304-99337, 99341-99350) may be reported for treatment of psychiatric conditions, rather than using Psychiatry Services codes, when appropriate.

SOURCE:

Speranza Therapeutics has engaged the Wells Health Group to provide Reimbursement Guidance for claims reporting of the S.T. Genesis percutaneous nerve field stimulatory (PNFS) system and the professional services associated with the application of the device.

Wells Health Group is a health policy consulting and government relations firm based in Washington D.C. WHG is strategically located on Pennsylvania Avenue between the Capitol and the White House and only three blocks from HHS, CMS, and FDA administration.

WHG's comprehensive analytics and reimbursement pathways are founded on 70+ years of successful healthcare industry and government relations experience. Our expertise spans the healthcare industry innovation for drugs, devices, and services in multiple therapeutic areas.

Pivoting through the various nuances of government statutes and policies, we are guiding the Speranza Therapeutics team to support and inform their workflow. We come from industry and have a unique perspective which informs our work with Speranza Therapeutics.

WHG's innovative approach to health policy consulting is built on a two-step sequential process:

- A core set of essential strategy *analytics from diagnosis, treatment plan, site of care, and benefit category to coding, coverage, and payment*
- Focused *reimbursement pathways*

We identify the foundation of reimbursement hurdles or opportunities and prioritize executable milestones to maximize reimbursement.

WHG and the Speranza Therapeutics team are collaborating to apply for a new CPT®/HCPCS code. We are gathering the data necessary to support the need for a new code through the LMN process and claim information.

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Wells Health Group | Sources: AMA CPT® 2020 Professional Edition Guidelines | Medicare Claims Processing Manual