

Wells Health Group

Innovators in Health Policy



S.T. Genesis Launch Reimbursement Guidance

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WHG recommends a dual pathway billing structure to report the application of the S.T. Genesis percutaneous nerve field stimulatory (PNFS) system. The device CPT code should be reported separately on the claim form from the professional services CPT codes associated with the application of the device.

1. The S.T. Genesis device is FDA cleared for a non-implantable neurology procedure; *Percutaneous Nerve Stimulator For Opioid Withdrawal*. There are no specific CPT codes for the newly granted FDA Product Code, PNFS procedure or the device.
 - For reporting the S.T. Genesis Device, a percutaneous nerve field stimulatory (PNFS) system, use the CPT[®] Code 64999 (miscellaneous) - *Unlisted procedure, nervous system*.
 - Please note that miscellaneous codes are covered and 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.
 - It is inappropriate to use existing CPT Codes such as 64553 - *Percutaneous implantation of neurostimulator electrode array* and/or HCPCS Code L8679 - *Implantable neurostimulator, pulse generator, any type*.
2. For reporting professional services associated with the application of the percutaneous nerve field stimulatory (PNFS) system, the recommendation is for the practice to follow their existing practice guidelines and AMA Guidance.
 - For reporting Evaluation and Management office visits (CPT Codes 99202-99205 New Patient, 99211-99215 Existing Patient).
 - For reporting Psychiatry (CPT Codes 90785-90899)
 - For reporting Health Behavior (CPT Codes 96156-96171)
3. Diagnosis - ICD-10-CM and ICD-10-PCS codes drive the treatment plan of care. The primary and secondary diagnoses codes drive the reimbursement process.

F11 Opioid Related Disorders Potential Codes	
<u>Code(s)</u>	<u>Description</u>
F11.10	Opioid abuse, uncomplicated
F11.11	Opioid abuse, in remission
F11.120 to F11.129	Opioid abuse with intoxication
F11.14	Opioid abuse with opioid-induced mood disorder
F11.150 to F11.159	Opioid abuse with opioid-induced psychotic disorder
F11.181 to F11.188	Opioid abuse with other opioid-induced disorder
F11.19	Opioid abuse with unspecified opioid-induced disorder

FDA Product Code detail, AMA CPT Codes and supporting AMA Guidance provided below.

FDA S.T. Genesis Information

S.T. Genesis is an FDA 510(K) Cleared Class 2 Medical Device

FDA Indications for Use:

The 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.

FDA Product Code:	PZR (A newly granted FDA product Code effective 2/5/2018)
FDA Definition:	Stimulate Nerve Branches To Aid In The Reduction Of Symptoms Associated With Substance Use Disorders.
Device Name:	Percutaneous Nerve Stimulator For Opioid Withdrawal
Physical State:	A Signal Generator Connected To Percutaneous Electrodes.
Technical Method:	Electrical Stimulation Of Nerve Branches Using Percutaneous Electrodes.
Target Area:	Cranial And Occipital Nerve Branches.
Regulation Medical Specialty:	Neurology
Review Panel:	Neurology
Regulation Description:	Percutaneous Nerve Stimulator For Substance Use Disorders.
Premarket Review:	Neuromodulation and Physical Medicine Devices (DHT5B)
Regulation Number	882.5896 - Percutaneous nerve stimulator for substance use disorders.

Implanted Device?	No
Life-Sustain/Support Device?	No

FDA NEWS RELEASE

November 15, 2017 – Excerpts from the FDA News Release:

Today, the U.S. Food and Drug Administration granted a new indication to an electric stimulation device for use in helping to reduce the symptoms of opioid withdrawal.

“Given the scope of the epidemic of opioid addiction, we need to find innovative new ways to help those currently addicted live lives of sobriety with the assistance of medically assisted treatment. There are three approved drugs for helping treat opioid addiction. While we continue to pursue better medicines for the treatment of opioid use disorder, we also need to look to devices that can assist in this therapy,” said FDA Commissioner Scott Gottlieb, M.D. “The FDA is committed to supporting the development of novel treatments, both drugs and devices, that can be used to address opioid dependence or addiction, as well as new, non-addictive treatments for pain that can serve as alternatives to opioids.”

... To permit marketing of this device for this use, the FDA reviewed data from a single-arm clinical study of 73 patients undergoing opioid physical withdrawal. The study evaluated patients’ clinical opiate withdrawal scale (COWS) score, which is a clinical assessment conducted by a health care professional that measures opioid withdrawal symptoms such as resting pulse rate, sweating, pupil size, gastrointestinal issues, bone and joint aches, tremors and anxiety. COWS scores range from 0 to more than 36 — the higher the number, the more severe the withdrawal symptoms are to a patient.

CPT® Coding Pathway and Challenge

The S.T. Genesis innovative device is FDA cleared under the newly granted FDA Product Code PZR: Percutaneous Nerve Stimulator For Opioid Withdrawal product code effective 2/5/2018 with corresponding new indications for use; 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.

The end result is that the medical community now has the availability of a new procedure to help with medically assisted detox.

The inevitable consequence is that the newly granted FDA indications for use do not provide a clear pathway to a specific CPT code for billing the device.

The S.T. Genesis device is FDA cleared for a **non-implantable** neurology procedure; Percutaneous Nerve Stimulator For Opioid Withdrawal. There are no specific CPT codes for the PNFS procedure or the device.

Please Note: AMA Guidelines - CPT® 2020 Professional Edition – page 468:

(For percutaneous electrical stimulation of a cranial nerve using needle[s] or needle electrode[s] [eg, PENS, PNT], use 64999)

(For percutaneous neuromuscular stimulation or neuromodulation using needle[s] or needle electrode[s] [eg, PENS, PNT], use 64999)

(The AMA Guidance language has been the same for at least the past two years and only calls out PENS, PNT devices and no reference to the to the new FDA class PNFS.)

Therefore, it is inappropriate to use existing CPT Codes such as 64553 - *Percutaneous implantation of neurostimulator electrode array* and/or HCPCS Code L8679 *Implantable neurostimulator, pulse generator, any type*. These codes are for an implantable procedure of an FDA designated implantable device.

Reimbursement Guidance Detail

Dual pathway billing structure to report the application of the S.T. Genesis percutaneous nerve field stimulatory (PNFS) system. The device CPT code should be reported separately on the claim form from the professional services CPT codes associated with the application of the device.

For reporting the S.T. Genesis device - Use the CPT Code 64999 - Unlisted procedure, nervous system S.T. Genesis, 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.

- In addition, include a very descriptive letter of medical necessity.
- The recommendation is for the submitted charge for the device only to be at a minimum \$1,000.00 or higher. (This recommended charge is for the device **only** and not for the application of the device)

For reporting professional services associated with the application of the percutaneous nerve field stimulatory (PNFS) system, the recommendation is for the practice to follow their existing practice guidelines and AMA Guidance. (Listed below are some but not all of the potential CPT code sets)

- For reporting Evaluation and Management office visits (CPT Codes 99202 - 99215)
 - 99202 - 99205 New Patient
 - 99211 - 99215 Existing Patient
 - AMA Guidelines:
The following codes (99202-99215) are used to report evaluation and management services provided in the office or in an outpatient or other ambulatory facility. A patient is considered an outpatient until inpatient admission to a health care facility occurs.

To report services provided to a patient who is admitted to a hospital or nursing facility in the course of an encounter in the office or other ambulatory facility, see

the notes for initial hospital inpatient care (page 15) or initial nursing facility care (page 25).

For services provided in the emergency department, see 99281-99285.

For observation care, see 99217-99226.

For observation or inpatient care services (including admission and discharge services), see 99234-99236.

- For reporting Psychiatry (CPT Codes 90785 - 90879)
 - 90785 Interactive Complexity
 - 90791 - 90899 Psychiatric Diagnostic Procedures
 - 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 (99202-99255, 99281-99285, 99304-99337, 99341-99350) or other services when performed. Evaluation and Management Services (99202-99285, 99304-99337, 99341-99350) may be reported for treatment of psychiatric conditions, rather than using Psychiatry Services codes, when appropriate.

Hospital care in treating a psychiatric inpatient or partial hospitalization may be initial or subsequent in nature (see 99221-99233).

Some patients receive hospital evaluation and management services only and others receive hospital evaluation and management services and other procedures. If other procedures such as electroconvulsive therapy or psychotherapy are rendered in addition to hospital evaluation and management services, these may be listed separately (eg, hospital care services [99221-99223, 99231-99233] plus electroconvulsive therapy [90870]), or when psychotherapy is done, with appropriate code(s) defining psychotherapy services.

Consultation for psychiatric evaluation of a patient includes examination of a patient and exchange of information with the primary physician and other informants such as nurses or family members, and preparation of a report. These services may be reported using consultation codes (see Consultations).

(Do not report 90785-90899 in conjunction with 90839, 90840, 97151, 97152, 97153, 97154, 97155, 97156, 97157, 97158, 0362T, 0373T)

- For reporting Health Behavior (CPT Codes 96156-96171)
 - 96156 HEALTH BEHAVIOR ASSESSMENT/RE-ASSESSMENT New Code for 2020
 - 96158 - 96159 Health and behavior intervention, individual
 - 96160 - 96161 Administration of health risk assessment instrument
 - 96164 - 96165 Health and behavior intervention, group
 - 96167 – 96171 Health and behavior intervention, family
 - AMA Guidelines:

Health behavior assessment and intervention services are used to identify and address the psychological, behavioral, emotional, cognitive, and interpersonal factors important to the assessment, treatment, or management of physical health problems.

The patient's primary diagnosis is physical in nature and the focus of the assessment and intervention is on factors complicating medical conditions and treatments. These codes describe assessments and interventions to improve the patient's health and well-being utilizing psychological and/or psychosocial interventions designed to ameliorate specific disease-related problems.

Health behavior assessment: includes evaluation of the patient's responses to disease, illness or injury, outlook, coping strategies, motivation, and adherence to medical treatment. Assessment is conducted through health - focused clinical interviews, observation, and clinical decision making.

Health behavior intervention: includes promotion of functional improvement, minimizing psychological and/ or psychosocial barriers to recovery, and management of and improved coping with medical conditions. These services emphasize active patient/family engagement and involvement. These interventions may be provided individually, to a group (two or more patients), and/or to the family, with or without the patient present.

Codes 96156, 96158, 96159, 96164, 96165, 96167, 96168, 96170, 96171 describe services offered to patients who present with primary physical illnesses, diagnoses, or symptoms and may benefit from assessments and interventions that focus on the psychological and/or psychosocial factors related to the patient's health status. These services do not represent preventive medicine counseling and risk factor reduction interventions.

For patients that require psychiatric services (90785- 90899), adaptive behavior services (97151, 97152, 97153, 97154, 97155, 97156, 97157, 97158, 0362T, 0373T) as well as health behavior assessment and intervention (96156, 96158, 96159, 96164, 96165, 96167, 96168, 96170, 96171), report the predominant service performed. Do not report 96156, 96158, 96159, 96164, 96165, 96167, 96168, 96170, 96171 in conjunction with 90785-90899 on the same date.

Evaluation and management services codes (including counseling risk factor reduction and behavior change intervention [99401-99412]) should not be reported on the same day as health behavior assessment and intervention codes 96156, 96158, 96159, 96164, 96165, 96167, 96168, 96170, 96171 by the same provider.

Health behavior assessment and intervention services (96156, 96158, 96159, 96164, 96165, 96167, 96168, 96170, 96171) can occur and be reported on the same date of service as evaluation and management services (including counseling risk factor reduction and behavior change intervention [99401, 99402, 99403, 99404, 99406, 99407, 99408, 99409, 99411, 99412]), as long as the health behavior assessment and intervention service is reported by a physician or other qualified health care professional and the evaluation and management service is performed by a physician or other qualified health care professional who may report evaluation and management services.

Do not report 96158, 96164, 96167, 96170 for less than 16 minutes of service.

(For health behavior assessment and intervention services [96156, 96158, 96159, 96164, 96165, 96167, 96168, 96170, 96171] performed by a physician or other qualified health care professional who may report evaluation and management services, see Evaluation and Management or Preventive Medicine Services codes)

(Do not report 96156, 96158, 96159, 96164, 96165, 96167, 96168, 96170, 96171 in conjunction with 97151, 97152, 97153, 97154, 97155, 97156, 97157, 97158, 0362T, 0373T)