# 2025 Hospital/ASC Billing Guide

Inspire Medical Systems

Inspire IV



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# Inspire Medical Systems Hospital Billing Guide

Inspire Medical Systems, Inc. (Inspire) developed this material to provide general information about payer coverage and coding for Inspire Upper Airway Stimulation (UAS). It is intended for illustrative purposes only, and is not intended to be construed as legal, clinical or reimbursement advice, or a guarantee of reimbursement coverage or payment.

Inspire makes no express or implied warranty or guarantee that the coding or other information in this material is current, complete, or error-free. As always, providers are ultimately responsible for coding and understanding and complying with existing Medicare coverage policies and any other coverage requirements established by third party payers, including, without limitation, any provider specialty requirements. Providers should verify policies with payers, and consult with their reimbursement specialists, financial advisors or legal counsel for questions and issues regarding coding, coverage, and all other reimbursement matters.

For questions regarding reimbursement of Inspire UAS, please email reimbursement@ inspiresleep.com.

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### Important Safety Information

Inspire is not for everyone. It is a surgically implanted system that is intended to treat obstructive sleep apnea in patients who are not effectively treated by, or able to tolerate CPAP. Talk to your patients about risks, benefits and expectations associated with Inspire. Risks associated with the surgical implant procedure may include infection and temporary tongue weakness. In rare cases tongue paresis and atrophy may occur. Some patients may require post implant adjustments to the system's settings in order to improve effectiveness and ease any initial discomfort they may experience. Important safety information and product manuals can be found at inspiresleep.com/safety-information/ or call 1-844-OSA-HELP.

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## **Device and Procedure Description**

### Device

Inspire Hypoglossal Nerve Stimulation (HGNS) therapy is a neurostimulation system for the treatment of moderate to severe obstructive sleep apnea. The system detects breathing patterns while the patient is sleeping and stimulates the hypoglossal nerve (cranial nerve XII) to move the tongue and soft palate from obstructing the airway.

The Inspire IV system consists of three implantable components:

- Generator Like all neurostimulators, the generator provides the electrical stimulation pulse.
- Stimulation Lead The stimulation lead delivers the stimulation pulse to the hypoglossal nerve.
- Breathing Sensor Lead The breathing sensor lead detects breathing patterns and relays this information to the generator.

### **Upper Airway Examination Coding**

Drug-induced sleep endoscopy (DISE) is a commonly required diagnostic procedure for evaluating palatal collapse for Hypoglossal Nerve Stimulation. During the procedure, artificial sleep is induced by midazolam and/or propofol, and the pharyngeal collapse patterns are visualized using a flexible fiberoptic nasopharyngoscope. The level (palate, oropharynx, tongue base, hypopharynx/epiglottis), the direction (anteroposterior, concentric, lateral), and the degree of collapse (none, partial, or complete) are examined.

### **Implant Procedure**

The generator is placed in a subcutaneous pocket created via blunt dissection, typically in the upper chest. Following surgical exposure, the stimulation lead is placed in the upper neck with the cuff wrapped around the hypoglossal nerve. It is tunneled subcutaneously to the upper chest and connected to the generator. The breathing sensor lead is placed into the plane between the external and internal intercostal muscles and connected to the generator. The system is programmed and periodically interrogated and re-programmed to meet the patient's needs.

### Analysis and Programming Procedures

During electronic analysis and programming of the implanted neurostimulator, settings are analyzed and adjusted. Whenever programming is performed, it is essential that physicians individually name and document the specific parameters changed for coding purposes. Common settings may include:

### **Stimulation Settings**

- Amplitude
- Patient Control Lower Limit
- Patient Control Upper Limit
- Start Delay
- Pause Time
- Therapy Duration
- Pulse Width
- Rate
  - Electrode Configuration

### **Sensing Settings**

- Exhalation Sensitivity
- Exhalation Threshold
- Invert
- Inhalation Sensitivity
- Inhalation Threshold
- Hard Off Period
- Soft Off Period
- Max Stim Time

### Coverage

### **FDA Approval**

Inspire HGNS therapy received PMA approval from the FDA on April 30, 2014. As of April 21, 2020, the FDA has approved an expanded range for Inspire therapy to include 18-21 year old patients. On June 8, 2023, the FDA expanded the Apnea-Hypopnea Index (AHI) range to greater than or equal to 15 and less than or equal to 100. The warning label for BMI also increased from 32 to 40.

Note: this Guide is for Inspire IV, though on August 2nd, 2024, Inspire received FDA approval for the Inspire V system. More information related to Inspire V will be released at a later date.

### Medicare Coverage

Medicare and other payers determine whether to cover the procedure or technology as a health benefit based on the published literature as well as business considerations. The first requirement is FDA approval.

An FDA-regulated product must receive FDA approval or clearance (unless exempt from the FDA premarket review process) for at least one indication to be eligible for consideration of Medicare coverage (except in specific circumstances). However, FDA approval or clearance alone does not entitle that technology to Medicare coverage.

8.7.2013, Federal Register, Vol. 78, No. 152, page 48165

All Medicare Administrative Contractors (MACS) have developed positive Local Coverage Determination policies for Inspire. These policies extend coverage for the procedure or technology for certain diagnoses or specific scenarios.

It is the responsibility of the provider to be aware of existing Medicare coverage policies before providing service to Medicare beneficiaries. Please reference your local MAC for exact Medicare coverage criteria in your region.

Traditional Medicare does not require or allow prior authorization or prior approval for procedures. To limit the risk of Medicare non-coverage, hospitals should contact their local MAC's Medical Director in advance. Hospitals may also contact Inspire Medical Systems for support in this process.

**Note:** Medicare Advantage plans are managed by commercial payers but are still required to follow Medicare coverage determinations. Those payers may require prior authorization for Medicare Advantage patients.

### Private Payer Coverage

Private payers also require FDA approval. Once approved, coverage is determined according to the framework of each patient's specific plan, rather than on a geographic basis like Medicare.

Also, unlike traditional Medicare, private payers often require prior authorization for an elective procedure such as HGNS implantation. Before scheduling a patient's HGNS procedure, the hospital can contact Inspire Medical Systems' Prior Authorization support team for assistance with prior authorizations. Proceeding without a required prior authorization may result in a denial and non-payment. Prior authorization is also a good time to check for the payer's billing requirements specific to implantable devices.

### **Reimbursement Denials**

Private payers sometimes deny prior authorizations or submitted claims. Medicare may also deny a submitted claim. Hospitals may wish to appeal these denials. See page 13 for information on the Medicare appeal process. For private payer denials, hospitals and ASCs can contact Inspire Medical Systems for support. When doing so, it is helpful to provide the payer's denial letter or the Explanation of Benefits outlining the reasons for denial.

# **Upper Airway Examination Coding**

### Diagnosis Codes

Diagnosis coding for endoscopic evaluation of the upper airway may involve the following code:

ICD-10-CM Diagnosis Code	Code Description
G47.33	Obstructive sleep apnea (adult) (pediatric)

### **Procedure Codes**

Pre-operative anatomical assessment of the upper airway is required for all Inspire patients. The procedure most often performed is a drug-induced sleep endoscopy (DISE), which is an evaluation of the upper airway after pharmacologic induction of unconscious sedation. The following code may be used for a drug-induced sleep endoscopic examination.

CPT® Code	Code Description
42975	Drug-induced sleep endoscopy, with dynamic evaluation of velum, pharynx, tongue base, and larynx for evaluation of sleep disordered breathing, flexible, diagnostic

(Do not report 42975 in conjunction with 31231, unless performed for a separate condition [ie, other than sleep-disordered breathing] and using a separate endoscope) (Do not report 42975 in conjunction with 31575, 92511)

### **APC Codes**

For hospital outpatient payments, Medicare assigns each CPT<sup>®</sup> code to a specific APC. Each APC has a fixed payment amount which includes the cost of any devices. The Upper Airway Examination Coding procedures map to the following APCs:

CPT <sup>®</sup> Code	APC	Code Description	SI
42975	5153	Level 3 Airway Endoscopy	JI

2025 APCs as published in CMS 1786-FC Addendum B. Nov 2024

# **Implant Coding**

### **Diagnosis Codes**

Inspire Hypoglossal Nerve Stimulation (HGNS) therapy is used to treat a subset of patients with moderate to severe obstructive sleep apnea (OSA) (apnea-hypopnea index [AHI] of greater than or equal to 15 and less than or equal to 100).

Diagnosis coding for HGNS implantation may involve the following code:

ICD-10-CM Diagnosis Code	Code Description
G47.33	Obstructive sleep apnea (adult) (pediatric)

For Medicare there is a dual diagnosis requirement. Coverage for hypoglossal nerve stimulation procedures on patients who meet coverage criteria must include both a primary ICD-10-CM diagnosis code indicating the reason for the procedure and a secondary ICD-10-CM diagnosis code indicating the Body Mass Index (BMI) is less than 35 kg/m<sup>2</sup> as set forth in the LCD Covered Indications. The Local Medicare Administrative Contractors' (MACs) billing articles for HGNS require reporting a primary diagnosis code of OSA and a secondary diagnosis code from group below for coverage:

ICD-10-CM Diagnosis Code	Code Description
Z68.1	Body mass index [BMI] 19.9 or less, adult
Z68.20	Body mass index [BMI] 20.0-20.9, adult
Z68.21	Body mass index [BMI] 21.0-21.9, adult
Z68.22	Body mass index [BMI] 22.0-22.9, adult
Z68.23	Body mass index [BMI] 23.0-23.9, adult
Z68.24	Body mass index [BMI] 24.0-24.9, adult
Z68.25	Body mass index [BMI] 25.0-25.9, adult
Z68.26	Body mass index [BMI] 26.0-26.9, adult
Z68.27	Body mass index [BMI] 27.0-27.9, adult
Z68.28	Body mass index [BMI] 28.0-28.9, adult
Z68.29	Body mass index [BMI] 29.0-29.9, adult
Z68.30	Body mass index [BMI] 30.0-30.9, adult
Z68.31	Body mass index [BMI] 31.0-31.9, adult
Z68.32	Body mass index [BMI] 32.0-32.9, adult
Z68.33	Body mass index [BMI] 33.0-33.9, adult
Z68.34	Body mass index [BMI] 34.0-34.9, adult

Inspire Medical Systems, Inc.

# Hospital Outpatient Codes – Implant Procedure CPT® Procedure Codes

Hospitals report outpatient procedures using CPT codes. Procedures involving HGNS may involve the following code:

CPT®Code	Code Description	Components
64582	Open implantation of hypoglossal nerve neurostimulator array, pulse generator, and distal respiratory sensor electrode or electrode array	Generator, Stimulation Lead and Breathing Sensor Lead

### APC

For hospital outpatient payments, Medicare assigns each CPT<sup>®</sup> code to a specific Ambulatory Payment Classification (APC). Each APC has a fixed payment amount which includes the cost of any devices. The HGNS implantation procedure may involve the following APCs:

CPT <sup>®</sup> Code	APC Code	APC Description	SI
64582	5465	Level 5 Neurostimulator and Related Procedures	JI

2025 APCs as published in CMS 1786-FC Addendum B. Nov 2024.

### **HCPCS II Device Codes**

CPT® codes are assigned for the HGNS implant procedure. HCPCS II codes are assigned to identify the device itself.

### Outpatient

Coding for the HGNS device may involve the HCPCS II codes listed below. Some payers may contract on C-codes while others may contract on L-codes.

### ASC

For Medicare cases performed in an ASC setting, it is not recommended to include separate line items for HCPCS Level II codes. Instead, payment is bundled under the primary procedure code. Commercial insurances may still require C or L codes be included on claims.

HCPCS II Code	Code Description
C1767	Generator, neurostimulator (implantable), non-rechargeable
C1778	Lead, neurostimulator (implantable)
C1787	Patient programmer, neurostimulator
L8688	Implantable neurostimulator pulse generator, dual array, non-rechargeable, includes extension
L8680	Implantable neurostimulator electrode, each

In an outpatient facility, Medicare uses code C1778 for both the stimulation lead and the breathing sensor lead. Some payers may use L8680 for both. Prior authorization is a good time to check for private payer's device-coding requirements.

# Revision, Removal, and Replacement Procedure Coding

### **CPT®** Procedure Codes

In addition to implantation, the HGNS device may require revision, removal, or replacement at some time during its life cycle. Hospital outpatient procedures may involve the following codes:

CPT <sup>®</sup> Code	Code Description	Components
61886	Insertion or replacement of cranial neurostimulator pulse generator or receiver, direct or inductive coupling; with connection to 2 or more electrode arrays	Generator
61888	Revision or removal of cranial neurostimulator pulse generator or receiver	Generator
64583*	Revision or replacement of hypoglossal nerve neurostimulator array and distal respiratory sensor electrode or electrode array, including connection to an existing generator	Stimulation Lead and Breathing Sensor Lead
64584**	Removal of hypoglossal nerve neurostimulator array, pulse generator, and distal respiratory sensor electrode or electrode array	Generator, Stimulation Lead, and Breathing Sensor Lead

\*If only one lead is being revised or replaced, it is recommended to append modifier 74 to 64583

\*\*If only a portion of the device is being removed (ie: stimulation lead, breathing sensor lead, or generator), it is recommended to append modifier 74 to 64584

### APC Codes

As mentioned above, for hospital outpatient payments, Medicare assigns each CPT<sup>®</sup> code to a specific APC. Each APC has a fixed payment amount which includes the cost of any devices. The HGNS revision, removal, or replacement procedures map to the following APCs:

CPT <sup>®</sup> Code	APC Code	APC Description	SI
61886	5465	Level 5 Neurostimulator and Related Procedures	Jl
61888	5463	Level 3 Neurostimulator and Related Procedures	JI
64583	5463	Level 3 Neurostimulator and Related Procedures	JI
64584	5432	Level 2 Nerve Procedures	Q2

2025 APCs as published in CMS 1786-FC Addendum B. Nov 2024.

The Status Indicator (SI) of JI shows primary codes for which all other procedures performed at the same encounter are considered adjunctive and not paid separately. Status Indicator Q2 means that these codes are packaged and not paid separately when reported with another code with Status Indicator T.

# **Analysis and Programming Coding**

The HGNS device may also require periodic Analysis and Programming.

### Analysis and Programming Diagnosis Coding

Diagnosis coding for routine HGNS Analysis and Programming may involve the following code:

ICD-10-CM Diagnosis Code	Code Description
Z45.42	Encounter for adjustment and management of neurostimulator
G47.33	Obstructive sleep apnea (adult) (pediatric)

### Polysomnogram Procedure Coding

The HGNS device may require programming during an in-lab sleep study. CPT<sup>®</sup> coding for PSG may include the following code:

CPT Code	Code Description	Service
95810	Polysomnography; age 6 years or older, sleep staging with 4 or more additional parameters of sleep, attended by a technologist	Polysomnogram performed during programming
CPT Code	Code Description	Service
95970	Electronic analysis of implanted neurostimulator pulse generator/ transmitter (e.g., contact group(s), interleaving, amplitude, pulse width, frequency (Hz), on, off cycling, burst, magnet mode, dose lockout, patient selectable parameters, responsive neurostimulation, detection algorithms, closed loop parameters, ar passive parameters) by physician or other qualified health care professional; v brain, cranial nerve, spinal cord, peripheral nerve, or sacral nerve neurostimula pulse generator/transmitter, without programming	nd (not at the time of
95976	Electronic analysis of implanted neurostimulator pulse generator/ transmitter (e.g., contact group(s), interleaving, amplitude, pulse width, frequency (Hz), on/ off cycling, burst, magnet mode, dose lockout, patient selectable parameters, responsive neurostimulation, detection algorithms, closed loop parameters, and passive parameters) by physician or other qualified health care professional; w simple cranial nerve neurostimulator pulse generator/transmitter programming physician or other qualified health care professional.	d (not at the time of
95977	Electronic analysis of implanted neurostimulator pulse generator/ transmitter (e.g., contact group(s), interleaving, amplitude, pulse width, frequency (Hz), on/ off cycling, burst, magnet mode, dose lockout, patient selectable parameters, responsive neurostimulation, detection algorithms, closed loop parameters, an- passive parameters) by physician or other qualified health care professional; w complex cranial nerve neurostimulator pulse generator/transmitter programm by physician or other qualified health care professional	d (not at the time of

# <u>Code 95970 is not assigned for device analysis when performed at the time of generator implantation. CPT® manual instructions state that code 95970 describes only "subsequent" electronic analysis of "a previously implanted" generator.</u>

Code 95976 is defined for simple programming and code 95977 is defined for complex programming. Simple programming refers to changing three or fewer of the parameters listed. Complex programming refers to changing four or more parameters.

For coding purposes, it is essential that physicians individually name and document the specific parameters changed whenever programming is performed.

### APC Codes

CPT® Code	APC Code	APC Description	SI
95810	5724	Level 4 Diagnostic Tests and Related Services	S
95970	5734	Level 4 Minor Procedures	Q1
95976	5741	Level 1 Electronic Analysis of Devices	S
95977	5742	Level 2 Electronic Analysis of Devices	S

The HGNS Analysis and Programming codes map to the following APCs:

2025 APCs as published in CMS 1786-FC Addendum B. Nov 2024.

Status Indicator S means that the code is always paid at 100% of the rate even when submitted with other higher-ranked codes. Status Indicator Q1 means the code is packaged when billed on the same date of service with any other code with a status indicator of S, T, V, or X.

# **Billing Requirements**

### Hospital Outpatient Billing - Implant Procedure

Medicare has specific instructions for submitting hospital outpatient claims related to implantable devices. Hospitals are strongly encouraged to separately bill devices using a device category C-code or other appropriate HCPCS code for implantable devices, along with the charge for the device. Complete and accurate reporting of the codes and charges for implanted devices is critical to ensure the relative weights for the services are accurate. This will ensure proper payments to hospitals for the procedures that use implanted devices.

Pub. 100-04 Medicare Claims Processing Centers for Medicare & Medicaid Services (CMS) Transmittal 132 Date: March 30, 2004

This means for Medicare claims, device charges on the UB-04 listed under Column 47 - Total Charges that are on the same line as a C-Code and an acceptable revenue code are billed correctly, accurately capturing the charges for use in future payment rate calculations.

The most appropriate revenue code for HGNS is 0278, Medical/Surgical Supplies: Other Implants. This revenue code was developed to separate high-cost implants from low-cost supplies, which improves charge consistency when creating revenue-code-specific cost-to-charge ratios. Charges for the procedure to implant the device are shown in revenue code 0360, Operating Room Services. An example of an outpatient UB-04 using this billing method for HGNS can be found on page 11.

Alternately, device charges listed in Column 47 on the same line of the UB-04 as CPT code 64582, using revenue code 0360, Operating Room Services, are also acceptable and support future payment-rate calculations. A review of EOBs shows various private payers accepting each of these approaches. It is recommended that hospitals request any specific device-billing requirements when working with Inspire Medical Systems to obtain prior authorization from a private payer.

Billing that does *not* support appropriate cost capture and will lead to undervalued future payments include:

- Incorrectly listing the device on the UB-04 as a non-covered charge (Column 48)
- Using an undesignated revenue code
- Failing to markup the device in keeping with the hospital's applicable cost-to-charge ratio

The latter may occur with revenue code 0360, which can include service charges and a mix of low-cost and high-cost supplies.

### ASC Billing – Implant Procedure

For commercial claims requiring the addition of HCPCS level II codes, the most appropriate revenue code

for HGNS is 0278, Medical/Surgical Supplies: Other Implants. Charges for the procedure to implant the device are shown in revenue code 0490, Ambulatory Surgical Care. An example of an ASC claim using this billing method for HGNS can be found on page 12.

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0270	OTHER DEVICE/IMPLANT		C1767	01012025	1	\$XXXXX	xx	
0278	OTHER DEVICE/IMPLANT		C1778	01012025	2	\$XXXXX	xx	
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2025 Outpatient Facility - UB-04 Medicare Billing Example

\*BMI Diagnosis code is required on Medicare claims

Please ensure the Prior Authorization number is included on every claim submitted to commercial and Medicare Advantage insurance providers where prior authorization is required

### 2025 ASC CMS-1500 Medicare Billing Example

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\*BMI Diagnosis code is required on Medicare claims

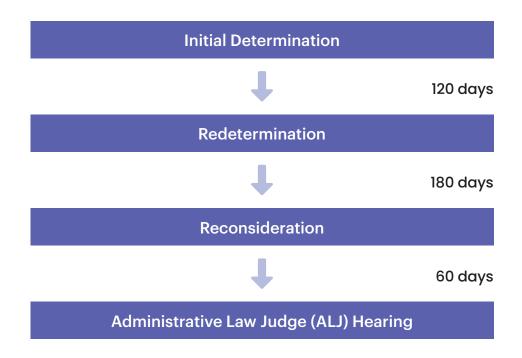
Please ensure the Prior Authorization number is included on every claim submitted to commercial and Medicare Advantage

### **Medicare Appeal Process**

Medicare Claims are typically processed within 30 days of submission.

- Medicare requires a signature on each appeal. Please sign the appeal letter and the redetermination form and send to the address provided with:
  - Copy of the denial
  - Patient pre-op notes: polysomnography (PSG), drug induced sleep endoscopy (DISE) and surgical consult
  - Copy of completed patient selection checklist
  - Op-notes
  - Your local MAC coverage policy (reach out to reimbursement@inspiresleep.com for a copy)

Please see an overview of the Medicare appeals process below.



For questions regarding reimbursement, please email reimbursement@inspiresleep.com.