Inspire Medical Systems

Physician Billing Guide

2019

inspire®

UPPER AIRWAY STIMULATION

Inspire Medical Systems Physician Billing Guide

This Physician Billing Guide was developed to help providers correctly bill for Inspire Upper Airway Stimulation (UAS) therapy. This Guide provides background information on payer coverage for implantable devices as well as proper coding and billing for Medicare and private payers. The contents are intended to augment the physician's current awareness of coding and coverage for implantable devices.

Inspire Medical Systems has made every effort to ensure that the information in this Guide is suitable, accurate, and appropriate to describe and code the services provided in the care and management of patients undergoing a UAS implant procedure for obstructive sleep apnea. The sample codes displayed should be used to facilitate appropriate coding and should not be construed as recommendations or guidelines in establishing policy, physician services or procedures, physician practice, or standards of care.

For questions regarding reimbursement, please call the Inspire Reimbursement Hotline at 1-833-897-0939 or email questions to reimbursement@inspiresleep.com.

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Device and Procedure Description

DEVICE

Inspire Upper Airway Stimulation (UAS) 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 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.

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 via incision into the plane between the external and internal intercostal muscles in the lower chest. It is tunneled subcutaneously and connected to the generator. The system is programmed and periodically interrogated and re-programmed to meet the patient's needs.

Coverage

FDA APPROVAL

Inspire UAS therapy received PMA approval from the FDA on April 30, 2014.

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

Although not required, Medicare may develop national or local coverage policies specific to the procedure or technology. These policies may extend coverage for the procedure or technology for certain diagnoses or in specific scenarios, or they may identify the procedure or technology as generally non-covered. At this time, there is no Medicare national coverage policy on the UAS device, however some Medicare Administrative Contractors (MACs) have released policies and guidelines for UAS on the local or regional level.

It is the responsibility of the provider to be aware of existing Medicare coverage policies before providing the service to Medicare beneficiaries.

When no policy exists, Medicare coverage determinations can be based on Medicare's "medically reasonable and necessary" requirement. MACs consider a service medically reasonable and necessary if it is:

- Safe and effective
- Not experimental or investigational
- Appropriate, including the duration and frequency that's considered appropriate for the item or service, in terms of whether it's:
  - Furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient's condition or to improve the function of a malformed body member;
  - Furnished in a setting appropriate to the patient's medical needs and condition;
  - Ordered and furnished by qualified personnel;
  - One that meets, but does not exceed, the patient's medical need; and
  - At least as beneficial as an existing and available medically appropriate alternative.

CMS Publication 100-08, Medicare Program Integrity Manual, Chapter 13 – Local Coverage Determinations, §13.5.1

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

Note: Medicare Advantage plans are managed by commercial payers. 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.

Unlike traditional Medicare, private payers often require prior authorization for an elective procedure such as UAS implantation. Before scheduling a patient's UAS procedure, the physician can contact Inspire Medical Systems' Prior Authorization program to determine the availability of coverage. Proceeding without a required prior authorization typically results in denial and non-payment.

REIMBURSEMENT DENIALS

Private payers sometime deny prior authorizations or a submitted claim. Medicare may also deny a submitted claim. See Appendix A for information on the Medicare appeal process. For private payer denials, physicians 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.

Coding

DIAGNOSIS CODES

Inspire Upper Airway Stimulation (UAS) 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 65).

Diagnosis coding for UAS implantation may involve the following code:

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

This code includes obstructive sleep apnea hypopnea.

Diagnosis coding for routine UAS interrogation and reprogramming may involve the following code:

ICD-10-CM Diagnosis Code	Code Description
Z45.42	Encounter for adjustment and management of neuropacemaker (brain) (peripheral nerve) (spinal cord)

Implant Procedure

The initial UAS implant procedure may involve the following codes:

CPT Procedure Code	Code Description	Component
64568	Incision for implantation of cranial nerve (eg, vagus nerve) neurostimulator electrode array and pulse generator	Generator and stimulation lead
+ 0466T	Insertion of chest wall respiratory sensor electrode or electrode array, including connection to a pulse generator (List separately in addition to code for primary procedure) (Use 0466T in conjunction with 64568)	Breathing sensor lead

Regular Category I CPT code 64568 is assigned for placement of the generator and the stimulation lead. Because UAS stimulates the hypoglossal nerve, the system qualifies as a cranial nerve neurostimulator.

[1] CPT Copyright 2017 American Medical Association. All rights reserved. CPT® is a registered trademark of the American Medical Association. Applicable FARS/DFARS Restrictions Apply to Government Use. Fee schedules, relative value units, conversion factors and/or related components are not assigned by the AMA, are not part of CPT, and the AMA is not recommending their use. The AMA does not directly or indirectly practice medicine or dispense medical services. The AMA assumes no liability for data contained or not contained herein.

The breathing sensor lead is a distinct component and is represented by Category III CPT code +0466T. As indicated by the + symbol, this is an add-on code and cannot be assigned by itself. Code +0466T for the breathing sensor lead must always be assigned together with code 64568 for the generator and stimulation lead.

Revision, Removal, and Replacement Procedures

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

CPT Procedure Code	Code Description	Component
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
64569	Revision or replacement of cranial nerve (eg, vagus nerve) neurostimulator electrode array, including connection to existing pulse generator	Stimulation lead
64570	Removal of cranial nerve neurostimulator electrode array and pulse generator	Generator and Stimulation lead
64585	Revision or removal of peripheral neurostimulator electrode array	Stimulation lead
0467T	Revision or replacement of chest wall respiratory sensor electrode or electrode array, including connection to existing pulse generator	Breathing sensor lead
0468T	Removal of chest wall respiratory sensor electrode or electrode array	Breathing sensor lead

Regular Category I CPT codes for cranial neurostimulators are used for revision, removal, and replacement procedures involving the generator and/or the stimulation lead. Category III codes are used for revision, replacement, and removal of only the breathing sensor lead.

Interrogation and Programming

The UAS device may also require interrogation and programming.

CPT Procedure Code	Code Description	Service
95970	Electronic analysis of implanted neurostimulator pulse generator/ transmitter (eg, 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; with brain, cranial nerve, spinal cord, peripheral nerve, or sacral nerve neurostimulator pulse generator/transmitter, without programming	Device interrogation *only*, without programming, subsequent visits only (not at the time of generator implantation)
95976	Electronic analysis of implanted neurostimulator pulse generator/ transmitter (eg, 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; with simple cranial nerve neurostimulator pulse generator/transmitter programming by physician or other qualified health care professional	Device interrogation and *simple* programming (not at the time of generator implantation)
95977	Electronic analysis of implanted neurostimulator pulse generator/ transmitter (eg, 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; with complex cranial nerve neurostimulator pulse generator/transmitter programming by physician or other qualified health care professional	Device interrogation and *complex* programming (not at the time of generator implantation)

Code 95970 is not assigned for device interrogation 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.

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

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

Billing Requirements

PHYSICIAN BILLING

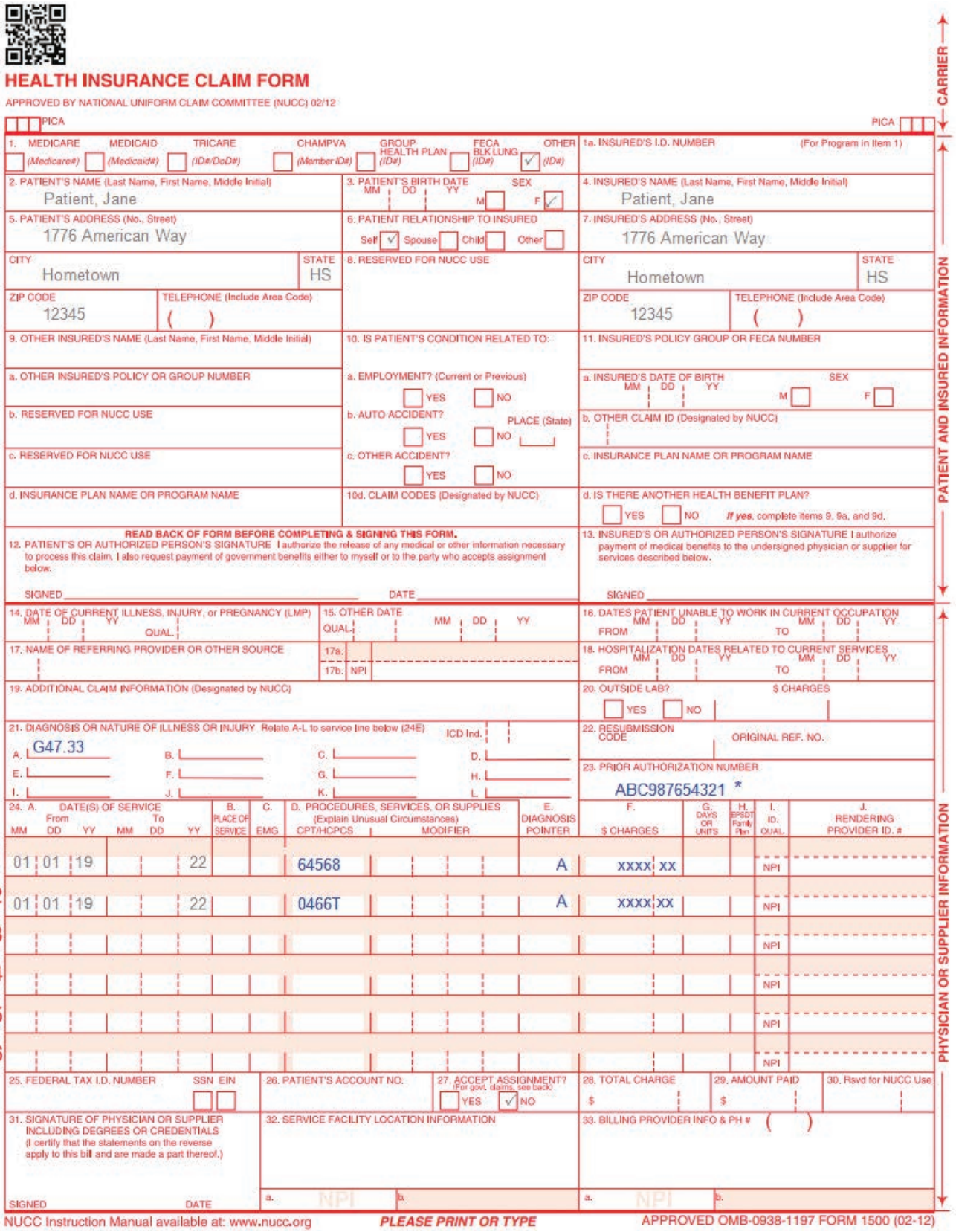
Medicare has specific instructions for submitting physician claims. Prior authorization is a good time to check for the payer's billing requirements specific to implantable devices.

Physician Billing on the CMS-1500

Claim Form Item	Values	Notes
Item 21A	Diagnosis (primary)	Display the primary ICD-10-CM diagnosis codes (see page 6).
Item 21 B-L	Diagnosis (other)	Display ICD-10-CM diagnosis codes for the patient's secondary diagnoses.
Item 23	Prior Authorization Number	Display the payer's prior authorization number if obtained.
Item 24D	Procedures, Services, or Supplies	Display the CPT code for each procedure or service rendered, with one CPT code in each line. Include modifiers as needed, eg, 51, Multiple procedures.
Item 24E	Diagnosis Pointer	Relate the services in 24 D to the diagnosis codes in 21 A-L

An example of physician billing for UAS implantation in the hospital outpatient setting can be found on page 9.

PHYSICIAN CMS-1500 BILLING EXAMPLE



HEALTH INSURANCE CLAIM FORM

APPROVED BY NATIONAL UNIFORM CLAIM COMMITTEE (NUCC) 02/12

PICA

1. MEDICARE (Medicare#) | MEDICAID (Medicaid#) | TRICARE (ID#/DoD#) | CHAMPVA (Member ID#) | GROUP HEALTH PLAN (ID#) | FECA BLK LUNG (ID#) | OTHER (ID#) ✓

1a. INSURED'S I.D. NUMBER (For Program in Item 1)

2. PATIENT'S NAME (Last Name, First Name, Middle Initial): Patient, Jane

3. PATIENT'S BIRTH DATE MM DD YY | SEX M ☐ F ✓

4. INSURED'S NAME (Last Name, First Name, Middle Initial): Patient, Jane

5. PATIENT'S ADDRESS (No., Street): 1776 American Way

6. PATIENT RELATIONSHIP TO INSURED: Self ✓ Spouse ☐ Child ☐ Other ☐

7. INSURED'S ADDRESS (No., Street): 1776 American Way

CITY: Hometown | STATE: HS

8. RESERVED FOR NUCC USE

CITY: Hometown | STATE: HS

ZIP CODE: 12345 | TELEPHONE (Include Area Code): ( )

ZIP CODE: 12345 | TELEPHONE (Include Area Code): ( )

9. OTHER INSURED'S NAME (Last Name, First Name, Middle Initial)

10. IS PATIENT'S CONDITION RELATED TO:

11. INSURED'S POLICY GROUP OR FECA NUMBER

a. OTHER INSURED'S POLICY OR GROUP NUMBER

a. EMPLOYMENT? (Current or Previous) YES ☐ NO ☐

a. INSURED'S DATE OF BIRTH MM DD YY | SEX M ☐ F ☐

b. RESERVED FOR NUCC USE

b. AUTO ACCIDENT? YES ☐ NO ☐ PLACE (State)

b. OTHER CLAIM ID (Designated by NUCC)

c. RESERVED FOR NUCC USE

c. OTHER ACCIDENT? YES ☐ NO ☐

c. INSURANCE PLAN NAME OR PROGRAM NAME

d. INSURANCE PLAN NAME OR PROGRAM NAME

10d. CLAIM CODES (Designated by NUCC)

d. IS THERE ANOTHER HEALTH BENEFIT PLAN? YES ☐ NO ☐ *If yes*, complete items 9, 9a, and 9d.

READ BACK OF FORM BEFORE COMPLETING & SIGNING THIS FORM.

12. PATIENT'S OR AUTHORIZED PERSON'S SIGNATURE I authorize the release of any medical or other information necessary to process this claim. I also request payment of government benefits either to myself or to the party who accepts assignment below.

SIGNED _____ DATE _____

13. INSURED'S OR AUTHORIZED PERSON'S SIGNATURE I authorize payment of medical benefits to the undersigned physician or supplier for services described below.

SIGNED _____

14. DATE OF CURRENT ILLNESS, INJURY, or PREGNANCY (LMP) MM DD YY QUAL.

15. OTHER DATE QUAL. MM DD YY

16. DATES PATIENT UNABLE TO WORK IN CURRENT OCCUPATION MM DD YY FROM TO MM DD YY

17. NAME OF REFERRING PROVIDER OR OTHER SOURCE

17a.

17b. NPI

18. HOSPITALIZATION DATES RELATED TO CURRENT SERVICES MM DD YY FROM TO MM DD YY

19. ADDITIONAL CLAIM INFORMATION (Designated by NUCC)

20. OUTSIDE LAB? YES ☐ NO ☐ $ CHARGES

21. DIAGNOSIS OR NATURE OF ILLNESS OR INJURY. Relate A-L to service line below (24E) ICD Ind.

A. G47.33 B. C. D.

E. F. G. H.

I. J. K. L.

22. RESUBMISSION CODE ORIGINAL REF. NO.

23. PRIOR AUTHORIZATION NUMBER: ABC987654321 *

24. A. DATE(S) OF SERVICE From MM	DD	YY	To MM	DD	YY	B. PLACE OF SERVICE	C. EMG	D. PROCEDURES, SERVICES, OR SUPPLIES (Explain Unusual Circumstances) CPT/HCPCS	MODIFIER	E. DIAGNOSIS POINTER	F. $ CHARGES	G. DAYS OR UNITS	H. EPSDT Family Plan	I. ID. QUAL.	J. RENDERING PROVIDER ID. #
1	01	01	19		22			64568		A	xxxx xx			NPI	
2	01	01	19		22			0466T		A	xxxx xx			NPI	
3														NPI	
4														NPI	
5														NPI	
6														NPI	

25. FEDERAL TAX I.D. NUMBER SSN EIN

26. PATIENT'S ACCOUNT NO.

27. ACCEPT ASSIGNMENT? (For govt. claims, see back) YES ☐ NO ✓

28. TOTAL CHARGE $

29. AMOUNT PAID $

30. Rsvd for NUCC Use

31. SIGNATURE OF PHYSICIAN OR SUPPLIER INCLUDING DEGREES OR CREDENTIALS (I certify that the statements on the reverse apply to this bill and are made a part thereof.)

SIGNED DATE

32. SERVICE FACILITY LOCATION INFORMATION

a. NPI b.

33. BILLING PROVIDER INFO & PH # ( )

a. NPI b.

NUCC Instruction Manual available at: www.nucc.org **PLEASE PRINT OR TYPE** APPROVED OMB-0938-1197 FORM 1500 (02-12)

CARRIER

PATIENT AND INSURED INFORMATION

PHYSICIAN OR SUPPLIER INFORMATION

Please ensure the Prior Authorization number is included on every claim submitted to commercial insurance providers.

Disclaimers

Inspire Medical Systems has authorized the completion of this Guide for the benefit of physicians implanting Inspire UAS therapy. Readers of this Guide are advised that the contents of this publication are to be used as guidelines and are not to be construed as policies of Inspire Medical Systems.

Inspire Medical Systems specifically disclaims liability or responsibility for the results or consequences of any actions taken in reliance on the statements, opinions, or suggestions in this Guide.

Inspire Medical Systems makes no representations or warranties with respect to the contents of the Guide and disclaims any implied guarantee or warranty of fitness for any particular purpose. Inspire Medical Systems will not be liable to any individual or entity for any losses or damages that may be occasioned by the use of this Guide.

Appendix A: Medicare Appeal Process

Medicare Claims are typically processed within 30 days of submission

- If denied – The physician must file a request for redetermination within 120 days from the date of receipt of the Remittance Advice.
- To receive a Physician Appeals Packet and/or with any questions you may have, please contact the Inspire Reimbursement Hotline at 866-897-0939 or reimbursement@inspiresleep.com.
- A templated Redetermination appeal is included in the packet for claims that have been denied due to the NCD for Vagus Nerve Stimulation (160.18). If the denial is for a different reason, please contact the Inspire Reimbursement Hotline at 866-897-0939 or reimbursement@inspiresleep.com.
- 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 EOB
  - Patient pre-op notes: polysomnography (PSG), drug induced sleep endoscopy (DISE) and surgical consult
  - Copy of completed patient selection checklist
  - Op-notes
  - Clinical articles and coding information included in the packet

MACs generally issue a decision within 60 days of receipt of the request for redetermination.

- If denied – The physician must file a request for reconsideration within 180 days of receipt of the decision.
- Again, a templated reconsideration appeal is included in the packet for claims that have been denied due to the NCD for Vagus Nerve Stimulation (160.18). If the denial is for a different reason, please contact the Inspire Reimbursement Hotline at 866-897-0939 or reimbursement@inspiresleep.com.

- Medicare requires a signature on each appeal – please sign the appeal letter and reconsideration form and send to the address provided with:
  - Copy of the EOB
  - Patient pre-op notes (PSG, DISE and surgical consult)
  - Copy of completed patient selection checklist
  - Op-notes
  - Clinical articles and coding information included in the packet
- Generally, a QIC sends a decision to all parties within 60 days of receipt of the request for reconsideration

Included in the packet is an appeal for programming claims. The appeal follows the implantation appeal process.

- Please complete the form and the appeal provided.
- Medicare requires a signature on each appeal – please sign the letter and the form and send with
  - Copy of the EOB
  - Patient pre-op notes (PSG, DISE and surgical consult)
  - Visit notes
  - Clinical articles and coding information included in the packet

For questions regarding reimbursement, please call the Inspire Reimbursement Hotline at 1-833-897-0939 or email questions to reimbursement@inspiresleep.com.