Inspire Medical Systems

PHYSICIAN BILLING GUIDE | 2024

Inspire®

Inspire Medical Systems Physician Billing Guide

This Physician Billing Guide was developed to help providers correctly bill for Inspire Hypoglossal Nerve Stimulation (HGNS) 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 HGNS implant procedure for obstructive sleep apnea (OSA). 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 email reimbursement@inspiresleep.com.

Inspire Medical Systems Physician Billing Guide

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 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 palatial 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. 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.

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.

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 therapy. These policies extend coverage for the procedure or technology for certain diagnoses or in specific scenarios.

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

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 physician can contact Inspire Medical Systems' Prior Authorization support team for assistance with prior authorizations. Proceeding without a required prior authorization may result in 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. 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.

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 DISE if performed:

CPT®[1] Procedure Code	Code Description	RVU	
		Work RVU	Facility RVU
42975	Drug-induced sleep endoscopy, with dynamic evaluation of velum, pharynx, tongue base, and larynx for evaluation of sleep disordered breathing, flexible, diagnostic	1.58	2.91

(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)

2024 RVUs as published in 2024 Physician Fee Schedule Final Rule
Note: Facility RVU values reflect physician time and work for services performed in a facility (i.e. hospital or ASC) setting.

Implant Coding

Implant 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 for 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/m2 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 the 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

Implant Procedure Codes

The initial HGNS implant procedure may involve the following codes:

CPT® Procedure Code	Code Description	RVU		Components
		Work RVU	Facility RVU	
64582	Open implantation of hypoglossal nerve neurostimulator array, pulse generator, and distal respiratory sensor electrode or electrode array	14	25.13	Generator, Stimulation Lead, Breathing Sensor Lead

Revision, Removal and Replacement Procedure Coding

In addition to implantation, the HGNS 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	RVU		Components
		Work RVU	Facility RVU	
61886	Insertion or replacement of cranial neurostimulator pulse generator or receiver, direct or inductive coupling; with connection to 2 or more electrode arrays	9.93	27.03	Generator
61888	Revision or removal of cranial neurostimulator pulse generator or receiver	5.23	12.17	Generator
64583*	Revision or replacement of hypoglossal nerve neurostimulator array and distal respiratory sensor electrode or electrode array, including connection to an existing generator	14.50	25.94	Stimulation Lead and Breathing Sensor Lead
64584**	Removal of hypoglossal nerve neurostimulator array, pulse generator, and distal respiratory sensor electrode or electrode array	12.00	21.89	Generator, Stimulation Lead, and Breathing Sensor Lead

*If only one lead is being revised or replaced, it is recommended to append modifier 52 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 52 to 64584

Analysis and Programming Coding

Analysis and Programming Diagnosis Coding

Diagnosis coding for routine HGNS analysis and programming may involve the following codes:

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. The appropriate polysomnogram (PSG) code to be used in conjunction with device programming is:

CPT® Procedure Code	Code Description	RVU			Service
		Work RVUs	Fac	Non-Fac	
95810	Polysomnography; age 6 years or older, sleep staging with 4 or more additional parameters of sleep, attended by a technologist	2.50	3.47*	18.72	Polysomnogram performed during programming

*Modifer 26: RVU's for Professional Component of PSG only

Analysis and Programming Procedure Coding

CPT® Procedure Code	Code Description	RVU			Service
		Work	Fac	NF	
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	.35	.54	.56	Device analysis *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	.73	1.15	1.17	Device analysis 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	.97	1.53	1.56	Device analysis and *complex* programming (not at the time of generator implantation)

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.

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.

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

Billing Requirements

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 (BMI/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

DISE CMS-1500 2024 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 MM DD YY TO

17. NAME OF REFERRING PROVIDER OR OTHER SOURCE

17a.

17b. NPI

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

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	24			22		42975		A	xxxx	xx		NPI	
2														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)

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PATIENT AND INSURED INFORMATION

PHYSICIAN OR SUPPLIER INFORMATION

Implant CMS-1500 2024 Billing Example

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

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CITY: Hometown STATE: HS

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CITY: Hometown STATE: HS

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 _____

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SIGNED _____

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15. OTHER DATE QUAL. MM DD YY

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

17. NAME OF REFERRING PROVIDER OR OTHER SOURCE

17a.

17b. NPI

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

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. Z68.XX* 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	24			22		64582		AB	xxxx xx			NPI	
2														NPI	
3														NPI	
4														NPI	
5														NPI	
6														NPI	

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PATIENT AND INSURED INFORMATION

PHYSICIAN OR SUPPLIER INFORMATION

**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

Disclaimers

Inspire Medical Systems has authorized the completion of this Guide for the benefit of physicians implanting Inspire HGNS 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.

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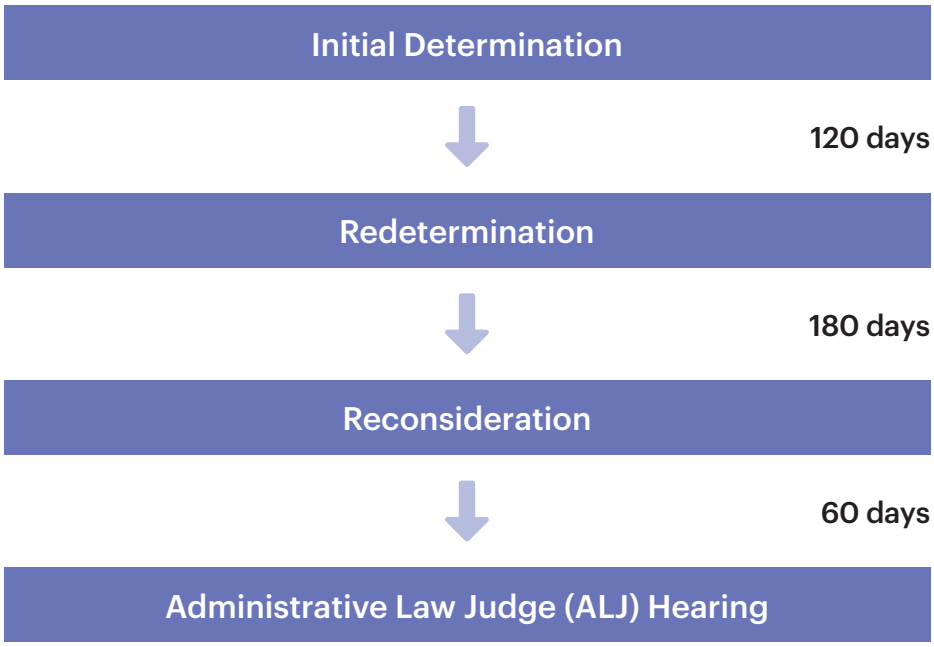
Appendix A: Medicare Appeal Process

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.