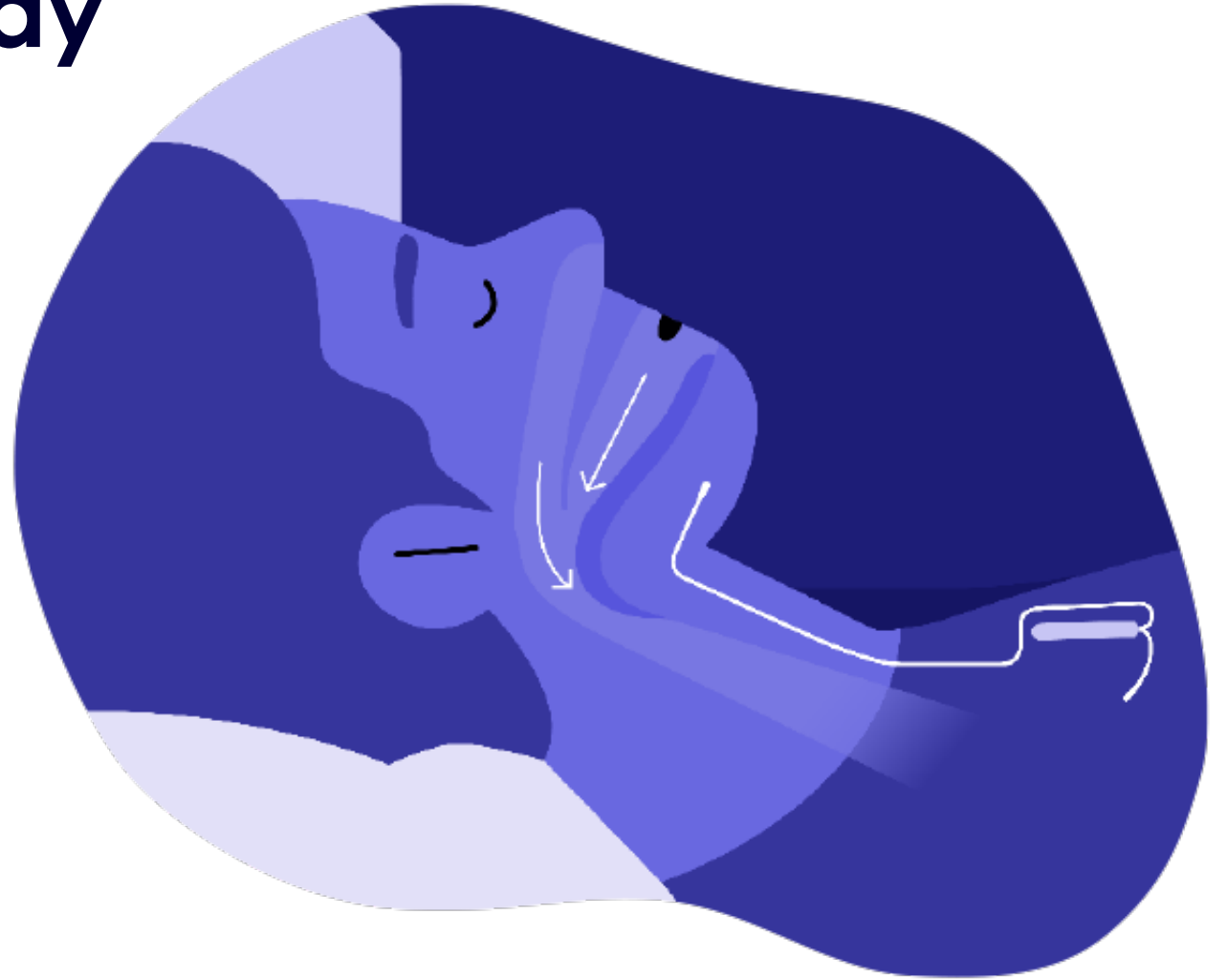


Inspire® Upper Airway Stimulation Therapy Documentation & Policy Overview



801-094-001, Rev. A

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 **Inspire**
Sleep Apnea Innovation

General Criteria

- Patient Age
- BMI
- CPAP Failure or Intolerance
- Overall Apnea Hypopnea Index (AHI)
- Central and Mixed Apneas
- Qualifying DISE report
- Qualifying Sleep Study



Patient Review Form

Patient Age >

Overall Apnea Hypopnea Index (AHI) >

Central and Mixed Apneas >

BMI >

CPAP Failure or Intolerance >

Qualifying DISE report >

Patient Name/ID: _____

Coverage Criteria	Important Notes	Patient Detail
Age: Patient is 18 or older	FDA guidelines requires that patients be at least 18 years old for the Inspire procedure.	DOB:
Overall AHI is between 15 and 65	Confirm study is fully diagnostic or an in-lab split night. Respiratory Event Index (REI) is often used as a surrogate for AHI. For purposes of a home sleep test, REI=AHI.	AHI:
Central and mixed apneas are < 25% of total	Some PSGs/HSTs do not break down central/mixed apneas. Confirm that sleep study includes central and mixed apneas or an index of central and mixed apneas. Calculation of central or mixed percentage: (central + mixed) / (Total AHI) x 100 = CM% Total AHI = all apneas, hypopneas and unclassified (all scored events)	CM%:
Documented Body Mass Index (BMI)	Most commercial plans require patient's BMI < 32. It is recommended that patient's BMI < 35.	BMI: BMI Date:
CPAP Failure of Intolerance	CPAP failure is defined as AHI > 15 despite CPAP usage. CPAP intolerance is defined as less than 4 hours per night, 5 nights per week or the CPAP is returned.* Look for specific reasoning for intolerance (e.g. claustrophobia, mask leaks, facial rash, etc.) Did patient try multiple masks, different mask pressures, etc.?	CPAP Failure:
DISE: Absence of complete concentric collapse (CCC)	AP collapse or absence of CCC at velum, velopharynx, nasopharynx, soft palate, or genu. Complete lateral collapse or complete concentric collapse are not okay.	DISE:

Documentation Required for Prior Authorization



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Consult Note



< Required:

- ✓ Documented BMI
- ✓ CPAP failure or intolerance
 - Reasons for failure/intolerance
 - Efforts made (e.g., multiple masks and pressure settings)

< Recommended:

- ✓ Oral appliance tried or considered
- ✓ OSA symptoms, previous surgeries, other therapies tried and failed

CPAP Failure Versus Intolerance



- ◀ **CPAP failure:**
 - ✓ AHI greater than 15 despite CPAP usage

- ◀ **CPAP intolerance:**
 - ✓ CPAP usage less than 4 hours per night, 5 nights per week or the CPAP has been returned
 - CPAP compliance report is best practice

Commercial definitions vary plan to plan

Drug-Induced Sleep Endoscopy (DISE)

At the level of the velum, there was partial anterior-to-posterior collapse and very minimal lateral collapse of the lateral walls of the oropharynx and nasopharyngeal region. There was no evidence of complete concentric collapse. Driving further at the level of the oropharynx, there was very minimal to no collapse at the level of the oropharynx and near-complete collapse at the level of the base to tongue in an anterior to posterior fashion. The epiglottis was notably normal in shape without any additional evidence of collapse. Examination to the level of the voice box was notable for no evidence of significant masses or lesions. At this point, the nasopharyngoscope was retrieved and the patient was turned back over to Anesthesia. Anesthesia provided...

< CCC:

- ✓ Patients must not have complete concentric collapse (CCC) at the level of the soft palate
 - Soft palate verbiage may be interchanged with velopharynx, velum, nasopharynx, or genu

Qualifying Sleep Study (HSAT or PSG)



- ◀ **A breakdown of the apneas is critical**
 - ✓ Breakdown = separate count of obstructive, central and mixed apneas
 - ✓ Calculate the central and mixed apnea percentage of total AHI
 - Must be less than 25%
- ◀ **Documented overall or total AHI**
 - ✓ Cannot use positional or sleep stage AHI's
 - ✓ Between 15 and 65
 - ✓ Variation in policies: 15-65, lower limit at 20, no upper limit

Some commercial policies require the study to be performed within 24 months of the initial Inspire consult date
- ◀ **For Medicare Advantage:**
 - ✓ Hypopneas must be scored at 4% desaturation
 - ✓ Must be performed within 24 months of the initial Inspire consult

Sleep Study: Summary Example

RESPIRATORY EVENT SUMMARY:

The patient had 211 apneas, there are
➤ 107 obstructive, 0 unclassified,
100 central, and 4 mixed apneas; and
19 hypopneas for a combined apnea-
hypopnea index (AHI) of 29.3 <
respiratory events per hour.

< AHI = 29.3

< Central/Mixed Apneas

- ✓ Total central + mixed apneas (*numerator*)
 - $100 + 4 = 104$
- ✓ Total apneas + hypopneas (*denominator*)
 - $107 + 0 + 100 + 4 + 19 = 230$
- ✓ $104 / 230 = 0.45 \times 100 = 45\%$
 - Patient DOES NOT meet criteria

Sleep Study: WatchPat

Sleep Summary	
Start Study Time:	11:09:35PM
End Study Time:	5:48:33AM
Total Study Time:	6 hrs, 38 min
Sleep Time	4 hrs, 50 min
% REM of Sleep Time:	14.4

Respiratory Indices				
	Total Events	REM	NREM	All Night
pRDI:	124	47.1	22.0	25.6
pAHI:	> 91	47.1	14.0	18.8
ODI:	56	35.7	7.5	11.6
pAHIc:	> 4	0.8	0.8	0.8
%CSR	0.0			

< AHI = 18.8

< Central/Mixed Apneas

- ✓ pAHIc = central and mixed breakout
 - $4 / 91 = .04 \times 100 = 4\%$
 - Patient meets criteria

Sleep Study: Graph Example

Respiratory Summary	Central Apneas	Obstructive Apneas	Mixed Apneas	Total Apneas	Hypopneas	Apneas + Hypopneas	RERA's	Total Events
Number of Events	> 16	> 66	> 0.00	> 82	> 18	> 100	0.00	100
Mean Dur (sec)	18.8	17.4	0.00	17.7	23.7	18.8	0.00	18.8
Max Dur (sec)	30	31.5	0.00	31.5	37.5	37.5	0.00	37.5
Total Dur (min)	5	19.1	0.00	24.2	7.1	31.3	0.00	31.3
% of TST	1.4	5.2	0.00	6.6	1.9	8.6	0.00	8.6
Index (#/h TST)	2.6	10.8	0.00	13.4	3.0	> 16.4	0.00	16.4

^ AHI = 16.4

^ Central/Mixed Apneas

- ✓ Total central + mixed apneas (numerator)
 - 16 + 0 = 16
- ✓ Total apneas + hypopneas (denominator)
 - 82 + 18 = 100

- ✓ $16 / 100 = 0.16 \times 100 = 16\%$
 - Patient meets criteria

Payer BMI and Sleep Study Info

BMI Outside of ≤ 32

- **BMI <35**
 - BCBS of TN
 - Caresource
 - Capital District Physician's Health Plan
 - Health New England
 - Husky Health
 - Independence BCBS
 - Medical Mutual
 - Priority Health
 - Presbyterian Health Plan
 - Scott and White Health Plan
 - UPMC
- **BMI ≤ 34**
 - Wellmark BCBS
- **BMI < 32**
 - Aetna

24 Month to Consult Sleep Study

- All Medicare Advantage Plans
- Aetna
- BCBS of MI
- Centene Plans
- Capital BCBS
- Caresource
- Fidelis Care
- GEHA
- Harvard Pilgrim
- Health New England
- Health Partners
- Humana
- Husky Health
- Moda Health
- Pacific Source
- Presbyterian Health Plan
- Providence Health Plan
- Scott and White Health Plan
- Security Health Plan
- Tufts Health Plan
- UPMC
- Wellmark BCBS

AHI Payer Exceptions

AHI No Upper Limit

- BCBS of AZ
- BCBS of AL
- BCBS of AR
- BCBS of FL / Florida Blue
- BCBS of ID
- BCBS of IL
- BCBS of Kansas City
- BCBS of KS
- BCBS of LA
- BCBS of MA (AIM Does Not)
- BCBS of MI
- BCBS of MN
- BCBS of MS
- BCBS of NC
- BCBS of ND
- BCBS of NE
- BCBS of NM
- BCBS of OK
- BCBS of RI
- BCBS of SC
- BCBS of TN
- BCBS of TX
- Capital BCBS
- Carefirst BCBS
- Highmark BCBS
- Horizon BCBS
- Independence BCBS
- Lifewise Health Plan
- MVP
- Premera BCBS
- Regence BCBS
- Security Health Plan

AHI ≥ 20

- Ambetter
- AvMed
- BCBS of ND
- UHC
- BCBS of MS
- BCBS of NE
- BCBS of Western NY
- Buckeye Health Plan
- Capital BCBS
- CarePartners of CT
- Centene
- Cleveland Clinic Employee Health Plan
- Fidelis
- Highmark BCBS
- NYSHP Empire
- Oxford Freedom
- Oscar Health Plan
- Preferred One
- Premera BCBS
- UMR
- United Healthcare
- WEA Trust

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Questions?

Helpline: priorauthorizationsupport@inspiresleep.com

