FUTURE Local Coverage Article:
Response to Comments: Hypoglossal Nerve Stimulation for the Treatment of Obstructive Sleep Apnea (A57938)

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Please Note: Future Effective Date.

Contractor Information

CONTRACTOR NAME	CONTRACT TYPE	CONTRACT NUMBER	JURISDICTION	STATE(S)
Noridian Healthcare Solutions, LLC	A and B MAC	01111 - MAC A	J - E	California – Entire State
Noridian Healthcare Solutions, LLC	A and B MAC	01112 - MAC B	J - E	California - Northern
Noridian Healthcare Solutions, LLC	A and B MAC	01182 - MAC B	J - E	California - Southern
Noridian Healthcare Solutions, LLC	A and B MAC	01211 - MAC A	J - E	American Samoa Guam Hawaii Northern Mariana Islands
Noridian Healthcare Solutions, LLC	A and B MAC	01212 - MAC B	J - E	American Samoa Guam Hawaii Northern Mariana Islands
Noridian Healthcare Solutions, LLC	A and B MAC	01311 - MAC A	J - E	Nevada
Noridian Healthcare Solutions, LLC	A and B MAC	01312 - MAC B	J - E	Nevada
Noridian Healthcare Solutions, LLC	A and B MAC	01911 - MAC A	J - E	American Samoa Guam Hawaii Northern Mariana Islands

Article Information

General Information

Future Effective

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Article Title
Response to Comments: Hypoglossal Nerve Stimulation for the Treatment of Obstructive Sleep Apnea

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Article Guidance

Article Text:

The evidence related to hypoglossal nerve stimulation (HNS) for treatment of obstructive sleep apnea was presented at the Contractor Advisory Committee (CAC) meetings in June 2019. The advice of the CAC members and Subject Matter Experts was considered in the development of the proposed policy. The following are the comment summaries and contractor responses for the Proposed Local Coverage Determination (LCD) DL38310 (Hypoglossal Nerve Stimulation for the Treatment of Obstructive Sleep Apnea) which was posted for comment and presented at the September 9, 2019, Open Public Meeting. All comments were reviewed and incorporated into the final LCD where applicable.

Response to Comments

Future Effective

Response to Comments

NUMBER	COMMENT	RESPONSE
1	Several commenters requested a removal or clarification of the Limitation statement "Active psychiatric illness" because it is a vague description with the potential of disqualifying patients who are actively under the care of a mental health professional, and have adequate control of their symptoms.	A more correct term might be a serious mental illness that reduces the ability to carry out activities of daily life and would interfere with the patient's ability to operate the HNS and report problems to the attending provider. This decision would be made by the treating physician(s). After further review, the language in the final policy will be clarified to state active psychiatric care that is poorly controlled.
2	A couple of commenters asked for clarification of the limitation regarding beneficiaries with implantable devices that could experience unintended interaction with the HNS implant system. Comments included a recent publication that suggested there are no adverse interactions with cardiac implantable devices, and no reports of adverse findings with concurrent use of both devices.	Thank you for the literature and your comments. The literature received revealed a small sample size. Noridian expects that additional literature regarding the safety and efficacy of this service will be forthcoming. Until additional literature is received no change will be made to the policy as the language is consistent with the STAR criteria and the FDA approval.
3	One commenter wants the term 'coexisting non-respiratory sleep disorder that would confound functional sleep assessment' to be clarified. Patients with narcolepsy and idiopathic hyper-somnolence may be refused treatment based on the wording of this	Thank you for the comment. This limitation allows for the provider performing and evaluating the sleep study to exercise judgement in making a final diagnostic decision whether the beneficiary qualifies for HNS. The language does not prevent

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	limitation.	a provider from performing a sleep assessment. This is intended to inform providers if a sleep assessment cannot be satisfactorily performed, it would be difficult to qualify for HNS.
4	Several comments were received regarding the training required for the Drug Induced Sleep Endoscopy (DISE), to determine the presence of complete concentric collapse (CCC). It was suggested the number of procedures (15) required for certification of a physician, be reduced and portions of the testing be incorporated into an online test environment with video clips. The commenters stated that certification is appropriate, however 15 seems excessive. A comment was included that proposed the first 10 video-documented DISE clips be presented to the second opinion expert reviewer for interpretation.	Thank you for the comment. No peer reviewed articles were submitted with this request. There was a consensus among the subject matter experts (SMEs) that the second party review is appropriate and the 15 procedures was a conservative but good number, allowing for greater success with implantation. Should data be forthcoming and demonstrates that similar results are being obtained on the first 5-10, it may be submitted through the reconsideration process.
5	Several comments were received that requested the language be clarified under Shared Decision Making (SDM). Several stated **i**t was not clear if the referring physician would need to document the implant is appropriate for the patient and similar documentation would be needed from the implanting provider. In addition, there were issues with questioning why one specialist would need referrals from other specialists regarding this procedure.	Thank you for your comments. Shared decision making (SDM), by definition, is between the provider and the patient and does not mean between the various providers. The language in the final policy will be clarified to indicate that SDM is between the attending providers and the patient, and not between multiple providers
6	Several commenters indicated the Provider Specialties section address the limitation of allowing only board certified Otolaryngologists for implantation. Comments also submitted pointed to the evaluation, referral, and post implant evaluation should be performed by board eligible or certified sleep physicians. They suggested that post implant should remain the responsibility of the implanting physician. In addition, a comment was submitted that noted in some geographical areas, Neurosurgeons who perform similar nerve stimulation surgeries, should be allowed to implant the device, and ENT Head and Neck surgeons are often implanter partners for Sleep physician referrers.	Thank you for the comments. The Subject Matter Experts (SME) that provided input for this service at the CAC Meeting agreed with the provider specialty limitation. They agreed that all providers performing this service and the follow-up care should meet specified educational requirements. In the original Star trial and follow-up through five years, all the implanting surgeons were ENT, and approved per the FDA criteria. There was no documentation submitted with the comment to support the commenters' recommendation for inclusion of additional specialty providers.
7	Comment were received that suggested that all patients considered for HNS be evaluated first by a Sleep Medicine Physician who is trained in HNS	There is no data to support this referral requirement for evaluation by a sleep medicine physician who is trained in HNS titration. In

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	titration. The reason was presented as most of the Limitations would be eliminated and would allow many patients to benefit from HNS.	addition, we are allowing what the STAR criteria allowed and limited for consideration. If data is available to support your position, please submit full articles following the reconsideration process.
8	One commenter submitted a CV for consideration to be permitted to perform HNS implant.	Noridian does not credential providers. All providers performing and reporting services to Noridian should ensure that they meet the requirements set forth in the LCD.
9	Several commenters suggested adding as a criteria point, the failure of Oral Advancement Therapy (OAT)/Mandibular Advancement Devices (MAD) in addition to the failure of CPAP. The advantage was presented as another non-surgical approach and healthcare cost savings.	Thank you for the comment. No change to the policy is warranted at this time as no data was submitted to support this change.
10	One comment received requested that current physicians who were certified on DISE and completed implant training by the FDA approved manufacturer prior to the date of this final LCD, be grandfathered as a certified implanter and have LCD language that addresses this population.	Noridian appreciates your comments and agrees. Providers that underwent FDA approved device manufacturer DISE training prior to the date of this LCD, shall be deemed to meet the criteria for satisfactory performance of DISE without further documentation. All such providers shall maintain certification of completion of this training, supply proof of training by manufacturer, and DISE results should be made available upon request.
11	A couple of commenters requested that CPAP refusal or non-acceptance should be included with CPAP failure or intolerance as criteria. The refusal/non-acceptance should be clearly documented along with conversations of the benefits of CPAP and the limitations of HNS.	Thank you for your comments. Failure of conservative therapy should be tried and failed and or not tolerated prior to a surgical approach. No change at this time.
12	One commenter requested the Limitation of tonsil size be removed stating there is no evidence for this restriction.	Thank you for your comment. Pronounced anatomical abnormalities were used as exclusion criteria on the STAR trial. Tonsil size of 3 or 4 (tonsils visible beyond the pillars or extending midline) was presented as such an example. No peer review data was submitted to validate this claim and was not recommended by any of our Subject Matter Experts (SMEs) during our evidentiary CAC. The reconsideration process is always open for appropriate data to be presented after the LCD is finalized

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13	Several providers commented on vague language regarding Limitations. Several examples included the following: neuromuscular disease, uncontrolled HTN, pregnancy planning. It was suggested that additional clarifications are warranted**.**	The items in the Limitations are those found in the STAR criteria and serve as a reference for criteria of those patients that have been studied for HNS implantation. Evidence to support a change in the limitations was not submitted with the comments. The reconsideration process is available once the policy becomes effective with the submission of full-text peer reviewed articles.
14	One commenter corrected the anatomy of the hypoglossal nerve.	Thank you for your comment. The description of the hypoglossal nerve will be corrected in the final policy.
15	One commenter raised the issue that the LCD requires utilizing only an accredited sleep study facility and noted that home studies are allowed with documentation of medical necessity for home study (refer to L36861).	Thank you for your comment. Please refer to LCD L36861 which allows for home sleep studies if patients meet the criteria. No change to be made at this time.
16	A couple of providers commented on an "obstructive" apnea that is due to high loop gain or ventilator control instability. It was indicated these patients cannot tolerate CPAP, and HNS would not work well with this sleep apnea type, and should be excluded. Additionally, one of the providers indicated patients with diagnosis of atrial fibrillation and heart failure should also be excluded.	Thank you for the comments. No change is being made to the policy at this time. There was no peer reviewed data submitted with the comment. Full text articles may be submitted for reconsideration once the policy is effective following the reconsideration process outlined on our website.
17	One commenter suggested that the LCD was requiring a formal referral from a sleep medicine physician to an Otolaryngologist for implanting of HNS. In addition, it was pointed out that it did not seem necessary for the implanting physician to document the additional conversations with multiple providers regarding the surgery.	Thank you for your comments. The LCD is requiring SDM between the patient and the treating physician (specifically the implanting provider); this does not refer to provider and provider consultations. Both physicians are required to have conversations regarding risks and benefits with the patient (SDM). See Comment/Response #5.
18	Another commenter asked that cadaver courses be eliminated from the training requirement for implantation.	Thank you for your comment. The manufacturer requires cadaver training before granting certification of the implantation of the FDA approved device. Therefore, no change is being made to the policy at this time.
19	One commenter stated endoscopy studies, during sleep and wake, is a standard of otolaryngologist	Thank you for the comment. There is evidence to support the training and there was no additional

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	training and should not require further certification by a third party including an FDA approved manufacturer.	evidence presented to the contrary. There is no evidence that DISE training is part of a general training program for Otolaryngologists. SME's, including otolaryngologists, agreed with the Company approved training.
20	A commenter addressed the fact that attending physicians are not able to be board certified until they are in practice for a year. This would restrict access to trained implanting otolaryngologists. Fellowship is not required to perform HNS.	Thank you for the comment and Board eligible otolaryngologists has been added to the final LCD.

Associated Documents

Related Local Coverage Document(s)

LCD(s)

DL36861 - Hypoglossal Nerve Stimulation for the Treatment of Obstructive Sleep Apnea

L36861 - Hypoglossal Nerve Stimulation for the Treatment of Obstructive Sleep Apnea

Related National Coverage Document(s)

N/A

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