Noncovered Services (L33777): Medicare Part A/B local coverage determination (LCD) comment summary

LCD Number
L33777

Contractor Name
First Coast Service Options, Inc.

Contractor Numbers
09101 – Florida
09201 – Puerto Rico/Virgin Islands
09102 – Florida
09202 – Puerto Rico
09302 – Virgin Islands

Contractor Type
MAC Part A/B

LCD Title
Noncovered Services

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Start Date of Comment Period:
January 19, 2017

End Date of Comment Period:
March 9, 2017

Comments received:
For comment #’s 1 through 6, the JN MAC contractor acknowledges that a number of comments on behalf of providers, the Florida Society of Sleep Medicine and European societies, were received in support of the coverage of CPT® code 64568 and Category III CPT® codes +0466T, 0467T and 0468T for hypoglossal nerve stimulation for obstructive sleep apnea (OSA).

For comment #’s 9 through 14, the JN MAC contractor acknowledges that a number of comments on behalf of providers and the Florida Society of Ophthalmology were received in support of the coverage of Category III CPT® codes 0449T and +0450T (Insertion of aqueous drainage device, without extraocular reservoir, internal approach, into the subconjunctival space; initial device and each additional device) for patients with Primary Open Angle Glaucoma (POAG).

Comment #1: The Florida Society of Sleep Medicine urges First Coast Service Option’s Inc. (First Coast) to recognize the important role that hypoglossal nerve stimulation (HNS) plays in the treatment of well-selected OSA patients. It is in the best interest of our patients that First Coast cover HNS therapy for the approved patient selection criteria. We request coverage for this therapy, only for the approved patient selection criteria which includes patients who fail or are otherwise intolerant to continuous positive airway pressure (CPAP) therapy and are properly screened using drug-induced sleep endoscopy to ensure they are appropriately suited for this technology.

Contractor response: CPT® codes 0466T, 0467T, 0468T and 64568 are not reasonable and necessary under §1862(a) (1) (A) of the Social Security Act for patients with an obstructive sleep apnea (OSA) diagnosis. Upon review of the published peer reviewed literature, only one small trial with intermediate term results was published in the United States. The trial had 126 participants initially, with 95 of the participants completing the 48 month follow-up. The mean age of the participants at baseline was 54.5 years; the participants were 83% male and 97% Caucasian. The 12 month trial data released had 83 responders and 43 nonresponders following device implantation. Some of the nonresponders had increased apnea events following device implantation. The patient population in the trial is not reflective of a Medicare population. It is not unusual that there will be a paucity of information for an emerging technology or
service and the Medical Policy department may noncover a service awaiting information in the public domain on safety and efficacy based on the quality of evidence. Acceptance by individual health care providers, or even a limited group of health care providers, does not indicate general acceptance by the medical community.

**Comment #2:** Implantation of the hypoglossal nerve stimulator is not first line therapy. However, in selected continuous positive airway pressure (CPAP) intolerant OSA patients, hypoglossal nerve stimulation may be the only treatment that can effectively treat their sleep apnea. If guidelines restrict this therapy to patients who have been appropriately screened, I strongly believe the therapy is an important option for patients.

**Contractor response:** Please see response #1.

**Comment #3** The American Academy of Otolaryngology-Head and Neck Surgery considers upper airway stimulation (UAS) via the hypoglossal nerve for the treatment of adult obstructive sleep apnea syndrome to be an effective second-line treatment of moderate to severe obstructive sleep apnea in patients who are intolerant or unable to achieve benefit with positive pressure therapy (PAP). Not all adult patients are candidates for UAS therapy and appropriate polysomnographic, age, BMI and objective upper airway evaluation measures are required for proper patient selection.

**Contractor response:** Please see response #1.

**Comment #4:** The International Surgical Sleep Society supports Cranial nerve (hypoglossal nerve) stimulation as effective in the treatment of sleep disordered breathing/obstructive sleep apnea syndrome in adults (and/or children) when applied to selected patients based on their anatomy, physiology, body mass index and neck size, prior therapy and co-morbidities. The patient should have undergone an appropriate evaluation(s) prior to treatment which may include polysomnography, home sleep testing, awake or drug induced sleep endoscopy and possible cephalometric or other radiographic evaluations.

**Contractor response:** Please see response #1.

**Comment #5:** The German Association of Otorhinolaryngology, Head and Neck Surgery support (Inspire™ Upper Airway Stimulation) neurostimulation of the hypoglossal nerve for treatment in obstructive sleep apnea.

**Contractor response:** Please see response #1.

**Comment #6:** I consider Inspire’s hypoglossal nerve stimulator to be a very important procedure for a narrow but clearly identifiable profile of OSA patients, those with a BMI of 32 or less with moderate to severe OSA. This is an excellent therapy for well-selected patients who have failed CPAP.

**Contractor response:** Please see response #1.

**Comment #7:** The Vagal Nerve Stimulator (VNS) is a device currently used for epilepsy and the treatment of resistant depression. The Vagal Nerve Stimulator, for the epilepsy indication, is covered under National Coverage Determination (NCD) 160.18 and is currently billed with CPT® code 64568 to report the initial implantation of the VNS device. The proposed non-coverage of CPT® code 64568 for initial implantation of the Vagal Nerve Stimulator would cause disruption to the coverage for VNS for epilepsy treatment.

**Contractor response:** Regarding the CPT code 64568 [Incision for implantation of cranial nerve (e.g. vagus nerve) neurostimulator electrode array and pulse generator], services will be denied when this code is used to specify the implantation of the hypoglossal nerve stimulator. Effective for services performed on or after July 1, 1999. VNS is reasonable and necessary for patients with medically refractory partial onset seizures for whom surgery is not recommended or for whom surgery has failed. CPT® code 64568 for the initial implantation of the FDA approved vagal nerve stimulator (VNS) for treatment of refractory epilepsy would not be denied.

**Comment #8:** Since the Inspire system was approved (PMA) by the FDA in April of 2014, there has been quite a bit of confusion with hospitals and payers, including MACs, on the proper method to code this procedure. The correct CPT® code to use for this therapy is CPT® code 64568. The AMA issued three new CPT codes to address the implantation, revision/replacement, or removal of the Respiratory Sensing lead. As the implant can only be performed concurrent with the implant of the neurostimulator and electrodes, this Category III code (0449T) was approved as an add-on code secondary to CPT 64568. CPT® code 64568 is for the implantation of a cranial nerve neurostimulator and electrode array. The Inspire system also uses an implanted respiratory sensor to detect respiration, and is the basis for confusion. Inspire is requesting that the Category I CPT® code 64568 be removed from the draft LCD DL33377 Noncovered Services along with the three Category III CPT® codes +0467T, 0467T and 0468T.

**Contractor response:** Please see response #’s 1 and 7.

**Comment #9:** Request that First Coast revise its “PROPOSED/DRAFT Non-covered Services” LCD (DL33777) to delete CPT codes 0449T and +0450T from the LCD’s list of non-covered codes. Denying coverage of the XEN implant would be a disservice to Florida’s Medicare beneficiaries. This new device has the potential to replace trabeculectomies and glaucoma drainage implants (tube shunts) as the gold standard for management for refractory glaucoma due to its excellent outcomes and safety profile.

**Contractor response:** CPT® codes 0449T and 0450T are not reasonable and necessary under §1862(a) (1) (A) of the Social Security Act for patients with a glaucoma diagnosis. Upon review of the published peer reviewed literature, there is not enough data published in the public domain to justify the utility of Category III CPT® codes 0449T and 0450T (Insertion of aqueous drainage device, without extracocular reservoir, internal approach, into the subconjunctival space; initial device and each additional device). The literature reviewed is of low to moderate quality with small study populations and short term follow-up. It is not unusual that there will be a paucity of information for an emerging technology or service and the Medical Policy department may noncover a service awaiting information in
the public domain on safety and efficacy based on the quality of evidence. Acceptance by individual health care providers, or even a limited group of health care providers, does not indicate general acceptance by the medical community.

Comment #10: The purpose of this letter is to request the approval of the codes that allow us to perform ab-interno implants for the treatment of refractory glaucoma. In the last few years, multiple procedures have been approved. These procedures, although good, are not adequate for more advanced and complicated cases. For this refractory glaucoma, we only have more aggressive approaches at our disposal. With the approval by the FDA of a new device, XEN described per CPT® Category III code 0449T (Insertion of aqueous drainage device, without extraocular reservoir, internal approach, into the subconjunctival space; initial device), Ophthalmologists specializing in glaucoma treatment can move on to the next level of care, the MIGS (Minimally Invasive Glaucoma Surgeries), for the advanced disease. Having had experience over the last 10 years with trabeculectomies, glaucoma drainage devices and their successes and failures, to offer similar results with a significant lower complication rate is invaluable. Performing this implant with the outcomes and the safety profile it has shown, would allow safer glaucoma surgery with a more predictable outcome.

Contractor response: Please see response #9.

Comment #11: The MIGS categories of devices, and the XEN device, do fill an unmet need in surgical ophthalmology, specifically with patients who have primary open angle glaucoma that is refractory to maximal medical therapy. Non-coverage would be a great dis-service to our patients, particularly those that have failed prior therapeutic options and continue to have refractory glaucoma. It is important that these patients have access to these micro invasive devices. Request that First Coast evaluate the category MIGS devices when implanted for the treatment of refractory glaucoma and that First Coast consider covering these devices, including the XEN device, for the treatment of these patients, and request deletion in the "PROPOSED/DRAFT Non-covered Services" LCD (DL33777) of CPT codes 0449T and +0450T from the list of non-covered codes.

Contractor response: Please see response #9.

Comment #12: The procedure, described by CPT ®Category III codes 0499T and +0450T (insertion of aqueous drainage device, without extraocular reservoir, internal approach, into the subconjunctival space; initial device and each additional device) is an important innovation in the treatment of glaucoma as it is dramatically less invasive and complex than the current alternative for penetrating glaucoma filtration procedures; trabeculectomy and glaucoma shunt implant surgery. By withholding the new XEN procedure, the senior citizen population of Florida is being denied a significant advancement in surgical glaucoma therapy. This is a disservice and should be rectified immediately.

Contractor response: Please see response #9.

Comment #13: The "gold-standard" treatment for glaucoma is the trabeculectomy. Although there have been advances, with the use of antimetabolites during surgery and slight modification to the technique, trabeculectomy has essentially remained unchanged for fifty years. The procedure described by CPT ®Category III codes 0499T and 0450T (insertion of aqueous drainage device, without extraocular reservoir, internal approach, into the subconjunctival space; initial device and each additional device) represents one of the most significant advances and is a novel approach to a common disease that is only increasing in prevalence as our population ages and lives longer. This procedure carries much less risk with potentially comparable results. XEN, aqueous drainage device, is an appropriate tool in our armamentarium of surgical approaches to glaucoma and request that you determine that the above-mentioned codes are covered services.

Contractor response: Please see response #9.

Comment #14: The Florida Society of Ophthalmology request that you remove CPT ®Category III codes 0449T and +0450T from the draft local coverage determination (LCD) DL33777 Noncovered Services. Unlike some other minimally invasive glaucoma implants, this device the XEN described by CPT ®Category III codes 0449T and 0450T may be used independent of cataract removal.

Contractor response: Please see response #9.