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August 31, 2015

Andy Slavitt
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1633-P
7500 Security Boulevard
Baltimore, MD 21244-1850

**Re: CMS- 1633-P: Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs, Short Inpatient Hospital Stays; Transition for Certain Medicare-Dependent, Small Rural Hospitals under the Hospital Inpatient Prospective Payment System**

Dear Acting Administrator Slavitt:

The American Academy of Audiology (the "Academy") is the world's largest professional organization of, by, and for audiologists, representing over 12,000 members. The Academy promotes quality hearing and balance care by advancing the profession of audiology through leadership, advocacy, education, public awareness, and support of research. The Academy appreciates the opportunity to offer comments in response to the Centers for Medicare and Medicaid Services (CMS) proposed updates to the Hospital Outpatient Prospective Payment System (HOPPS) for CY 2016, as published in the *Federal Register* on July 8, 2015. The Academy's comments are provided below.

**I. Proposed Reclassification of CPT codes 92601-92604 to Status Indicator "S"**

The Academy recognizes CMS' efforts to review, revise, and reorganize Ambulatory Payment Classifications (APCs) across the HOPPS in order to collectively group services that are clinically similar with similar resource costs. To support CMS in its efforts, the Academy proposes a more appropriate APC classification for CPT codes 92601-92604 to improve clinical homogeneity and to foster greater efficiency across the HOPPS APC structure. The Academy recommends that the status indicator for CPT codes 92601-92604 be changed from "Q1" to "S", and that these codes be included in APC 5722: Level 2 Diagnostic and Related Services to ensure clinical consistency; or APC 5721: Level 1 Diagnostic and Other Related Services to reflect cost consistency.

*Background*

CPT codes 92601-92604 describe post-operative services to determine the status of a cochlear implant system and to adjust electrical nerve stimulation parameters to provide hearing to severe-to profoundly deafened patients. These codes and their descriptors are listed below:

92601 Diagnostic analysis of cochlear implant, patient younger than 7 years of age; with programming
92602 Diagnostic analysis of cochlear implant, patient younger than 7 years of age; subsequent reprogramming
92603 Diagnostic analysis of cochlear implant, age 7 years or older; with programming
92604 Diagnostic analysis of cochlear implant, age 7 years or older; subsequent reprogramming

Prior to CY 2015, CPT codes 92601-92604 were assigned the status indicator "X." The "X" status indicator meant that these codes were categorized as ancillary services, paid under the OPPS with a separate APC payment. CMS viewed these services as major procedures and their payment structure reflected this classification. In the CY 2014 final rule, CMS changed the status indicator for these codes from "X" to "Q1" and deferred implementation until CY 2015. The 2016 OPPS proposed rule maintains the "Q1" status indicator for these codes.

Codes with a status indicator of "Q1" are packaged with codes that have a status indicator of S, T, or V. This means that if a cochlear implant procedure code is billed on the same date of service as an STV-packaged code the cochlear implant procedure code will not be reimbursed through a separate payment. This "Q1" designation is intended to facilitate the bundling of related services billed on the same day; however, further analysis shows that the majority of the services being performed on the same date as the cochlear implant procedures are unrelated to the cochlear implantation process.

*Analysis of OPPS Cost Files Data*

The Academy reviewed the OPPS claims data for 2014 and applied the 2016 OPPS conditional packaging payment rules to identify claims where another procedure was paid in lieu of CPT codes 92603 and 92604. CPT codes 92601 and 92602 did not have enough claims to analyze, as those codes are used for the patients under 7 years of age. The objective of this analysis was to determine how many of the procedures paid in lieu of 92603-92604 were related to the cochlear implant services.

In analyzing the data for CPT code 92603, the initial diagnostic analysis, the Academy found that 79 percent of the procedures that would be paid in lieu of 92603 were clinically unrelated to the cochlear implant service (see Table 1). For CPT code 92604, the subsequent programming of cochlear implants, 62 percent of the procedures to be paid in lieu of 92604 were clinically unrelated to the cochlear implant service (see Table 2). Overall, by applying the conditional packaging rule , we learned that 64 percent of the procedures that would be paid in lieu of CPT codes 92603 and 92604 were clinically unrelated to the these services.

**Table 1: 92603 (Diagnostic analysis of cochlear implant, age 7 years or older, with programming)**

Total billed: 1,114
Total paid (separately payable, no other services billed): 943

*Procedures that would have been paid in lieu of 92603 (applying 2016 rules):*

| Procedure Code | Description | Number billed | Related Service |
|---|---|---|---|
| G0463 | Hospital outpatient clinic visit for | 119 | No |

| | | | |
|---|---|---|---|
| | assessment/management of a patient | | |
| 92586 | Auditory evoked potentials, limited | 16 | Yes |
| 92626 | Evaluation of auditory rehabilitation status | 12 | Yes |
| 31579 | Diagnostic laryngoscopy | <10 (=4 estimated) | No |
| 70480 | CT, outer, middle, or inner ear | <10 (=4 estimated) | Yes |
| 71020 | Chest x-ray | <10 (=4 estimated) | No |
| 92585 | Auditory Brainstem Response, comprehensive | <10 (=4 estimated) | Yes |
| 95974 | Cranial neurostimulation, complex | <10 (=4 estimated) | No |
| 96372 | Therapeutic, prophylactic, or diagnostic injection | <10 (=4 estimated) | No |
| | | **Total: 135 (79%)** | **Unrelated** |
| | | **Total: 36 (21%)** | **Related** |

**Table 2: 92604 (Diagnostic analysis of cochlear implant, age 7 years or older, subsequent reprogramming)**

Total billed: 9,657
Total paid (separately payable, no other services billed): 8,646

*Procedures paid in lieu of 92604 (applying 2016 rules):*

| Procedure Code | Description | Number billed | Related Service |
|---|---|---|---|
| G0463 | Hospital outpatient clinic visit for assessment/management of a patient | 496 | No |
| 92626 | Evaluation of auditory rehabilitation status | 140 | Yes |
| 92552 | Pure tone audiometry, air only | 128 | Yes |
| 92550 | Tympanometry | 52 | Yes |
| 92586 | Auditory evoked potentials, limited | 33 | Yes |
| 92585 | Auditory evoked potentials, comprehensive | 26 | Yes |
| 95974 | Cranial neurostimulation, complex | 18 | No |
| 10021 | Fine Needle Aspiration | <10 (3 estimated) | No |
| 17000 | Destruction, premalignant lesion | <10 (3 estimated) | No |
| 20610 | Aspiration or injection of major joint or bursa | <10 (3 estimated) | No |
| 31231 | Nasal endoscopy | <10 (3 estimated) | No |
| 31575 | Laryngoscopy, flexible fiberoptic | <10 (3 estimated) | No |
| 31579 | Laryngoscopy with stroboscopy | <10 (3 estimated) | No |
| 51729 | Urodynamics, with voiding pressure study | <10 (3 estimated) | No |
| 51784 | Eletromyography of anal or urethral sphincter | <10 (3 estimated) | No |
| 64642 | Chemodenervation of one extremity | <10 (3 estimated) | No |
| 64646 | Chemodenervation of trunk muscle | <10 (3 estimated) | No |
| 67028 | Intravitereal injection of pharmacological agent | <10 (3 estimated) | No |
| 69220 | Debridement, mastoidectomy cavity | <10 (3 estimated) | No |

| | | | |
|---|---|---|---|
| 69511 | Radial mastoidectomy | <10 (3 estimated) | No |
| 69620 | Mryingoplasty | <10 (3 estimated) | No |
| 69930 | Implantation of cochlear device | <10 (3 estimated) | Yes |
| 70450 | Computed tomography, head or brain | <10 (3 estimated) | No |
| 70480 | Computed tomography, outer, middle, inner ear | <10 (3 estimated) | Yes |
| 70481 | CT, outer, middle, inner ear with contrast | <10 (3 estimated) | Yes |
| 70490 | CT, soft tissue neck | <10 (3 estimated) | No |
| 70491 | CT, soft tissue neck, with contrast | <10 (3 estimated) | No |
| 70553 | MRI, with contrast | <10 (3 estimated) | No |
| 71020 | Radiologic exam, sternum | <10 (3 estimated) | No |
| 71250 | CT, thorax | <10 (3 estimated) | No |
| 73702 | CT, lower extremity, with and without contrast | <10 (3 estimated) | No |
| 74176 | CT, abdomen and pelvis | <10 (3 estimated) | No |
| 74178 | CT, abdomen and pelvis with and without contrast | <10 (3 estimated) | No |
| 76705 | Ultrasound, abdominal, single organ | <10 (3 estimated) | No |
| 76830 | Ultrasound, transvaginal | <10 (3 estimated) | No |
| 76856 | Ultrasound, pelvic (nonobstetric) | <10 (3 estimated) | No |
| 76881 | Ultrasound, extremity | <10 (3 estimated) | No |
| 90837 | Psychotherapy, 60 minutes | <10 (3 estimated) | No |
| 94010 | Spirometry | <10 (3 estimated) | No |
| 94640 | Pressurized or nonpressurized inhalation treatment | <10 (3 estimated) | No |
| 95867 | Electromyography, cranial nerve | <10 (3 estimated) | No |
| 95909 | Motor and sensory nerve conduction, 5-6 studies | <10 (3 estimated) | No |
| 96413 | Chemotherapy administration, up to one hour | <10 (3 estimated) | No |
| 99285 | Emergency department visit | <10 (3 estimated) | No |
| G0008 | Administration of influenza virus | <10 (3 estimated) | No |
| G0009 | Administration of pneumococcal vaccine | <10 (3 estimated) | No |
| | | **Total: 623 (62%)** | **Unrelated** |
| | | **Total: 388 (38%)** | **Related** |

**Table 3: Summary of claims paid in lieu of CPT codes 92603-92604**

| | | |
|---|---|---|
| 1182 | Total in lieu | 100% |
| 758 | Unrelated | 64% |
| 424 | Related | 36% |
| 660 | Underpayment | 56% |

This analysis also shows that approximately 56 percent of the procedures paid in lieu of CPT codes 92603-92604 would provide a lower APC payment to the facility than if CPT codes 92603-92604 had been paid properly as a primarily procedure (see Table 3). This contradicts CMS' widely stated objective

to ensure that the higher/highest paying APC be paid when multiple services are provided. Also, packaging an unrelated procedure with a different procedure in a different APC is likely to impact rate-setting for the APCs of both the ancillary procedure and the procedure into which it is inappropriately packaged.

The NPRM CPT Cost Statistics data provides added support to the argument that cochlear implant services meet the criteria for the "S" status indicator. The vast majority of the time, the initial diagnostic session and the subsequent reprogramming sessions are performed independently of any other services. This has been consistent for several years, with over 92 percent of the sessions submitted as single procedure claims (see Table 4). This data demonstrates that the cochlear implant service is the major, primary service for the patient visit.

**Table 4: Cochlear Implant Service Frequency: 2014-2016 OPPS Rules**

| | 2014 Final Rule | | 2015 Final Rule | | 2016 Proposed Rule | | Total Claims Volumes | | |
|---|---|---|---|---|---|---|---|---|---|
| HCPCS | Single | Total | Single | Total | Single | Total | Single | Single % | Total |
| 92601 | 8 | 8 | 10 | 12 | 9 | 10 | 27 | 90.0% | 30 |
| 92602 | 23 | 23 | 17 | 20 | 27 | 29 | 67 | 93.1% | 72 |
| 92603 | 1,004 | 1,008 | 1,026 | 1,177 | 943 | 1,115 | 2973 | 90.1% | 3,300 |
| 92604 | 8,679 | 8,705 | 8,246 | 9,328 | 8,605 | 9,660 | 25,530 | 92.2% | 27,693 |
| | | | | | | **Overall:** | **28,597** | **92.0%** | **31,095** |

The data analysis strongly supports the Academy's position that CPT codes 92601-92604 should be reclassified as separately payable procedures and assigned the "S" status indicator. Because these services are most often billed independently of other services, the Academy believes that the application of status indicator "Q1" to CPT codes 92601-92604 inaccurately and inappropriately packages these procedures into other APCs. Precedent exists for this change. In the CY 2014 HOPPS final rule, CMS changed the status indicator for preventive services from "X" to "S" to ensure beneficiary access to those services.

The procedure, scheduling, resource use, and data reinforce that the cochlear implant initial diagnostic and subsequent reprogramming procedures are distinct, primary services performed independently of the implantation surgery, and are the first steps to the rehabilitation plan of care. These services use a combination of auditory electrophysiology measurements and behavioral data to program and refine the external components. This framework is comparable to other non-invasive electrophysiological diagnostic and treatment codes found in APC 5722: Level 2 Diagnostic and Related Services.

*Comparison of Similar Services within APC 5722*

To further support the reclassification of CPT codes 92601-92604 from a "Q1" to an "S" status indicator, the Academy compared these codes to other audiology codes that have been assigned status indicator "S." These include other audiology electrophysiology measures such as CPT codes 92584, electrocochleography, and 92585, auditory evoked potentials; comprehensive. Specifically, CPT codes 92584 and 92585 have been assigned to APC 5722 with the status indicator "S". Clinically, the

electrophysiological techniques used in the telemetry of the initial cochlear implant diagnostic include techniques also represented by codes within APC 5722, including neural response telemetry, auditory brainstem response, the electrically evoked compound action potential (similar to electrocochleography).

CPT codes 90867 and 90868 are two such codes that are clinically homogeneous to the cochlear implant procedure codes. Much like CPT codes 92601 and 92603, CPT code 90687 uses electroencephalography techniques and behavior observations to initiate treatment. CPT code 90867, therapeutic, repetitive Transcranial Magnetic Stimulation (TMS) treatment, involves the placement of a treatment coil on the patient's head and single pulse TMS is used to search for the target hand muscle to determine the motor threshold (MT) and treatment site. The provider engages in clinical monitoring to identify the treatment site. The treatment involves the provider advancing the treatment coil to the targeted treatment location and the prescribed treatment parameters are selected (frequency, intensity, number of stimuli, treatment train length, and inter-stimulus interval).

CPT code 90868, therapeutic TMS treatment; delivery and management, describes the subsequent delivery and management of the treatment and involves patient interaction regarding the procedure, and includes a brief focused interview and a discussion of any significant clinical changes that have occurred since prior treatments. This code follows a similar framework to that of CPT codes 92602 and 92604. Table 4 summarizes the list of codes that share similar clinical characteristics and geometric mean to CPT codes 92601 and 92603.

**Table 4: Similar Level 2 Diagnostic and Related Services with "S" indicator:**

| CPT | Short descriptor | Single frequency | Total frequency | Geometric mean |
|---|---|---|---|---|
| 92584 | Electrocochleography (1.96) | 637 | 793 | $138.82 |
| 92585 | Auditory evoked potentials, comprehensive | 2,569 | 2,713 | $238.80 |
| 95816 | EEG, including recording awake and drowsy (RVU-9) | 41,233 | 55,049 | $191.15 |
| 90867 | Transcranial magnetic stimulation, initial (3.52) | 72 | 72 | $200.33 |
| 90868 | Transcranial magnetic stimulation, subsequent | 2,228 | 2,239 | $216.65 |

*Comparison to Services within APC 5721*

A comparative clinical analysis of APC 5721: Level 1 Diagnostic and Other Related Services demonstrated that audiology codes represented in that APC were simpler in administration and significantly lower in time and resources. For example, the CPT codes 92544, optokinetic nystagmus test, and 92545, oscillating tracking test, are subparts of the basic vestibular evaluation that test for central balance issues. Each test requires the patient to attend to visual stimuli for up to 2 minutes in each direction. The tests confirm the presence of brainstem or cerebellar disorders, in conjunction with other studies.

Similarly, CPT code 95907, nerve condition study of 1-2 nerves, is comparable in the evaluation of 1 nerve under real-time evaluation, with stimuli adjustments. However, this code is significantly different in that one impulse generates one response as opposed to the multiple stimulation of the multiple electrode sites along the auditory nerve. The time spent in the test is considerably less as well, with

92507 taking an average of 15 minutes, as compared to the 50-80 minutes of service time with CPT codes 92603 and 92604.

Along with consideration of the homogeneity of the clinical characteristics of the procedures, a cost analysis of CPT codes 92601-92604 was performed. The geometric mean falls within the geometric means for both APC 5722: Level 2 Diagnostic and Other Related Services and APC 5721: Level 1 Diagnostic and Other Related Services. For APC 5721, the Academy found that while the codes were less complex and lacked the clinical similarities found in APC 5722, the cost structure was similar. Both APC 5722 and 5722 include codes with the status indicator "S", making these more appropriate APCs for these codes. The Academy recommends that CPT codes 92601-92604 be assigned the status indicator "S" and be included in either APC 5722 for clinical consistency, or APC 5721 for cost consistency.

*Patient Impact*

The Academy is concerned that maintaining the "Q1" designation for these codes may lead to system inefficiencies, contrary to the intent of the rule, as facilities would benefit from having the beneficiary return for audiology diagnostic tests on subsequent visits so that each individual service may be separately paid. For Medicare beneficiaries, scheduling appointments on multiple days can be extremely problematic, leading to missed appointments and insufficient follow-up care.

Further, cochlear implant centers provide invaluable services to patients, and with a limited number of centers, chronic under or nonpayment for critical services puts these centers at financial risk, thus potentially creating access issues for patients. Because the change from the separately payable "X" status indicator to the non-payable "Q1" status indicator was implemented in 2015, data is not yet available from hospital clinics to fully assess the impact of nonpayment or underpayment of cochlear implant services. The Academy anticipates the impact of such changes to include financial loss, decreased access for patients, and staff downsizing. The Academy understands that the intent of the HOPPS is to collectively group clinically similar services with similar resource use; however data shows that CPT codes 92601-92604 have not been appropriately classified with related services. By addressing this misclassification of CPT codes 92601-92604, CMS can avoid future problems related to the delivery of high quality, accessible health care for cochlear implant patients.

*Summary*

Cochlear implant procedure codes for initial diagnostic analysis (92601, 92603) and subsequent reprogramming (92602, 92604) meet the criteria for significant procedures and should be categorized as separately payable services. Evidence shows that their current designation of status indicator "Q1" has can led to underpayment or nonpayment of these services, even when the majority of the "STV" services were unrelated to the cochlear implantation process for the patient. This problematic classification appears to contradict CMS' desire to group clinically similar codes and more seriously, could adversely affect cochlear implant centers and jeopardize patient access to care.

## II. Proposed Reclassification of CPT code 92557 to Status Indicator "S"

The Academy also urges CMS to consider a re-designation of CPT code 92557 from the status indicator "Q1" to "S." CPT code 92557, comprehensive audiometric evaluation, is a bundled code that describes comprehensive audiometry threshold evaluation and speech recognition (CPT codes 92553 and 92566 combined). CPT code 92557 includes pure tone air and bone conduction audiometry, speech reception

thresholds, and word recognition- all core procedures performed by an audiologist when evaluating for a hearing loss. CPT code 92557, classified as ancillary by its status indicator, is in fact, a primary audiology service and essential to the diagnosis of a hearing loss. This is the primary service performed by an audiologist when providing a complete audiometric evaluation, and is not performed ancillary to any other services. As such, this service should be defined as a separately payable service with the status indicator "S."

The Academy believes that the status indicator of "Q1" inappropriately packages this vital audiology service, which can lead to system inefficiencies and inconsistency across the HOPPS APC structure. As cited with regard to the packaging of cochlear implant services, such inefficiencies can lead to unnecessarily scheduling patient appointments on different dates to ensure separate payment for individual services. Assigning CPT code 92557 the status indicator "S" will better support hospitals in their efforts to provide high quality, accessible, hearing health care for Medicare beneficiaries.

**III. Audiology Procedures: Diagnostic Tests and Related Services**

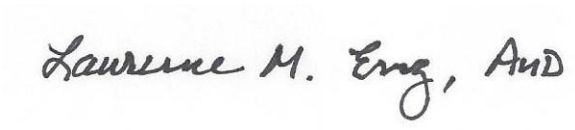
The Academy supports CMS' efforts to consolidate and streamline the number of APCs based on clinical and resource similarities, especially with regard to the formation of the new APCs for non-imaging Diagnostic Tests and Related Services. To ensure consistency in this initiative, the Academy recommends that the procedures in APC 5761: Level 1 Audiometry be consolidated into APC 5721: Level 1 Diagnostic Tests and Related Services, and APC 5722: Level 2 Diagnostic Tests and Related Services. APCs 5721 and 5722 include the CPT codes for vestibular and neurological audiology examinations that were previously assigned to APC 0363, and are utilized by audiologists in hospital clinics. Audiology procedures are clinically similar to many non-imaging diagnostic neurological, electrophysiological, and otorhinolaryngological tests. Like these services, audiology procedures utilize computerized equipment, electrodes, and supplies. They use subjective and objective measurements to assess hearing function. These procedures also require the cognition of a skilled professional to interpret the results of the assessment.

The Academy also recommends that the procedures in APC 5761: Level 1 Audiometry be consolidated into APC 5732: Level 2 Minor Procedures. Services in APC 5761 are rarely performed independently of a full comprehensive audiology examination. These services are diagnostic in nature, but share more clinical, resource use, and cost similarities with the services assigned to APC 5732. For example, CPT code 92567, tympanometry, found in APC 5761, uses the same equipment and supplies as CPT code 92568, acoustic reflex testing, threshold, assigned to APC 5732. Overall, the Academy supports the creation of APCs for non-imaging Diagnostic Tests and Related Services, and recommends that the audiology procedures referenced above be included within this classification.

* * * * *

The Academy appreciates the opportunity to comment on this proposed rule. Please contact Kate Thomas, director of payment policy and legislative affairs, by phone 703-226-1029 or via email at kthomas@audiology.org should you have any questions regarding the Academy's comment letter.

Sincerely,



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