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October 4, 2020

The Honorable Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1734-P
Via Online Submission

Re: File Code CMS-1734-P; CY 2021 Revisions to Payment Policies under the Physician Payment Schedule and Other Changes to Part B Payment Policies; (August 17, 2020)

Dear Administrator Verma,

The Academy of Doctors of Audiology (ADA) appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services (CMS) Notice of Proposed Rule Making (Proposed Rule) on the revisions to Medicare payment policies under the Physician Payment Schedule for calendar year (CY) 2021, published in the August 17, 2020 Federal Register (Vol. 85, No. 159 FR, pages 50074-50665).

The 2021 Medicare Physician Fee Schedule (MPFS) Proposed Rule is proposing a greater than 10% decrease in the 2021 conversion factor (from $36.09 in 2020 to $32.26 in 2021) as they attempt to increase the reimbursement for primary care and telehealth services. This reduction in the conversion factor will translate to an estimated 7% reduction in reimbursement for audiology and vestibular services. This is unsustainable and devastating to clinics as they attempt to grapple with reduced clinic capacities and the increased costs of personal protection equipment, both associated with combating COVID-19. While we appreciate that these reductions are due to your increased reimbursement for primary care services, we think that it is unfair to require other specialties to bear the financial brunt of these decisions rather than the federal government. The ADA respectfully requests that Congress suspend the budget neutrality requirement for the MPFS in order to fund this increased reimbursement for primary care services and maintain the current conversion factor and resulting allowable rate schedule for audiology services for 2021.

The Centers for Medicare and Medicaid Services (CMS) seeks comment regarding other benefit categories into which Communication Technology Base (CTB) services might fall. We believe that CTB codes fall within the scope of the audiology diagnostic benefit category and urge CMS to allow audiologists to bill and receive coverage from Medicare for these services. Audiologists provide audiologic testing under the Medicare diagnostic benefit category. They may provide virtual assessments as diagnostic services for patients when a physician or non-physician practitioner orders an assessment of hearing and/or balance that requires a battery of tests.

We appreciate that the statutorily established Medicare benefit classifies audiology services as diagnostic tests. However, ADA asserts that the examples outlined below describe services that appropriately involve the referring physician and stay within the Medicare diagnostic benefit, allowing Medicare beneficiaries timely access to care and avoiding potential overutilization of in-person visits. Should CMS determine that such services do not fall under the scope of the audiology diagnostic benefit category, ADA

respectfully requests the Agency provide details regarding its rationale, so that ADA will be able to better inform its audiology members regarding the true parameters of their benefit category.

Patient with a cochlear implant: A Medicare beneficiary recently received a cochlear implant (CI)—a surgically implanted device to help with severe to profound hearing loss. The physician refers the patient to an audiologist for CI analysis and programming (CPT codes 92601-92604). The audiologist programs and activates the external sound processor with the patient several weeks post-surgery, performing the diagnostic analysis. This initial programming typically occurs over a series of visits and is individualized to each patient, based on the results of the diagnostic analysis of auditory perception. Some patients may require additional programming in order to adjust the sound processor and to accommodate for improvements or declines in the patient's speech perception and environmental sound abilities and capacities.

The patient contacts the audiologist through the secure patient portal after the initial programming session to report that he/she is experiencing annoying or painful sounds or is not hearing well with the CI. After finishing clinical care for the day, the audiologist reviews the message received through the portal and responds with a series of questions to assess whether there is a malfunction with the CI equipment, a change in health status that may require medical attention, or a need for the audiologist to adjust the CI programming. The patient answers the initial questions and a few follow-up questions through the portal. Based on the patient's description of the problem and examples of specific situations in which discomfort arises or hearing is most challenging or what may precipitate these events, the audiologist determines that the hearing difficulties are likely due to equipment malfunction and recommends the patient contact the CI manufacturer's consumer line directly to troubleshoot the CI processor for possible repair or replacement.

The audiologist saves the clinical documentation of the assessment to the medical record and forwards a copy to the referring physician through the portal. This scenario illustrates a shorter interaction that could be reported with G2061/98970 (5-10 minutes cumulative).

However, if the initial exchange points to issues unrelated to equipment malfunction, the audiologist will proceed to ask additional questions to assess whether a potential change in health status has occurred or a need for further analysis and programming of the CI is medically necessary and warranted. This involves reviewing relevant medical history such as recent head trauma or injury to the surgical site of the implant, illness, hormonal changes, and/or medications. This can lead to a consult with the referring and/or attending physician that results in the patient's follow-up office visit with the physician, a recommendation for additional CI programming with the audiologist, or a discussion of strategies the patient can implement before returning for a regularly scheduled, face to face follow-up appointment for diagnostic analysis and programming. The audiologist saves the clinical documentation of the assessment to the medical record and forwards a copy to the referring physician through the portal. This scenario illustrates a lengthier interaction that could be reported with G2062/98971 (11-20 minutes, cumulative) or G2063/98972 (21 minutes or more, cumulative), depending on the patient's ability to describe symptoms and the level of follow-up probing required, and if the assessment does not lead to a related service within the next seven days.

Patient with tinnitus: A Medicare beneficiary was previously evaluated by the referring/attending physician and referred to an audiologist with a diagnosis of tinnitus. This includes the audiologist's diagnostic testing of tinnitus severity, current level of tinnitus handicap, and impact on daily function (CPT code 92625) and the results of this assessment confirms the diagnosis of debilitating tinnitus. The assessment may also include a brief depression screening, as allowed by state law and as required by Measure #134 of the Medicare Merit-Based Incentive Program (MIPS). The audiologist creates a plan of care for treating and managing the tinnitus and provides tinnitus management services to the patient.

The established patient contacts the audiologist through the secure patient portal four months later, reporting a sudden increase in tinnitus loudness, severity, and impact on concentration and sleep. The audiologist responds with a series of questions about health and medication changes and administers standardized questionnaires such as a tinnitus handicap inventory (THI), tinnitus handicap questionnaire (THQ) and/or tinnitus function inventory (TFI) via the portal to assess the current degree and type of tinnitus the patient is currently experiencing. The patient answers the initial questions and completes and responds to the questionnaire questions verbally or completes and forwards the questionnaire through the portal. The audiologist compares current findings to initial measures. Based on the patient's description of the problem and amount of tinnitus change and medical history, the audiologist determines the need to refer the patient to a neurotologist is warranted. The audiologist saves the clinical documentation of the assessment to the medical record and forwards a copy to the referring physician through the secure patient portal. This scenario illustrates a shorter interaction that could be reported with G2061/98970 (5-10 minutes cumulative).

However, if the initial exchange points to potentially complicated personal, emotional, or psychosocial issues, the audiologist will proceed to ask additional questions to assess the patient's depression level and risk of harm to self and others. If the patient reports significant—but not emergent—changes the audiologist will consult with the referring physician, which may lead to referring the patient to an appropriate physician or behavioral health professional for intervention and/or will provide additional tinnitus management strategies and counseling. If the audiologist identifies emergent needs that cannot be managed with audiologic management, the audiologist will immediately proceed with additional referrals (such as psychiatry, psychology, and/or primary care) and/or emergency actions and recommendations to ensure the safety of the patient because of their status as a mandated reporter. The audiologist saves the clinical documentation of the assessment to the medical record and forwards a copy to the referring physician through the secure patient portal. This scenario illustrates a lengthier interaction that could be reported with G2062/98971 (11-20 minutes, cumulative) or G2063/98972 (21 minutes or more, cumulative), depending on the patient's ability to describe symptoms and the reported severity level.

Codes analogous to E&M Codes

Audiology Evaluations

ADA strongly and respectfully requests that CMS should apply adjustments uniformly across analogous services and specialties, including for assessments furnished by audiologists. Audiologists specialize in preventing, assessing, and treating audiologic and balance (vestibular) disorders, using standardized quantitative and qualitative measures, including audiologic and vestibular testing, inventories, observations, and procedures with appropriately calibrated instrumentation. Audiologic and vestibular testing leads to the diagnosis of audiologic and/or balance disorders. The audiologist's assessment includes performance and interpretation of test results identifying the probable cause of impairment and

functional ability within hearing, balance, and other related systems. Audiologists also often identify the underlying disorder and diagnosis. Audiologists also serve on care teams and the results of audiologic and vestibular assessments play a critical role in physician and other qualified health care professional management of Medicare beneficiaries with audiologic and vestibular disorders. Given an audiologists role in improving communication and mitigating falls risk, ADA respectfully requests that CMS review audiology services and adjust work Relative Value Units (RVUs) for analogous evaluation codes primarily reported by audiologists to ensure relativity within the Medicare Physician Fee Schedule (MPFS). We offer the following examples of audiology evaluations that include work analogous to office/outpatient E/M services.

CPT Code	CPT Descriptor	ADA Description
92540	Basic vestibular evaluation, includes spontaneous nystagmus test with eccentric gaze fixation nystagmus, with recording, positional nystagmus test, minimum of 4 positions, with recording, optokinetic nystagmus test, bidirectional foveal and and peripheral stimulation, with recording, oscillating tracking test, with recording	Assesses vestibular function using a comprehensive battery of tests to aid in the differential diagnosis of balance disorders and distinguish between aural, peripheral and central pathologies. Informs a plan of care to manage and/or treat a balance disorder and prevent falls.
92557	Comprehensive audiometry threshold evaluation and speech recognition (92553 and 92556 combined)	Assesses behavioral responses from the patient using pure tone air and bone conduction, and speech threshold and recognition to aid in the differential diagnosis of hearing loss and audiologic disorders and determine the need for additional testing. Informs a plan of care to manage and/or treat a hearing disorder.
92620	Evaluation of central auditory processing, with report; initial 60 minutes	Assesses central auditory function through specialized audiologic testing to aid in the differential diagnosis of hearing and communication disorders. Informs a plan of care to manage and/or treat resulting central auditory disorders.
92625	Tinnitus assessment (includes pitch, loudness, matching, and masking)	Assesses behavioral responses from the patient to aid in the differential diagnosis of debilitating, bothersome tinnitus and associated audiologic disorders and determine the need for additional testing. Informs a plan of care to manage and/or treat the tinnitus and any possible accompanying hearing loss.
92626	Evaluation of auditory function for surgically implanted device(s) candidacy or postoperative status of a surgically implanted device(s); first hour	Assesses auditory function through behavioral and audiologic testing for medically necessity of and suitability for a surgically implanted hearing device, as well as post-surgical implant performance and outcomes. Informs the final surgical decision and post-surgical plan of care to improve functional hearing and communication abilities.

Currently, coverage of audiology services provided by licensed audiologists is contingent on the services being first ordered by a physician or appropriate non-physician practitioner. This order requirement does not exist in state licensure and is not required by the vast majority of private or public health insurers in the United States, including Medicare Part C, Medicaid, the Federal Health Benefit Plans (FEHP) or the U.S. Department of Veterans Affairs (VA). Also, it should be noted, that some of the non-physician practitioners (i.e. physician assistant (PA), nurse practitioner (NP), clinical psychologist, clinical social worker) who can order testing have less than or equivalent years of formal academic and clinical education than an audiologist and may have little or no background in or exposure to audiology or vestibular procedures and their interpretation. As audiologists are already responsible for determining medical necessity under Medicare, we respectfully request that this physician order requirement be rescinded as it does not exist in statute and solely exists in Center for Medicare and Medicaid Services (CMS) policies. The rescission of this order requirement is estimated to save CMS $108M over the next 10 years (Moran Co., 2020). This savings could be applied to the deficit created by the proposed increases in coverage for primary care and telehealth services.

Audiology has increased technological capacities as it pertains to the use of telehealth in patient interactions. These capacities and technologies are evidence based and reliable. As a result, we respectfully request that all audiologic and vestibular services (92504-92700) be allowed for Medicare coverage via telehealth when provided by a licensed audiologist and when the provision of care is substantially equal to that provided in a face to face encounter.

In the 2021 MPFS proposed rule, you allow for non-physician practitioners (NPP), such as NPs, clinical nurse specialists, PAs and certified nurse-midwives to supervise the performance of diagnostic tests performed by technicians. We respectfully request that licensed audiologists be added to this list and that they be allowed to supervise the performance of procedures in the audiology code set which have a technical/professional component (TC/PC) split (92537, 92538, 92540, 92541, 92542, 92544, 92545, 92546, 92548, 92549, 92585, 92586, 92587, and 92588) when they are performed by a technician under the direct supervision of a licensed audiologist and receive coverage for the provision of such services. If you now allow non-physician practitioners, most of which who have no clinical knowledge or expertise in the performance or interpretation of audiologic or vestibular procedures, to supervise the performance of these procedures it makes sense that audiologists, who can independently perform and interpret these procedures, should also be allowed to supervise the actions of these procedures and have these services covered.

In the 2021 MPFS proposed rule, you are allowing modifications to medical record documentation requirements for physicians and certain NPPs. We respectfully request that licensed audiologists be added to the group that can review and verify (sign and date) the documentation entered into the medical record by members of their medical team for their own, appropriately supervised services that are paid under the PFS. The medical team for audiology could include graduate students in audiology or speech language pathology, audiology assistants or technicians.

In 2008, in the Update to Audiology Policy, CMS clearly indicated that any audiology service that is provided by a licensed audiologist must be billed to Medicare under the National Provider Identifier (NPI) of the rendering audiologist and should not be billed "incident to" the ordering physician. This policy also stated that, for Medicare coverage, most audiology services (on the Audiology Code List) must be provided by a licensed audiologist, licensed physician, or licensed non-physician practitioner practicing within their scope of practice. The exception were services that had a TC/PC split. We would like to ensure that technicians and other "incident to" billing providers be held to these regulations and that these regulations continue to be enforced.

CMS is proposing, through the Support Act provisions, to expand the list of recipients covered under the Open Payments Act provisions to include PAs, NPs, clinical nurse specialists, certified registered nurse anesthetists, and certified nurse midwives. Audiologists prescribe, order and/or dispense significant numbers of durable medical equipment (DME), specifically hearing aids, cochlear implants, and osseointegrated devices, to Medicare Part C, Medicaid, FEHP, and VA beneficiaries. Including audiology in the Support Act provisions, would provide additional opportunities within our industry to bring light and public attention to such issues like consulting arrangements, charitable contributions, honoraria, research, gifts, entertainment, travel/lodging, food/ beverage, payments or transfers of value, in cash or in kind, continuing education, debt forgiveness, loans, and acquisitions. Inclusion in this program would encourage transparency about these financial relationships between provider and manufacturer; provide information on the nature and extent of these relationships; help to identify relationships that can both lead to the development of beneficial new technologies but also produce wasteful or fraudulent healthcare spending; help prevent inappropriate influence on research, education and clinical decision making, specifically kickbacks; and level the playing field for providers across the clinical spectrum.

We noted that the 2021 proposed MPFS requires changes to the Initial Preventative Physical Examination (IPPE) and Annual Wellness Visit (AWV). Untreated hearing loss or vertigo have been found to significantly increase healthcare costs and utilization (Reed et al, 2019, Kovacs, et al, 2019) and significantly affect quality of life (Li-Korotky, 2012). We respectfully request that hearing screenings and falls risk assessments also be enhanced in the IPPE and AWV. Like substance abuse screenings, otoscopy, cerumen management, acoustic hearing screenings and falls risk assessments should be required procedures in every IPPE and AWV visit.

As it pertains to the Merit Based Incentive Payment System, we would respectfully request that the following measures be added to the Audiology Specialty Set. These include:

- Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling (Quality ID #431 (NQF 2152)
    - Assigned to procedures: 92537, 92538, 92540, 92541, 92542, 92544, 92545, 92546, 92547, 92548, 92549, 92550, 92552, 92553, 92557, 92570, 92584, 92585, 92586, 92620, 92621,92625, 92626, and 92627
- Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented (Quality ID #317)
    - Assigned to procedures: 92537, 92538, 92540, 92541, 92542, 92544, 92545, 92546, and 92625

On behalf of ADA, I thank you for your attention to these important issues. Please contact me at dabel@audigy.com or Stephanie Czuhajewski at sczuhajewski@audiologist.org if you have any questions, or if we can assist you in any way.

Sincerely,

Debbie Abel, Au.D.

Debbie Abel, Au.D., President

References:

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Reed NS, Altan A, Deal JA, et al. Trends in Health Care Costs and Utilization Associated with Untreated Hearing Loss Over 10 Years. *JAMA Otolaryngol Head Neck Surg*. 2019;145(1):27-34. doi:10.1001/jamaoto.2018.2875

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