May 19, 2024

Hearing Care Professionals Technical Review Committee
Nebraska Department of Health & Human Services
P.O. Box 94986
Lincoln, NE 68509-4986

RE: Nebraska Credentialing Review for the Nebraska Hearing Society, Credentialing Review Program (407)

Dear Technical Review Committee members,

My name is Samantha Sikorski. I am licensed by the state of Wisconsin as a Hearing Instrument Specialist and am a Certified Professional Compliance Officer – an earned credential through the American Academy of Professional Coders (AAPC).

Although I spend the majority of my work days dispensing, cleaning, and programming hearing aids, a significant portion of my week is spent auditing and training both Hearing Instrument Specialists *and* audiologists who participate in Managed Care. As such, I have a unique perspective when it comes to patient access and provider scope of practice.

About Cerumen

Cerumen is defined by the American Academy of Otolaryngology – Head and Neck Surgery as impacted when one or more of the following conditions are met[i]:

1. Cerumen impairs the examination of clinically significant portions of the external auditory canal, tympanic membrane, or middle ear condition;
2. Extremely hard, dry irritative cerumen causes symptoms such as pain, itching, hearing loss, etc.;
3. Cerumen is associated with foul odor, infection, or dermatitis; or
4. Obstructive, copious cerumen of any consistency that cannot be removed without magnification and instrumentation requiring physician skills.

Cerumen impaction is the most common ear complaint and affects >30% of the elderly and cognitively impaired.[ii] It is common among hearing impaired individuals who utilize hearing aids and a typical reason for hearing aids to malfunction. Air conduction hearing aids are placed in an ear canal where the presence of cerumen is natural; however, build-up of such will cause performance issues in the hearing device and wearers naturally seek assistance from their licensed hearing care professional (HCP) for help.

Subsequently, when this happens, those who are found to have occluding cerumen are referred out to their primary care physician (PCP) for removal. When the blockage is removed, the patient/client returns back to the HCP for a professional cleaning of the hearing aid.

Medical Necessity

When one elects to participate in Managed Care programs, and then renders a service or performs a procedure, they are required to comply with all state, federal, and payer rules to ensure the item/service/procedure was reasonable and medically necessary.

The additional challenge with cerumen is that the medical field and the health benefits plans that cover the removal of such only considers it medically necessary when the patient is occluded ***and*** symptomatic.[ii] Neither the use of hearing aids, nor the proper functioning of hearing aids, is considered when determining if it is medically necessary to remove non-occluded ear canals. Therefore, patients who present with occlusion, but are not symptomatic, are encouraged to "leave their cerumen alone." [ii]

Removal of cerumen from an individual's canal who are asymptomatic does not meet the definition of medical necessity,[ii,iii,iv] which is a required component of medical billing when using the HCPCS coding system.

The HCPCS system is divided into two subsystems: level I codes, called Common Procedural Terminology (CPT®), a registered trademark of the American Medical Association, and level II codes, the Healthcare Common Procedural Terminology (HCPCS). Between the two systems, there are just over 19,000 codes. Of those, there are three (3) codes that describe the procedure of removing wax from an ear canal. All of them are for the removal of ***impacted*** cerumen. This means that the ear canal must be occluded (for code compliance) and the patient must be symptomatic (to meet payer compliance and clinical best practices) before the procedure may be billed.

Of the two service codes available in CPT® and one in HCPCS, only the later, G0268, mandates the removal of cerumen be provided by a physician[v] but must also be provided on the same date of service as audiologic function testing. In every case, billing and coding rules require the ear canal to be impacted to meet the code and reimbursement criteria.

Code 69209 is the removal of impacted cerumen using irrigation and, according to the Centers for Medicare and Medicaid Services (CMS) and their Local Coverage Determination Policy, L33945, it "does not require a physician's skill."[iv]

Cerumen removal requires a physician's skill when the tympanic membrane cannot be observed (total occlusion or impaction), there are overt medical contraindications such as anatomical abnormalities, surgical modifications, or risk of infection, presence of medical conditions that pose undue risk of excessive bleeding (use of anticoagulants), or the cerumen cannot be removed safely without undue risk of abrasion, laceration, or tympanic membrane perforation.[vi]

Nebraska Total Care is a Managed Care Organization and Subsidiary of Centene Corporation. Centene's Payment Policy, CC.PP.008, outlines their reimbursement policy on the removal of cerumen. In the policy, it states that *"The routine removal of asymptomatic,*

non-impacted, non-obstructive cerumen does not generally require a physician's skill and is thus not reimbursed separately, or in addition to an E/M service."

No matter the payer, all procedure codes must have an applicable diagnosis code that points the payer to the chief complaint and justification for providing the service. Those diagnostic codes are selected from the International Classification of Diseases. We currently use the Clinical Modification of the 10th revision of the ICD.

Of the 69,832 diagnosis codes available in the ICD-10-CM three (3) diagnosis codes (well, technically there are 4, but you wouldn't want to get denied for using an unspecified code as providers are required to code to the highest degree of specificity, but I digress). Of the ICD-10 codes available, they are all for impacted cerumen. There are none for non-occluding cerumen as non-occluding cerumen is not considered to be medically relevant or "an issue affecting the patient."

Title XVIII of the Social Security Act allows coverage and payment for only those services considered medically reasonable and necessary.[vii]

> *(a) Notwithstanding any other provision of this title, no payment may be made under part A or part B for any expenses incurred for items or services—*
> *(1)(A) which, except for items and services described in a succeeding subparagraph, are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member,*
> *(B) in the case of items and services described in section 1861(s)(10), which are not reasonable and necessary for the prevention of illness*

Cerumen removed from a canal of an individual who is not symptomatic requires disclosure to the health plan that the procedure did not meet the payers definition of medical necessity by appending a GZ modifier to the HCPCS/CPT code; which pushes the entire cost of the procedure to patient responsibility.

Reimbursement & Costs of Care

Medicare will not separately reimburse cerumen removal performed by an audiologist. Procedure codes 69210 and G0268 performed by an audiologist are not reimbursable by Medicare under any circumstance.[vi]

While Medicare recognizes the education and experience of audiologists, payment rules stipulate they can only pay audiologists for medically necessary *diagnostic* testing – which includes incidental cerumen removal.[vi] This means that the purpose of the visit must be for an audiological evaluation to have the wax removed, which is done incidental to the diagnostic testing.

If there is no reimbursement, or medical basis for the removal of non-occluding cerumen, it is simply not a provided service by general physicians. Who, then, is available to help patients/clients struggling with poorly functioning hearing aids when partial wax occlusion is the culprit?

The healthcare debt among Americans is staggering. A Kaiser Family Foundation poll found that 41% of adults have healthcare debt and approximately 14 million people in the U.S. owe over $1,000 in medical debt.[viii] The average billed charge for cerumen removal to Medicare in Nebraska is $112.54.[ix]

Safety of Removal by Non-Physician Providers

Additionally, primary care physicians are not likely to remove the wax from the canal themselves[x]; in fact, only 19% of general physicians always performed the syringing themselves.[xi] Instead, they direct their medical assistant who is unlicensed and who has had little to no formal training on ear anatomy, physiology, and otologic conditions to do so; it is then billed "incident-to" the physician. The removal of cerumen is typically covered under the Evaluation and Management code 99211. Therefore, it is difficult to determine how many times this procedure is performed by medical assistants. The most current reports from Medicare (CY2021) show the code, 99211, was billed and reimbursed more than 8,500 times in the state of Nebraska.[ix] However, we are not able to extrapolate what percentage of these include the removal of cerumen vs some other evaluation/management service that does not require the presence of a physician.

As you have heard, in others' testimony, not every individual found to have excessive amounts of wax proceed with treatment or removal. Some families are savvy enough to look online. If you Google at-home remedies, more than 89.7 million results appear. There is a wide range of ways one can remove their wax at home - themselves; liquid options range from oils to water, DIY mixtures to a hydrogen peroxide-based OTC solution. One need not look far for tools to aid in the removal – and most do not adequately caution the user on safety nor do they suggest a visit with an ENT/MD first to ensure it is safe to proceed with any at home regimen.

Current Clinical Practice

I have hired two Medical Assistants and one LPN – all have felt very confident and comfortable using an ear lavage system. My most recent hire told me she has irrigated "more ears than she can count;" yet, she is unable to perform otoscopy and differentiate the wax from the canal wall – nor is she able to identify risk factors that would prohibit the use of a syringe to remove the wax.

I reached out to the director of the Medical Assistant program at a technical college here in Wisconsin who explained that "Ear Irrigation is a competency. We do a discussion and I do a demonstration. The students then work on each other. We use the Elephant with soft tips and I stress the importance of the tympanic membrane."

They are considered to have successfully completed the skill if they remember the 21 steps. While one of those steps (#2) is to check the physician's order and another (#13) is to continue until the impaction is cleared; there is not a single step to have a physician check the ear for perforation or other otologic symptoms post-procedure.

Institutions are running at less than full capacity due to staff shortages and wait times are increasing.[xii] Kaufman Hall reports that 66% of respondents' institutions are not able to run at full capacity and 32% of respondents say that patient concerns or complaints about access is on the rise.

Expanding the scope of practice to include cerumen management will increase both access and awareness of the benefits of clear ear canals. Additionally, it will reduce the burden medical facilities face trying to provide such a simple service in the midst of being short staffed and allow physicians to focus on more important medical decision making procedures and needs of their patients' health. Beyond those two important aspects, including the removal of cerumen will reduce the financial burden on tax payers and the Medicare/Medicaid program.

Coding:

There has been a significant amount of debate among audiology groups stipulating that hearing instrument specialists are not able to use the CPT code set as they are not "healthcare providers." In the instructions for CPT use, the American Medical Association defines a "physician or other qualified health care professional" as *an individual who is qualified by education, training, licensure/regulation (when applicable), and facility privileging (when applicable) who performs a professional service within his/her scope of practice and independently reports that professional service.*[xiii]

Current Procedural Terminology (CPT®) is a list of codes, and their descriptions, used to report services and procedures performed by *"physicians and other qualified health care professionals."* In 2000, the CPT code set was designated by the Dept. of Health and Human Services (DHS) as a national coding standard under the Health Insurance Portability and Accountability Act (better known as HIPAA). The HIPAA code set designation means that any practice using these codes to bill electronically is a Covered Entity and the CPT code set must be applied to services and procedures when communicating with physicians, other qualified healthcare professionals, patients, and third parties.

CPT codes live within the Healthcare Common Procedural Coding System (HCPCS) as level I codes and are 5-digit numeric codes; while level II codes, called HCPCS codes, are alpha-numeric and used to identify durable medical equipment, prosthetics, orthotics, and supplies when used outside of a physician's office. It is critical that practices/providers apply a code that appropriately describes the procedure/service rendered, that documentation supports the code, and that the service was appropriate and medically necessary.

Thus, it is important to note that the services described within the CPT code set are not there to regulate who is able to render or bill for the service; rather it is a way to communicate what service was provided and it is the state licensing board. It is the responsibility of the individual providing the service to ensure they are operating within their scope of practice as outlined by their licensing board.

Allowing hearing instrument specialists to provide this necessary service would not only allow for greater access, it has significant potential to save the Medicare system as well as encouraging hearing impaired persons to receive the full benefit from utilizing their hearing aids.

In closing, I would like to share a letter from an MD patient of mine who wrote an email in support of the expansion of scope for hearing instrument specialists in the state of Wisconsin.[x] I feel this letter summarizes the feeling of so many heard of hearing individuals so well. Referrals to audiologists are expensive and the wait to get an appointment just to make another hearing test appointment is an undue burden. "In over 45 years of family practice and after hundreds of ear lavages, by non MD providers, I have not seen any injury to a patient."

Respectfully Submitted,

Samantha E Sikorski, HIS CPCO

References:

[i] American Academy of Otolaryngology – Head and Neck Surgery® https://www.entnet.org/resource/cpt-for-ent-cerumen-removal/

[ii] Sevy JO, Hohman MH, Singh A. Cerumen Impaction Removal. [Updated 2023 Mar 1]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2024 Jan-. Available from: https://www.ncbi.nlm.nih.gov/books/NBK448155/

[iii] American Academy of Otolaryngology – Head and Neck Surgery® https://www.entnet.org/resource/cpt-for-ent-cerumen-removal/

[iv] https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdid=33945&ver=18&=

[v] CMS National Coverage Policy, Coverage Indications, Limitations, and/or Medical Necessity, Policy L33945: Cerumen (earwax) Removal

[vi] Medicare's Local Coverage Determination (LCD) policy, L33945

[vii] Section 1862 (a)(1)(A): Sec. 1862. [42 U.S.C. 1395y]

[viii] https://www.healthsystemtracker.org/brief/the-burden-of-medical-debt-in-the-united-states/

[ix] Centers for Medicare & Medicaid Services Data." Cms.gov, 2022, data.cms.gov/provider-summary-by-type-of-service/medicare-physician-other-practitioners/medicare-physician-other-practitioners-by-provider-and-service/data.

[x] Dr. John Henningsen, MD, NPI: 1578663225. Opinion on expansion of HIS's scope:

From: **JoAnn Henningsen** johenningsen0227@gmail.com
Subject: Ear cleaning
Date: November 29, 2023 at 1:14 PM
To: samantha@sikorskihearing.com

JH

Nov. 29,2023

To Whom it may concern:
It is my understanding that a bill is being introduced to expand the credentials for non-audiologists to allow cleaning of wax from ears.
My comment:
In over 45 years of family practice and after hundreds of ear lavages by non MD providers, I have not seen any injury to a patient.
By personal experience, I've had to wait days to see an audiologist-MD to have my ears cleaned so that I could have testing done for hearing aids.
Audiologists charge an inordinate amount of money to just get an appointment with them to have the simple procedure done.
There are not enough audiologists available to do this. Family doctors usually have their assistants do this procedure without additional charge.
To require yearly re-education for anyone to do this is absurd and entirely unnecessary.
Please do not unnecessarily increase the cost and inconvenience of this benign procedure.
Sincerely,

John Henningsen, MD

[xi] Sharp JF, Wilson JA, Ross L, Barr-Hamilton RM. Ear wax removal: a survey of current practice. BMJ. 1990 Dec 1;301(6763):1251-3. doi: 10.1136/bmj.301.6763.1251. PMID: 2271824; PMCID: PMC1664378.
[xii] https://www.kaufmanhall.com/insights/research-report/2023-state-healthcare-performance-improvement-report?utm_source=linkedin&utm_campaign=performance-improvement-report&utm_medium=social&utm_term=231024

[xiii] Association AM. *CPT Professional 2019*. American Medical Association Press; 2018.