

# Clinical Practice Guideline (Update): Earwax (Cerumen Impaction)

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## Abstract

**Objective.** This update of the 2008 American Academy of Otolaryngology—Head and Neck Surgery Foundation cerumen impaction clinical practice guideline provides evidence-based recommendations on managing cerumen impaction. Cerumen impaction is defined as an accumulation of cerumen that causes symptoms, prevents assessment of the ear, or both. Changes from the prior guideline include

- a consumer added to the development group;
- new evidence (3 guidelines, 5 systematic reviews, and 6 randomized controlled trials);
- enhanced information on patient education and counseling;
- a new algorithm to clarify action statement relationships;
- expanded action statement profiles to explicitly state quality improvement opportunities, confidence in the evidence, intentional vagueness, and differences of opinion;
- an enhanced external review process to include public comment and journal peer review; and
- 3 new key action statements on managing cerumen impaction that focus on primary prevention, contraindicated intervention, and referral and coordination of care.

**Purpose.** The primary purpose of this guideline is to help clinicians identify patients with cerumen impaction who may benefit from intervention and to promote evidence-based management. Another purpose of the guideline is to highlight needs and management options in special populations or in patients who have modifying factors. The guideline is intended for all clinicians who are likely to diagnose and manage

patients with cerumen impaction, and it applies to any setting in which cerumen impaction would be identified, monitored, or managed. The guideline does not apply to patients with cerumen impaction associated with the following conditions: dermatologic diseases of the ear canal; recurrent otitis externa; keratosis obturans; prior radiation therapy affecting the ear; previous tympanoplasty/myringoplasty, canal wall down mastoidectomy, or other surgery affecting the ear canal.

**Key Action Statements.** The panel made a *strong recommendation* that clinicians should treat, or refer to a clinician who can treat, cerumen impaction, defined as an accumulation of cerumen that is associated with symptoms, prevents needed assessment of the ear, or both.

The panel made the following *recommendations*: (1) Clinicians should explain proper ear hygiene to prevent cerumen impaction when patients have an accumulation of cerumen. (2) Clinicians should diagnose cerumen impaction when an accumulation of cerumen, as seen on otoscopy, is associated with symptoms, prevents needed assessment of the ear, or both. (3) Clinicians should assess the patient with cerumen impaction by history and/or physical examination for factors that modify management, such as  $\geq 1$  of the following: anti-coagulant therapy, immunocompromised state, diabetes mellitus, prior radiation therapy to the head and neck, ear canal stenosis, exostoses, and nonintact tympanic membrane. (4) Clinicians should not routinely treat cerumen in patients who are asymptomatic and whose ears can be adequately examined. (5) Clinicians should identify patients with obstructing cerumen in the ear canal who may not be able to express symptoms (young children and cognitively impaired children and adults), and they should promptly evaluate the need for intervention. (6) Clinicians should perform otoscopy to detect the presence of cerumen in patients with hearing aids during a health care encounter. (7) Clinicians should treat, or refer to a clinician who can treat, the patient with cerumen impaction with an appropriate intervention, which may include  $\geq 1$  of the following: cerumenolytic agents, irrigation,

or manual removal requiring instrumentation. (8) Clinicians should recommend against ear candling for treating or preventing cerumen impaction. (9) Clinicians should assess patients at the conclusion of in-office treatment of cerumen impaction and document the resolution of impaction. If the impaction is not resolved, the clinician should use additional treatment. If full or partial symptoms persist despite resolution of impaction, the clinician should evaluate the patient for alternative diagnoses. (10) Finally, if initial management is unsuccessful, clinicians should refer patients with persistent cerumen impaction to clinicians who have specialized equipment and training to clean and evaluate ear canals and tympanic membranes.

The panel offered the following as *options*: (1) Clinicians may use cerumenolytic agents (including water or saline solution) in the management of cerumen impaction. (2) Clinicians may use irrigation in the management of cerumen impaction. (3) Clinicians may use manual removal requiring instrumentation in the management of cerumen impaction. (4) Last, clinicians may educate/counsel patients with cerumen impaction or excessive cerumen regarding control measures.

### Keywords

cerumen, earwax, impaction, ear candling, ear coning, clinical practice guideline

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### Differences from Prior Guideline

This clinical practice guideline is as an update and replacement for an earlier guideline published in 2008 by the American Academy of Otolaryngology—Head and Neck Surgery Foundation (AAO-HNSF).<sup>1</sup> An update was planned

for 5 years after the initial publication date and was further necessitated by new primary studies and systematic reviews that suggest a need for modifying clinically important recommendations.<sup>2</sup> Changes in content and methodology from the prior guideline include the following:

- addition of a consumer advocate to the guideline update group (GUG);
- new evidence: 3 guidelines, 5 systematic reviews, and 6 randomized controlled trials (RCTs);
- emphasis on patient education and counseling with new explanatory tables;
- expanded action statement profiles to explicitly state quality improvement opportunities, confidence in the evidence, intentional vagueness, and differences of opinion;
- enhanced external review process to include public comment and journal peer review;
- new algorithm to clarify decision making and action statement relationships; and
- 3 new key action statements on managing cerumen impaction that focus on primary prevention, contraindicated intervention, and referral and coordination of care.

### Introduction

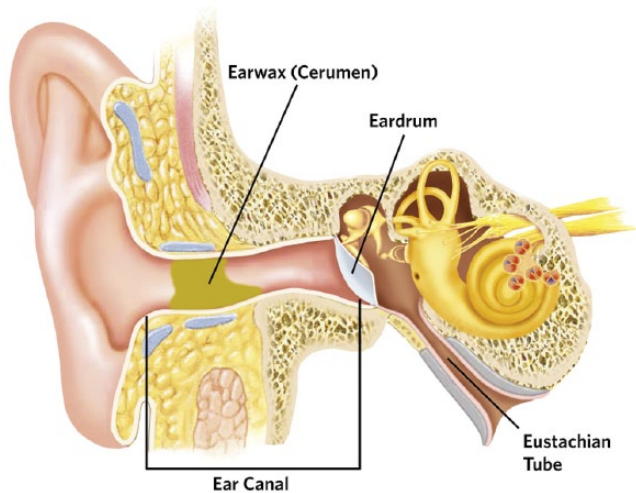
Cerumen, or “earwax,” is a naturally occurring substance that cleans, protects, and lubricates the external auditory canal. It is also the primary reason why the ear canal can become obstructed. While often harmless, blockage of the ear canal by cerumen can lead to a host of symptoms: hearing loss, tinnitus, fullness, itching, otalgia, discharge, odor, and cough.<sup>3</sup> In addition, cerumen impaction can prevent diagnostic assessment by preventing complete examination of the external auditory canal and/or eardrum (tympanic membrane) or by

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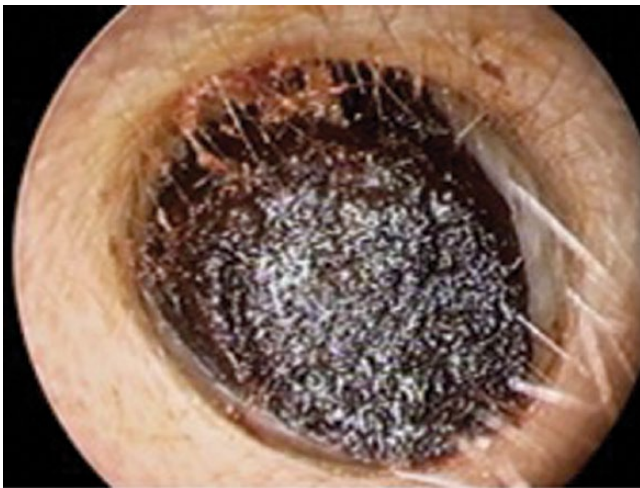
The clinical practice guideline is provided for information and educational purposes only. It is not intended as a sole source of guidance in managing cerumen impaction. Rather, it is designed to assist clinicians by providing an evidence-based framework for decision-making strategies. The guideline is not intended to replace clinical judgment or establish a protocol for all individuals with this condition and may not provide the only appropriate approach to diagnosing and managing this program of care. As medical knowledge expands and technology advances, clinical indicators and guidelines are promoted as conditional and provisional proposals of what is recommended under specific conditions, but they are not absolute. Guidelines are not mandates; these do not and should not purport to be a legal standard of care. The responsible physician, in light of all circumstances presented by the individual patient, must determine the appropriate treatment. Adherence to these guidelines will not ensure successful patient outcomes in every situation. The American Academy of Otolaryngology—Head and Neck Surgery Foundation, Inc emphasizes that these clinical guidelines should not be deemed to include all proper treatment decisions or methods of care or to exclude other treatment decisions or methods of care reasonably directed to obtaining the same results.

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**Figure 1.** Cerumen is formed in the outer two-thirds (cartilaginous portion) of the ear canal, not the inner third (bony portion) that ends at the eardrum. Impacted cerumen (green-like collection) can completely obstruct the ear canal. Adapted and reproduced with permission.<sup>7</sup>



**Figure 2.** Otoscopic view of impacted cerumen that completely fills the ear canal.<sup>8</sup>

interfering with diagnostic assessment (ie, audiometry, tympanometry).<sup>4</sup>

Cerumen forms when glandular secretions from the outer two-thirds of the ear canal mix with exfoliated squamous epithelium.<sup>5</sup> Normally, cerumen is eliminated or expelled by a self-cleaning mechanism, which causes it to migrate out of the ear canal assisted by jaw movement.<sup>6</sup> **Figure 1** provides an illustration of where cerumen occurs,<sup>7</sup> and **Figure 2** is a photograph of impacted cerumen.<sup>8</sup>

Accumulation of cerumen, caused by failure of the self-cleaning mechanism, is one of the most common reasons why patients seek medical care for ear-related problems.<sup>4,9</sup> Excessive or impacted cerumen is present in 1 in 10 children, 1 in 20 adults, and more than one-third of the geriatric and developmentally

delayed populations.<sup>3,10,11</sup> About 12 million people in the United States annually seek medical care for problematic cerumen, resulting in nearly 8 million cerumen removal procedures.<sup>12,13</sup> Nearly \$50 million was spent by Medicare in 2012 for cerumen-related procedures, and cerumen impaction was a diagnosis in up to 5% of Medicare patients.<sup>14</sup> Moreover, excessive or impacted cerumen in high-risk populations, such as the elderly and developmentally delayed, is underdiagnosed and likely undertreated.<sup>11,15,16</sup>

The target patient for this guideline is >6 months of age with a clinical diagnosis of cerumen impaction.

- *Cerumen* is defined as a mixture of secretions (sebum with secretions from modified apocrine sweat glands) and sloughed epithelial cells, and it is a normal substance present in the external auditory canal. As cerumen migrates laterally, it may mix with hair and other particulate matter.
- *Cerumen impaction*, as defined for this guideline, is an accumulation of cerumen that causes symptoms or prevents a needed assessment of the ear canal, tympanic membrane, or audiovestibular system or both.
- *Impaction vs obstruction*. Although “impaction” usually implies that cerumen is lodged, wedged, or firmly packed in the ear canal (**Figure 2**), our definition of cerumen impaction does not require a complete obstruction. This definition implies that the cerumen is associated with symptoms that may be attributable to it or that the cerumen prevents a necessary ear examination.

We have defined this term pragmatically to designate cerumen that requires management.<sup>3-5</sup> Some patients will present with nonimpacted cerumen that does not cause symptoms or prevent assessment of the ear and that is “asymptomatic.” Asymptomatic cerumen does not require active management. This guideline discusses considerations relevant to watchful waiting and surveillance.

## Guideline Purpose

The primary purpose of this guideline is to help clinicians identify patients with cerumen impaction who may benefit from intervention and to promote evidence-based management. Another purpose of the guideline is to highlight needs and management options in special populations or in patients who have modifying factors. A guideline is necessary, given evidence of practice variation in medicine and the literature. The secondary goal includes creating a guideline suitable for deriving a performance measure on cerumen impaction. This update is needed due to the time since the original publication and to the presence of new evidence.

The guideline is intended for all clinicians who are likely to diagnose and manage patients with cerumen impaction, and it applies to any setting in which cerumen impaction would be identified, monitored, or managed.

The guideline does *not* apply to patients with cerumen impaction associated with the following conditions: dermatologic

diseases of the ear canal; recurrent otitis externa; keratosis obturans; prior radiation therapy affecting the ear; exostoses or osteoma; neoplasms of the ear canal; previous tympanoplasty/myringoplasty, canal wall down mastoidectomy, or other surgery affecting the ear canal. However, the guideline discusses the relevance of these conditions in cerumen management. The following modifying factors are not the primary focus of the guideline but are discussed relative to their impact on management: nonintact tympanic membrane (perforation or tympanostomy tube), ear canal stenosis, exostoses, diabetes mellitus, immunocompromised state, anticoagulant therapy, or bleeding disorder.

The goal of this document is to update the original multidisciplinary guideline by examining previously and newly identified quality improvement opportunities in the management of impacted cerumen. The GUG sought to achieve this with a limited set of focused recommendations based on a transparent and explicit process that considers levels of evidence, harm-benefit balance, consumer input, and expert consensus to fill evidence gaps.

## Health Care Burden

Approximately 2% to 6% of the general population in the United Kingdom suffers from cerumen impaction at any given time.<sup>3</sup> Four percent of primary care patients will consult a clinician for cerumen impaction annually, and cerumen removal is the most common ear, nose, and throat procedure performed in the primary care setting in the United Kingdom.<sup>3</sup> Applying these rates to the US population suggests a prevalence of cerumen impaction of 12 million individuals, ranging between 6 and 18 million. One report cites 12 million office visits per year for cerumen removal in the United States.<sup>17</sup>

The total annual cost for managing cerumen in the United States is not readily available; however, an estimate of the cost for Medicare beneficiaries is available from reports of the Centers for Medicare and Medicaid Services. For 2012, \$46.9 million was spent on 1.3 million cerumen disimpactions. The percentage of Medicare beneficiaries receiving these services varied by state, ranging from 0.55% to 4.92%.<sup>14</sup>

Cerumen impaction is more common in the elderly and in patients with cognitive impairment. Estimates suggest that between 19% and 65% of patients >65 years old have cerumen impaction<sup>13,15</sup> and that elderly patients in nursing homes are likely at the upper end of this spectrum.<sup>10,18</sup> In the developmentally delayed adult population, 28% to 36% have excessive or impacted cerumen.<sup>10,11</sup> Moreover, the presence of cerumen impaction has been associated with hearing loss<sup>19</sup> and diminished cognitive function<sup>15</sup> in these populations.

The prevalence of cerumen impaction varies widely but is still high in healthy adults and children. In a study of 1507 adults screened for hearing loss, 2.1% had occluding cerumen.<sup>20</sup> Another study estimates that cerumen impaction is present in approximately 10% of children and 5% of healthy adults.<sup>10</sup> Impacted cerumen was the diagnosis for 3.6% of 8,611,282 emergency room visits for otologic complaints in the United States between 2009 and 2011.<sup>21</sup>

Patients seek treatment for cerumen impaction for a host of symptoms. Reported symptoms include pain, itching, sensation

of fullness, tinnitus, odor, drainage, and cough. Complete occlusion can also result in significant hearing loss.<sup>3</sup> Hearing loss can range from 5 to 40 dB depending on the degree of occlusion of the canal with cerumen.<sup>9,10</sup> While cerumen impaction may be asymptomatic in some cases, management may be necessary for diagnostic purposes so that the ear canal and/or tympanic membrane can be visualized or diagnostic assessment can be performed.<sup>22</sup>

Multiple treatment options exist for cerumen impaction: observation, cerumenolytic agents, irrigation, and manual removal other than irrigation.<sup>4,22</sup> Combinations of these treatment options also exist (eg, cerumenolytic followed by irrigation; irrigation followed by manual removal). Manual removal other than irrigation may be performed with a curette, probe, hook, forceps, or suction under direct visualization with headlight, otoscope, or microscope.<sup>3,5</sup> The training, skill, and experience of the clinician play a significant role in the treatment option selected.<sup>23</sup> In addition, patient presentation, patient preference, and urgency of the clinical situation influence choice of treatment.

Though generally safe, treatment of cerumen impaction can result in significant complications. Tympanic membrane perforation, ear canal laceration, infection of the ear, bleeding, or hearing loss occurs at a rate of about 1 in 1000 ear irrigations.<sup>9, 24,25</sup> Applying this rate to the approximate number of ear irrigations performed in the United States estimates that 8000 complications occur annually and likely require further medical services. Other complications that have been reported include otitis externa (sometimes secondary to external auditory canal trauma), pain, dizziness, and syncope.<sup>4,26</sup>

The primary outcome considered in this guideline is resolution or improvement in the signs and symptoms associated with cerumen impaction. Secondary outcomes include complications or adverse events. Cost, adherence to therapy, quality of life, return to work or activity, return physician visits, and effect on comorbid conditions (eg, sensorineural hearing loss, conductive hearing loss) were also considered. The high incidence and prevalence of cerumen impaction and the diversity of interventions available (**Table I**) make this an important condition for an up-to-date, evidence-based practice guideline.

## Methods

### General Methods and Literature Search

This guideline update was developed with an explicit and transparent a priori protocol for creating actionable statements based on supporting evidence and the associated balance of benefit and harm, as outlined in the “Clinical Practice Guideline Development Manual, Third Edition: A Quality-Driven Approach for Translating Evidence into Action.”<sup>27</sup>

The original cerumen impaction guideline<sup>1</sup> was first sent to a panel of expert reviewers, who were asked (1) to assess the key action statements and decide if they should be revised, kept as stands, or removed on the basis of relevancy, omissions, or controversies that the guideline spurred and (2) to identify any new literature or treatments that might affect the guideline recommendations. The reviewers concluded that the

**Table 1.** Interventions Considered in Cerumen Guideline Development.

Diagnosis	Targeted history Physical examination Otoscopy Binocular microscopy Audiologic evaluation
Treatment	Watchful waiting/observation Education/information Cerumenolytic agents Ear canal irrigation Manual removal other than irrigation (curette, probe, forceps, suction, hook) Cotton tip swabs Ear candling
Prevention	Cerumenolytic agents Hygiene Education Environmental controls

original guideline action statements remained valid but should be updated with minor modifications. A suggestion was also made for a new key action statement on the role of alternative therapies in management.

A literature search was performed by an information specialist to identify systematic reviews, clinical practice guidelines, and RCTs published since the prior guideline cutoff (September 2007). The following databases were searched from October 2007 to April 2015: MEDLINE (OvidSP), EMBASE (OvidSP), AMED (OvidSP), Cumulative Index to Nursing and Allied Health, PubMed, National Guidelines Clearinghouse, and Cochrane Controlled Trials Register. The databases were searched for the topic of interest with use of controlled vocabulary words and synonymous free text words (cerumen, earwax, and impaction). The search strategies were adjusted for the syntax appropriate for each database/platform.

The initial English-language search identified 1 potential clinical practice guideline, 6 systematic reviews, 5 RCTs, and 6 other studies. All searches were conducted on April 3, 2015. Systematic reviews were included if they met quality criteria of (1) clear objective and methods, (2) an explicit search strategy, and (3) valid data extraction. Additional evidence was identified, as needed, with targeted searches to support needs of the guideline development group in updating sections of the guideline text. Specifically, ear candling/coning was identified as an area of concern by the reviewers. The databases were also searched through use of controlled vocabulary words and synonymous free text words for the topic of interest (ear candling and ear coning) in this population. The search strategies were adjusted for the syntax appropriate for each database/platform. The search was not limited by date range or study design, but it was limited to the English language. After assessing the quality and relevance of all of the new search results, we retained 3 guidelines, 5 systematic reviews, and 6 RCTs.

The AAO-HNSF assembled a GUG representing the disciplines of otolaryngology–head and neck surgery, otology/

neurotology, family medicine, audiology, advanced practice nursing, pediatrics, geriatrics, a resident physician (otolaryngology), and a consumer advocate. The GUG also included a staff liaison from the AAO-HNSF, but this individual was not a voting member of the GUG and served only in an editorial capacity in writing the guideline. Several group members had significant prior experience in developing clinical practice guidelines.

The GUG had several conference calls and 1 in-person meeting, during which comments from the expert panel review and the literature search were reviewed for each key action statement. The GUG then decided to leave the statements unaltered, change slightly, or rewrite per the impact of the literature search, the reviewer comments, and the benefit-harm balance. The supporting text was then edited to explain any changes from the original key action statement, and the recommendation level was modified accordingly.

The evidence profile for each statement was then converted into an action statement profile, which was moved to immediately follow the action statement. Statements about the quality improvement opportunity, level of confidence in the evidence, differences of opinion, intentional vagueness, and any exclusion to which the action statement does not apply were added to the action statement profiles. These additions reflect the current methodology for guideline development by the AAO-HNSF and conform to the Institute of Medicine's standards for developing trustworthy guidelines.<sup>2,27</sup> The updated guideline then underwent GuideLine Implementability Appraisal to appraise adherence to methodologic standards, improve clarity of recommendations, and predict potential obstacles to implementation.<sup>28</sup> The GUG received summary appraisals in October 2015 and modified an advanced draft of the guideline on the basis of the appraisal.

The final draft of the updated clinical practice guideline was revised according to comments received during multidisciplinary peer review, open public comment, and journal editorial peer review. A scheduled review process will occur at 5 years from publication or sooner if new, compelling evidence warrants earlier consideration.

## Classification of Evidence-Based Statements

Guidelines are intended to reduce inappropriate variations in clinical care, produce optimal health outcomes for patients, and minimize harm. The evidence-based approach to guideline development requires that the evidence supporting a policy be identified, appraised, and summarized and that an explicit link between evidence and statements be defined. Evidence-based statements reflect both the *quality of evidence* and the *balance of benefit and harm* that is anticipated when the statement is followed. The definitions for evidence-based statements<sup>29</sup> are listed in **Tables 2** and **3**.

Guidelines are never intended to supersede professional judgment; rather, they may be viewed as a relative constraint on individual clinician discretion in a particular clinical circumstance. Less frequent variation in practice is expected for

**Table 2.** Strength of Action Terms in Guideline Statements and Implied Levels of Obligation.

Strength	Definition	Implied Obligation
Strong recommendation	A strong recommendation means that the benefits of the recommended approach clearly exceed the harms (or, in the case of a strong negative recommendation, that the harms clearly exceed the benefits) and that the quality of the supporting evidence is high (grade A or B). <sup>a</sup> In some clearly identified circumstances, strong recommendations may be based on lesser evidence when high-quality evidence is impossible to obtain and the anticipated benefits strongly outweigh the harms.	Clinicians should follow a strong recommendation unless a clear and compelling rationale for an alternative approach is present.
Recommendation	A recommendation means that the benefits exceed the harms (or, in the case of a negative recommendation, that the harms exceed the benefits) but that the quality of evidence is not as high (grade B or C). <sup>a</sup> In some clearly identified circumstances, recommendations may be based on lesser evidence when high-quality evidence is impossible to obtain and the anticipated benefits outweigh the harms.	Clinicians should also generally follow a recommendation but should remain alert to new information and sensitive to patient preferences.
Option	An option means that either the quality of evidence is suspect (grade D) <sup>a</sup> or that well-done studies (grade A, B, or C) <sup>a</sup> show little clear advantage to one approach vs another.	Clinicians should be flexible in their decision making regarding appropriate practice, although they may set bounds on alternatives; patient preference should have a substantial influencing role

<sup>a</sup>See **Table 3** for definitions of evidence grades.

**Table 3.** Aggregate Grades of Evidence by Question Type.<sup>a</sup>

Grade	Treatment	Diagnosis	Prognosis
A	Systematic review <sup>b</sup> of randomized trials	Systematic review <sup>b</sup> of cross-sectional studies with consistently applied reference standard and blinding	Systematic review <sup>b</sup> of inception cohort studies <sup>c</sup>
B	Randomized trials or observational studies with dramatic effects or highly consistent evidence	Cross-sectional studies with consistently applied reference standard and blinding	Inception cohort studies <sup>c</sup>
C	Nonrandomized or historically controlled studies, including case-control and observational studies	Nonconsecutive studies; case-control studies; or studies with poor, nonindependent, or inconsistently applied reference standards	Cohort study; control arm of a randomized trial, case series, or case-control study; poor quality prognostic cohort study
D	Case reports, mechanism-based reasoning, or reasoning from first principles		
X	Exceptional situations where validating studies cannot be performed and there is a clear preponderance of benefit over harm		

<sup>a</sup>American Academy of Otolaryngology—Head and Neck Surgery Foundation guideline development manual.<sup>27</sup>

<sup>b</sup>A systematic review may be downgraded to grade B because of study limitations, heterogeneity, or imprecision.

<sup>c</sup>A group of individuals identified for subsequent study at an early uniform point in the course of the specified health condition or before the condition develops.

a strong recommendation than what might be expected with a recommendation. Options offer the most opportunity for practice variability.<sup>30</sup> Clinicians should always act and decide in a way that they believe will best serve their patients' interests and needs, regardless of guideline recommendations. Guidelines represent the best judgment from a team of experienced clinicians and methodologists addressing the scientific evidence for a particular topic.<sup>29</sup>

Making recommendations about health practices involves value judgments on the desirability of various outcomes associated with management options. Values applied by the GUG sought to minimize harm and diminish unnecessary and inappropriate therapy. A major goal of the GUG was to be

transparent and explicit about how values were applied and to document the process.

## Financial Disclosure and Conflicts of Interest

The cost of developing this guideline, including travel expenses of all panel members, was covered in full by the AAO-HNSF. Potential conflicts of interest for all panel members in the past 5 years were compiled and distributed before the first conference call. After review and discussion of these disclosures,<sup>31</sup> the panel concluded that individuals with potential conflicts could remain on the panel if they (1) reminded the panel of potential conflicts before any related discussion, (2) recused themselves from a

**Table 4.** Summary of Guideline Action Statements.

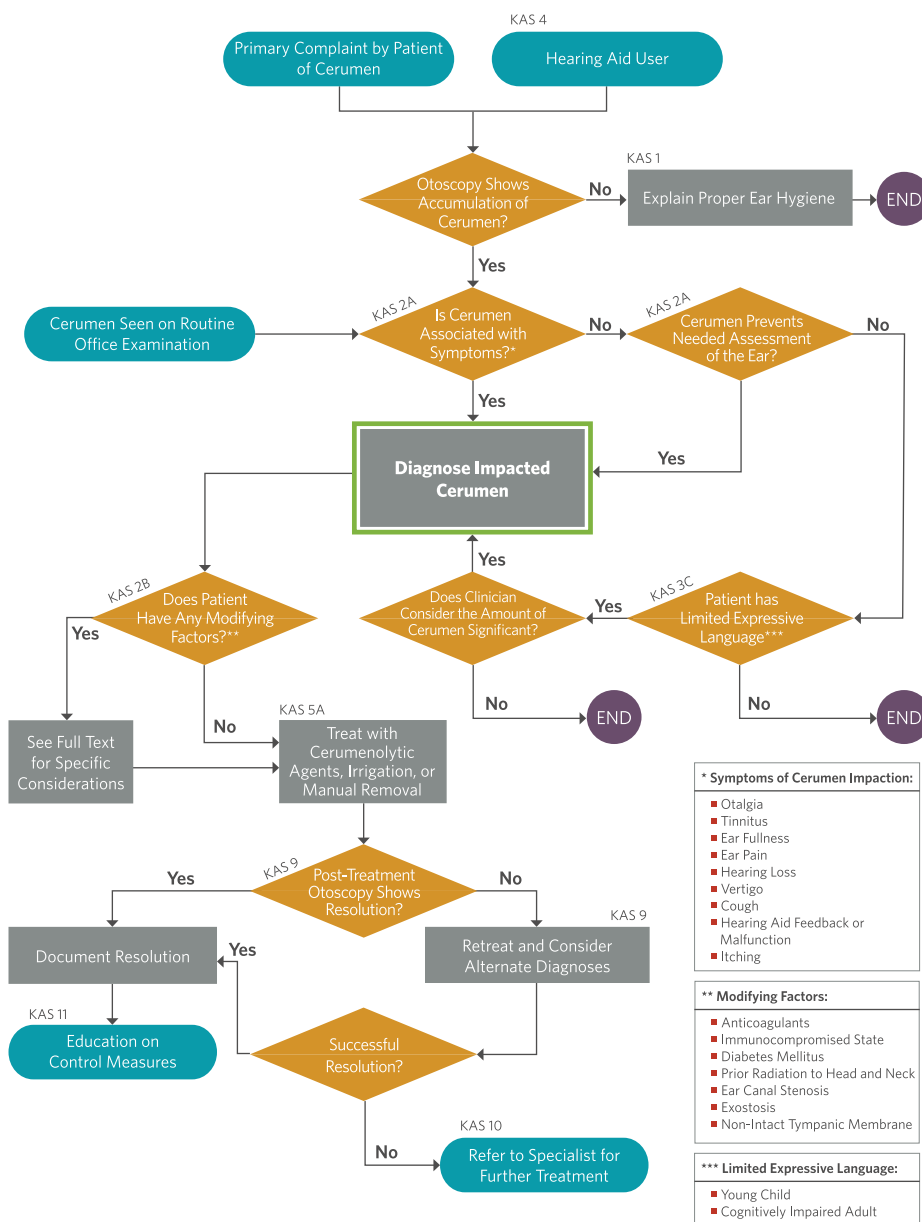
Statement	Action	Strength
1. Primary prevention	Clinicians should explain proper ear hygiene to prevent cerumen impaction when patients have an accumulation of cerumen.	Recommendation
2A. Diagnosis of cerumen impaction	Clinicians should diagnose cerumen impaction when an accumulation of cerumen, as seen on otoscopy, (1) is associated with symptoms, (2) prevents needed assessment of the ear, or (3) both.	Recommendation
2B. Modifying factors	Clinicians should assess the patient with cerumen impaction by history and/or physical examination for factors that modify management, such as $\geq 1$ of the following: anticoagulant therapy, immunocompromised state, diabetes mellitus, prior radiation therapy to the head and neck, ear canal stenosis, exostoses, nonintact tympanic membrane.	Recommendation
3A. Need for intervention if impacted	Clinicians should treat, or refer to another clinician who can treat, cerumen impaction when identified.	Strong recommendation
3B. Nonintervention if asymptomatic	Clinicians should not routinely treat cerumen in patients who are asymptomatic and whose ears can be adequately examined.	Recommendation
3C. Need for intervention in special populations	Clinicians should identify patients with obstructing cerumen in the ear canal who may not be able to express symptoms (young children and cognitively impaired children and adults), and they should promptly evaluate the need for intervention.	Recommendation
4. Intervention in hearing aid users	Clinicians should perform otoscopy to detect the presence of cerumen in patients with hearing aids during a health care encounter.	Recommendation
5A. Recommended interventions	Clinicians should treat, or refer to a clinician who can treat, the patient with cerumen impaction with an appropriate intervention, which may include $\geq 1$ of the following: cerumenolytic agents, irrigation, or manual removal requiring instrumentation.	Recommendation
5B. Contraindicated intervention (ear candling/coning)	Clinicians should recommend against ear candling/coning for treating or preventing cerumen impaction.	Recommendation
6. Cerumenolytic agents	Clinicians may use cerumenolytic agents (including water or saline solution) in the management of cerumen impaction.	Option
7. Irrigation	Clinicians may use irrigation in the management of cerumen impaction.	Option
8. Manual removal	Clinicians may use manual removal requiring instrumentation in the management of cerumen impaction.	Option
9. Outcomes assessment	Clinicians should assess patients at the conclusion of in-office treatment of cerumen impaction and document the resolution of impaction. If the impaction is not resolved, the clinician should use additional treatment. If full or partial symptoms persist despite resolution of impaction, the clinician should evaluate the patient for alternative diagnoses.	Recommendation
10. Referral and coordination of care	If initial management is unsuccessful, clinicians should refer patients with persistent cerumen impaction to clinicians who have specialized equipment and training to clean and evaluate ear canals and tympanic membranes	Recommendation
11. Secondary prevention	Clinicians may educate/counsel patients with cerumen impaction or excessive cerumen regarding control measures.	Option

related discussion if asked by the panel, and (3) agreed not to discuss any aspect of the guideline with industry before publication. Last, panelists were reminded that conflicts of interest extend beyond financial relationships and may include personal experiences, how a participant earns a living, and the participant's previously established "stake" in an issue.<sup>32</sup>

### Guideline Action Statements

Each evidence-based statement is organized in a similar fashion: a key action statement in bold, followed by the strength of the recommendation in italics and an action statement profile that explicitly states the quality improvement opportunity (and cor-

responding National Quality Strategy domain based on the original priorities),<sup>33</sup> aggregate evidence quality, level of confidence in evidence (high, medium, low), benefit, harms, risks, costs, and benefit-harm assessment. In addition, there are statements of any value judgments, the role of patient (caregiver) preferences, clarification of any intentional vagueness by the panel, exceptions to the statement, any differences of opinion, and a repeat statement of the strength of the recommendation. Several paragraphs subsequently discuss the evidence base supporting the statement. An overview of each evidence-based statement in this guideline can be found in **Table 4**, and the relationship among statements is illustrated in **Figure 3**.



**Figure 3.** Algorithm showing the interrelationship of guideline key action statements (KASs). The guideline does not apply to patients with cerumen impaction associated with the following conditions: dermatologic diseases of the ear canal; recurrent otitis externa; keratosis obturans; prior radiation therapy affecting the ear; previous tympanoplasty/myringoplasty, canal wall down mastoidectomy, or other surgery affecting the ear canal.

The role of patient preference in decision making deserves further clarification. For some statements, where the evidence base demonstrates clear benefit, although the role of patient preference for a range of treatments may not be relevant, clinicians should provide patients with clear and comprehensible information on the benefits and harms to facilitate understanding and shared decision making, which lead to better adherence and outcomes. In cases where evidence is weak or benefits are unclear, the practice of shared decision making—again, where the management decision is made by a collaborative effort between the clinician and an informed patient—is extremely useful. Factors related to patient preference include, but are not limited to, absolute benefits (numbers needed to treat), adverse effects (number

needed to harm), cost of drugs or procedures, and frequency and duration of treatment.

**STATEMENT 1. PRIMARY PREVENTION: Clinicians should explain proper ear hygiene to prevent cerumen impaction when patients have an accumulation of cerumen.** *Recommendation based on observational studies and a preponderance of benefit over harm.*

**Action Statement Profile for Statement 1**

- Quality improvement opportunity: Communicating safe preventive measures to patients (National Quality Strategy domain: patient and family engagement)



**Table 5.** Proper Care of Hearing Aids: Tips to Clean and Keep the Ear Canal Unobstructed.

1. Hearing aid users should have regular ear canal checks every 3 or 6 months.
2. Clean the wax trap in receiver-in-canal, completely-in-the-canal, in-the-canal, and in-the-ear hearing aids.
3. Replace the wax trap once per 3 months or whenever hearing aid is not working.
4. Those who use behind-the-ear hearing aids: detach the earmold from the hearing aid 1 ear at a time to avoid confusion that might arise due to switching of hearing aids.
5. Once the earmold is detached, soak it in mild soapy solution; do not use isopropyl alcohol, solvents, or oils to clean earmolds.
6. Clean the earmold, and rinse with water.
7. Dry the earmold, and remove any excess moisture or debris with a soft cloth or cotton ball.
8. If earmolds cannot be detached, wipe with a damp cloth to remove any visible earwax, or use a soft toothbrush or the brush provided with the hearing aids.
9. Check the earmold tube to be sure that it is clear before reattaching to hearing aid. If the tube is clogged, have it replaced by your hearing care professional.

<sup>a</sup>Adapted from Adams-Wendling et al (2008).<sup>84</sup>

- Aggregate evidence quality: Grade C, based on preponderance of survey studies and 1 prospective pilot study
- Level of confidence in evidence: Medium
- Benefit: Promote safe and effective self-care behaviors in ear hygiene; prevent self-inflicted harms, such as abrasions, cuts, and impaction; reduction in health care utilization
- Risks, harms, costs: Induced patient anxiety regarding an asymptomatic condition; time spent in counseling; potential for increased use of health care resources if self-cleaning with cotton-tipped applicators is abandoned
- Benefit-harm assessment: Preponderance of benefit
- Value judgments: Perception by the group that patients overmanipulate the ears (ie, cotton swab use) and that there is benefit in educating patients about proper ear hygiene
- Intentional vagueness: The term *proper ear hygiene* is used and is discussed in detail in the text. The term *accumulation* is used but not precisely defined, as it is up to the clinician to determine. This statement applies to patients with impacted cerumen and those who are at risk.
- Role of patient preferences: Small; patient can decline education
- Exceptions: None
- Policy level: Recommendation
- Differences of opinion: None

### Supporting Text

The purpose of this statement is to provide guidance to clinicians in educating patients on behaviors that promote safe and effective ear hygiene while minimizing self-inflicted harms, such as abrasions, cuts, and earwax impaction due to manipulation.

Ear hygiene is common in the United States and worldwide.<sup>4,34</sup> A number of survey studies have been conducted to assess the prevalence of self-ear cleaning and specific practices related to ear hygiene in various populations. In 2

studies, about 90% of respondents believed that ears should be cleaned; they also indicated that they clean their ears or their children's ears on a regular basis.<sup>34,35</sup> The most common reasons cited for ear hygiene practices were debris removal (dirt, dust, and wax), relief of itching, and cosmetic reasons.<sup>34,36</sup> The practice of cleaning one's ears has a strong familial influence, often beginning in childhood and continuing throughout adolescence into adulthood.<sup>35</sup> This suggests that clinicians need to include family members as well as the patient when discussing proper ear hygiene practices.

Cerumen production is a normal physiologic process. Preventive measures should be focused toward those individuals who are at greatest risk for developing occlusion and those with a history of impaction. Those particularly susceptible to cerumen impaction are children, the elderly, and the cognitively impaired.<sup>4</sup> Hearing aid users also have a higher incidence of impaction.<sup>37</sup> Several theories have been posed to explain this phenomenon, including overstimulation of cerumen production and impairment of normal cleaning mechanisms.<sup>3,5</sup> Therefore, the clinician should discuss proper care and cleaning of hearing aids with patients and caregivers (see **Table 5**).

Ear hygiene is commonly performed and is often incorporated into a person's daily hygienic routine.<sup>34,38</sup> Specific measures used to clean the ears range from washing the outer ear with soap and water to inserting objects into the ear canal (eg, bobby pins, cotton-tipped swabs, paper clips). Although empirical data are quite limited, consensus opinion from clinicians is that cerumen impaction may be exacerbated by using hearing aids and cotton-tipped swabs.<sup>39</sup> A higher incidence of cerumen has been reported in children whose ears were cleaned with cotton-tipped swabs.<sup>40</sup> One study found that inserting foreign objects into the ears was a common practice in >90% of health workers.<sup>41</sup> Although cotton buds were most commonly used, individuals also inserted ballpoint pen covers and tips, matchsticks, chicken feathers, and bobby pins into their ear canals to clean them. Approximately 9% reported injuries to their ears as a result of cleaning, including skin abrasions, eardrum perforation, and cerumen impaction.<sup>41</sup> In some countries, metal probes specifically designed for ear cleaning and wax removal at home are readily available and easy to purchase at markets and pharmacies.<sup>42</sup> While objects

**Table 6.** Frequently Asked Questions: Earwax Primary Prevention.

1. Is it necessary to treat your ears to prevent accumulation of earwax?	Prevention is best for certain groups of people, yet not everyone needs it. Among these who may be helped are the elderly, people with hearing aids, and those with a history of excessive earwax. Discussion with your doctor will help determine whether anything should be done for you.
2. What will happen if I just leave my ears alone and do not clean them?	Most people do not need a regular schedule for prevention of earwax accumulation. Some may find it necessary to have a cleaning procedure performed occasionally. Earwax is formed naturally by your body and helps protect your ear canal skin and kill germs. A doctor may find an excess of earwax at a regularly scheduled general checkup and perform a cleaning procedure.
3. What symptoms could be caused by excessive earwax?	Common complaints include itching, hearing problems, or a sense of fullness in the ear canal. Other problems that might occur include discharge, odor, cough, or ear pain.
4. Does it hurt to remove earwax?	The procedures used to remove earwax should not cause any pain. If you are putting a type of liquid into the ear, it may feel funny but should not hurt.
5. If earwax is removed, will my hearing get better?	The type of treatment used to prevent the buildup of wax in your ear should not usually affect your hearing. If your ear canal is completely or almost completely blocked by excess earwax, then removing the wax will allow your hearing to return to preimpaction levels.
6. How often should I remove wax from my ears?	There is no standard procedure for preventing earwax buildup, and for most people, nothing needs to be done unless excess wax develops. Ask your health care provider if there is anything special that you should do to prevent or reduce accumulation of earwax. There are several procedures with different periods for the treatment.
7. Is removing earwax expensive?	Most procedures use over-the-counter materials and are not expensive. Your health care provider can help with the choices.
8. Do cotton-tipped swabs remove wax from the ear?	Cotton-tipped swabs can remove some wax, but they often simply push the wax deeper into the ear and may worsen an impaction or traumatize the ear canal.
9. Whom can I see to clean my ears?	Many primary care clinicians have the ability to irrigate cerumen in their clinics. Alternatively, an otolaryngologist can remove obstructed cerumen.

for cleaning are ubiquitous, patients should be counseled not to insert any foreign objects into the ear canal, as these objects can cause injuries or worsen cerumen impaction by pushing cerumen deeper into the canal.

Susceptible patients can use some measures at home to control accumulation of cerumen. Common self-help measures include cerumenolytic drops and ear irrigations.<sup>43</sup> More information on frequently asked questions and patient education can be found in **Tables 6** and **7**.

**STATEMENT 2A. DIAGNOSIS OF CERUMEN IMPACTION: Clinicians should diagnose cerumen impaction when an accumulation of cerumen, as seen with otoscopy, (1) is associated with symptoms, (2) prevents needed assessment of the ear, or (3) both.** *Recommendation based on diagnostic studies with minor limitations and a preponderance of benefit over harm.*

#### Action Statement Profile for Statement 2A

- Quality improvement opportunity: Allow for accurate diagnosis and properly identify patients in need of treatment (National Quality Strategy domain: clinical processes/effectiveness)
- Aggregate evidence quality: Grade B for diagnostic studies with minor limitations regarding impact of cerumen on hearing and visualizations and grade C with respect to signs and symptoms associated with cerumen impaction
- Level of confidence in evidence: High

- Benefit: Identify individuals with cerumen impaction who require intervention, including those with otologic symptoms and those who require diagnostic assessment (raise awareness of the consequences of cerumen impaction—eg, cerumen impaction may prevent caloric stimulation during electronystagmography)
- Risks, harms, costs: Overdiagnosis of cerumen impaction based on symptoms as a criterion resulting in failure to identify another cause of the symptoms; no additional cost
- Benefit-harm assessment: Preponderance of benefit over harms
- Value judgments: Emphasis on clinical symptoms and signs for initial diagnosis; importance of avoiding unnecessary diagnostic tests; consensus on using the term *cerumen impaction* to imply cerumen that requires treatment
- Intentional vagueness: Symptoms are defined in the supporting text; prevention of needed assessments is defined by the clinician.
- Role of patient preferences: None
- Exceptions: None
- Policy level: Recommendation
- Differences of opinion: None

#### Supporting Text

The purpose of this statement is to identify patients who may be symptomatic from cerumen impaction, improve the accuracy of otologic examinations and diagnostic testing, and differentiate ears with healthy nonoccluding cerumen from those that need intervention.

**Table 7.** Patient Education: Dos and Don'ts of Cerumen (Earwax)

Do
1. Understand cerumen (earwax) is normal. Earwax not causing symptoms or blocking the ear canal should be left alone.
2. Understand symptoms of cerumen impaction (wax blocking the ear): decreased hearing, fullness, tinnitus, and distortion/changes to hearing aid function.
3. Seek medical evaluation if you have symptoms of hearing loss, ear fullness, and ear pain if you are not certain that they are from cerumen. Otitis media (fluid behind the eardrum), otitis externa (ear canal infection), and sudden inner ear hearing loss can all masquerade as cerumen impaction.
4. Ask your provider about ways that you can treat your cerumen impaction at home. You may have certain medical or ear conditions that may make some options unsafe.
5. Seek medical attention with ear pain, drainage, or bleeding. These are not symptoms of cerumen impaction and need further evaluation.
Don't
1. Overclean your ears. Excessive cleaning may irritate the ear canal, cause infection, and even increase the chances of cerumen impaction.
2. Put anything smaller than your elbow in your ear. Your mother was right! Cotton swabs, hair pins, car keys, toothpicks . . . these can all injure your ear and may cause a laceration (cut) in the ear canal, a perforation (hole) in the eardrum, and/or dislocation of the hearing bones, leading to hearing loss, dizziness, ringing, and other symptoms of ear injury.
3. Use ear candles. There is no evidence that they remove impacted cerumen, and candling can cause serious damage to the ear canal and eardrum.
4. Ignore your symptoms if home remedies are unsuccessful. Seek medical attention if attempts at home have not resolved the problem.
5. Irrigate or try cerumen-removing/softening drops if you have had ear surgery or a perforated eardrum, unless specifically cleared to do so by your otolaryngologist (ear, nose, and throat surgeon).
6. Forget to clean your hearing aids as the manufacturer and your hearing health professional recommend.

Although impaction implies 100% occlusion to many clinicians, we elected to use an operational definition for this guideline such that only problematic cerumen, even if it only partially occludes the canal, is considered impacted. Clinicians should diagnose cerumen impaction when an accumulation of cerumen causes symptoms, prevents needed assessment of the ear, or both. By this definition, cerumen in the ear canal is not considered “impacted” if it is not associated with symptoms or if an unobstructed view of the ear canal and tympanic membrane is not essential for patient care or diagnostic evaluation. Cerumen not meeting this definition of impaction requires no intervention (except in patients who are unable to report such symptoms; see below regarding at-risk patients).

Symptoms of cerumen impaction may include otalgia, tinnitus, fullness in the ear, pain, cough, and hearing loss.<sup>3,9,10</sup> Presence of any of these symptoms should prompt the clinician to examine the ear canal and, if cerumen is encountered, consider the diagnosis of impacted cerumen.

Additionally, some at-risk patients who cannot identify or express symptoms of cerumen impaction should be assessed. Some at-risk patients include elderly adults with concerns of dementia<sup>15,44</sup>; developmentally delayed or nonverbal patients with behavioral changes; and young children with fevers, parental concerns, or speech delay. The presence of cerumen in these patients can be considered impacted and removed.

Physical examination of the external canal can be performed with a handheld speculum, an otoscope<sup>8</sup> (Figure 4), or a binocular microscope. Cerumen may impair a clinician's ability to visualize the tympanic membrane and assess the status of the middle ear.<sup>45</sup> In a study examining a cohort of children ranging in age from 2 to 60 months, cerumen was removed in 89 (29%) of 279 children subsequently diagnosed with acute otitis media. While the data are limited, they suggest that cerumen can inhibit or

prevent diagnosis of middle ear disease. Accordingly, if cerumen impairs examination of the ear, it is defined as impacted.

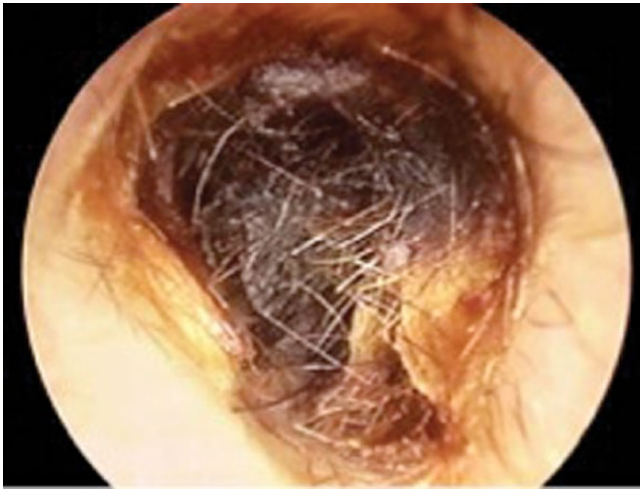
If cerumen is identified in the ear canal and may compromise auditory or vestibular testing, cerumen impaction is also diagnosed. The majority of audiologic tests cannot be performed accurately in the setting of complete or partial impaction; these tests include audiometry, immittance testing, electrocochleography, otoacoustic emissions, auditory brainstem responses, and real ear measurements during hearing aid fitting. Likewise, caloric testing for the assessment of vestibular function—during which warm or cool water or air is instilled into the ear canal—requires a clear and patent ear canal, as well as confirmation of an intact tympanic membrane, to be valid and safe. Of note, cerumen impaction does not meaningfully affect infrared tympanic temperature measurements.<sup>46</sup>

This operational definition is slightly different from that used by CPT Assistant but captures the same indications for intervention.<sup>47</sup>

**STATEMENT 2B. MODIFYING FACTORS:** Clinicians should assess the patient with cerumen impaction by history and/or physical examination for factors that modify management, such as  $\geq 1$  of the following: anticoagulant therapy, immunocompromised state, diabetes mellitus, prior radiation therapy to the head and neck, ear canal stenosis, exostoses, nonintact tympanic membrane. *Recommendation based on observational studies with a preponderance of benefit over harm.*

#### Action Statement Profile for Statement 2B

- Quality improvement opportunity: Avoiding harms from intervention in people at increased risk based



**Figure 4.** Otoscopic view of impacted cerumen, mixed with hair, completely obstructing the ear canal.<sup>8</sup>

on patient characteristics (National Quality Strategy domain: Patient safety)

- Aggregate evidence quality: Grade C, recommendations regarding diabetes mellitus and prior radiation therapy; Grade D, recommendations regarding immunocompromised state, anticoagulation, and anatomic abnormalities of the ear canal and tympanic membrane
- Level of confidence in evidence: Medium
- Benefits: Reduce complications
- Risks, harms, costs: Time of the assessment
- Benefit-harm assessment: Preponderance of benefit over harm
- Value judgments: Consensus that identifying modifying factors will improve outcomes
- Intentional vagueness: None
- Role of patient preferences: None
- Exceptions: None
- Policy level: Recommendation
- Differences of opinion: None

### Supporting Text

The purpose of this statement is to identify patient-specific and anatomic factors that may alter the management of cerumen impaction to achieve safer outcomes. The initial approach to the patient with cerumen impaction should include an assessment of complicating factors by both history and physical examination. Failure to identify such factors may lead to suboptimal care, harm, or inappropriate interventions.

Medical factors that should influence treatment choice for managing cerumen impaction include coagulopathy, immunocompromised state, and previous head and neck radiation. Anatomic factors, either congenital or acquired, can complicate the treatment of cerumen impaction. These factors may include ear canal shape and size, as well as abnormalities of the tympanic membrane.

Coagulopathies may include extrinsic or intrinsic abnormalities to clotting. History taking should include queries for antiplatelet therapy, anticoagulation medications, hepatic or renal failure, thrombocytopenia, and hemophilia. These patients should be counseled about increased risk of ear bleeding, and special care should be taken to reduce the likelihood of abrading or bruising the ear canal.

Clinicians should elicit histories of conditions that may compromise immune functioning, such as diabetes mellitus, renal failure, prior organ transplant, concurrent chemotherapy, HIV/AIDS, and immunomodulating drugs. Such individuals may be at higher risk for postprocedure otitis externa, especially when irrigation is employed.

Irrigation with tap water has been implicated as an etiologic factor in several studies of necrotizing (malignant) external otitis (osteomyelitis of the ear canal).<sup>48-51</sup> Immunocompromised AIDS patients have also been reported to be at risk of necrotizing otitis externa.<sup>52,53</sup> Driscoll et al demonstrated that the pH of diabetic cerumen is significantly higher than in persons without diabetes, which may facilitate the growth of pathogens.<sup>54</sup> Clinicians who utilize irrigation in this patient population must be especially careful to minimize trauma, consider using ear drops to acidify the ear canal postirrigation, and provide close follow-up.

Prior history of head and neck radiation should be elicited in the history taking of the patient with possible cerumen impaction. Targeted radiation to any site in the head and neck may deliver a radiation dose sufficient to permanently affect the external auditory canals. Radiated external auditory canals undergo histologic changes, including epithelial thinning and atrophy of the ceruminous glands.<sup>55</sup> The resulting cerumen is drier, more tenacious cerumen/keratin debris that requires delicate debridement. Injury to the ear canals may be slow or difficult to heal and could lead to osteoradionecrosis (ORN) of the ear canal and temporal bone. Underlying ORN may present as recurrent cerumen impaction, and so specific care must be taken at the time of treatment to determine the health of the external auditory canal after successful disimpaction. The onset of ORN of the temporal bone appears to be correlated with the radiation dose to the temporal bone itself, not the target, and may range from 1 year to decades posttreatment.<sup>56</sup> Radiation to the parotid gland, nasopharynx, and preauricular skin are noted in 2 contemporary case series as the most common radiation targets leading to ORN of the temporal bone.<sup>56,57</sup>

The presence of dermatologic conditions such as eczema, seborrheic dermatitis, and ectodermal dysplasia can complicate management of cerumen. While data are limited, these conditions can increase the frequency of cerumen impaction and the risk of otitis externa if present.<sup>47</sup>

Narrowing of the ear canal limits visualization and increases the likelihood of trauma. A narrow ear canal makes both irrigation and manual instrumentation more difficult to perform. Narrow canals can be found in otherwise normal subjects, in addition to patients with craniofacial disorders, Down syndrome, chronic external otitis, and posttraumatic states (including surgical).

Stenosis may be congenital or acquired. Congenital stenosis may involve both the lateral portion (cartilaginous) and the medial bony ear canal. Stenoses vary in severity from mild

constriction of the external auditory canal to complete atresia. Safe and effective irrigation is not always possible in patients with narrow or stenotic ear canals. Specialized equipment and procedures may be required to safely remove cerumen in these patients.

Diffuse exostoses and solitary osteomas of the external auditory canal are acquired bony growths that may severely limit the patency of the ear canal and may trap cerumen and keratin debris in the bony canal. These lesions may also prevent adequate visualization of the tympanic membrane. Exostoses are broad-based hyperostotic lesions that are typically multiple, bilateral, located in the medial ear canal near the eardrum, and associated with prior history of cold-water swimming.<sup>58</sup> Osteomas are less common. They are usually lateral in the bony ear canal, solitary, unilateral, and pedunculated.<sup>59</sup>

A perforated tympanic membrane or patent tympanostomy tube likewise limits the options available for cerumen removal. The suspicion of a nonintact tympanic membrane should be assessed by history and/or physical examination prior to selection of a disimpaction technique. Previous history of tympanic membrane perforation, any prior ear surgery, intratympanic injections, tympanostomy tubes, or barotrauma should prompt the clinician to suspect a nonintact eardrum and utilize disimpaction techniques other than irrigation. In addition, use of irrigation in the presence of a perforated tympanic membrane could produce caloric effects, resulting in vertigo. Some agents can also be toxic to the middle or inner ear. Mechanical removal of cerumen is the preferred technique when eardrum perforation is suspected.

Current otitis externa should also be identified by history or examination. If the ear canal is currently infected, irrigation should be avoided. Pain can be a presenting symptom of cerumen impaction but is not common and should alert the clinician to the possibility of infection or other pathology. If pain is present, the clinician should take care to assess the ear for signs of infection or other pathology prior to selecting a method of cleaning.

**STATEMENT 3A. NEED FOR INTERVENTION IF IMPACTED: Clinicians should treat, or refer to another clinician who can treat, cerumen impaction when identified.** *Strong recommendation based on RCTs with heterogeneity and with a preponderance of benefit over harm.*

#### Action Statement Profile for Statement 3A

- Quality improvement opportunity: Prioritize patients for intervention (National Quality Strategy domain: clinical processes/effectiveness)
- Aggregate evidence quality: Grade B, RCTs with heterogeneity
- Level of confidence in the evidence: High
- Benefits: Improved hearing and symptom relief compared with no treatment
- Risks, harms, costs: Potential complications related to treatment; direct cost of managing the impaction
- Benefit-harm assessment: Preponderance of benefit over harm

- Value judgments: None
- Intentional vagueness: None
- Role of patient preferences: Small
- Exceptions: None
- Policy level: Strong recommendation
- Differences of opinion: None

#### Supporting Text

The purpose of this statement is to specify under what circumstances cerumen should be removed.

Cerumen impaction has been associated with itching, ear pain, discharge from the ear canal, ear fullness, cough, hearing loss, tinnitus, and cognitive impairment in elderly patients.<sup>15</sup> Removing impacted cerumen can improve hearing.<sup>9,15,19,60</sup> If the patient has relevant symptoms (pain, tinnitus, hearing loss, aural fullness, or vertigo) and the ear is impacted with cerumen, cerumen impaction may be a contributing factor for the symptoms.

Screening studies show that cerumen impaction is a frequent reversible cause of hearing loss.<sup>11,61,62</sup> A randomized community-based screening study in Oman determined that 2.7% of the population had a unilateral hearing impairment. Of those who were identified with a unilateral hearing loss, 54% were deemed to have a “mild” impairment (hearing threshold, 26–40 dB), and half of that group had resolution of hearing loss after simply clearing the ear canal of cerumen at the time of screening.<sup>61</sup> In another study, residents at a privately owned intermediate care facility for the mentally retarded were examined annually over a 12-year period.<sup>11</sup> When examiners discovered patients with a new conductive hearing loss (>10-dB air-bone gap at  $\geq 2$  frequencies) and a complete or near-complete ear canal occlusion by cerumen, the conductive hearing deficit resolved after the impactions were removed. In an uncontrolled study of 125 consecutive patients who had been referred by general practitioners to an ear-syringing clinic in Bristol, United Kingdom, those who presented with difficulty hearing on the phone, ear pain, or “blocked ears” reported improvement or resolution of their symptoms 62% to 75% of the time after undergoing ear irrigation.<sup>60</sup> Forty to fifty percent of those who complained of itching or dizziness reported improvement after ear lavage.

Of note, while cerumen impaction may be the cause of reversible hearing loss, hearing acuity does not diminish until the cross-sectional area of the ear canal is reduced by at least 80%.<sup>63</sup> Accordingly, partial occlusion may not be the cause of hearing loss.

Older patients are often unaware that they have cerumen impaction or that removal of the impaction may improve their hearing.<sup>13,18,19,64</sup> In a random sample of 226 patients aged >65 years who were admitted to the nonintensive care units of a hospital in the United States, 35% had a cerumen impaction that blocked visualization of the tympanic membrane of 1 or both ears. After lavage with otoscopic confirmation of clearing, repeat hearing tests showed that subjects had improved hearing at several frequencies. There was no change in the control patients who were not impacted. Regardless of whether the subjects had cerumen impaction or not, the majority had

been unaware of their hearing deficits and had rated their hearing ability as either “good” or “fair.”<sup>19</sup> Accordingly, in older patients, directed history and ear examination are warranted to identify an impaction.

A study of cerumen removal in elderly subjects showed an improvement in cognitive performance when intelligence was assessed with the Raven’s standard progressive matrices test, which requires deductive reasoning.<sup>65</sup> Symptoms of irritation, pressure, and fullness in the ears improved as well; however, there was no change in perceived hearing loss.

The presence of cerumen may also hinder or prevent visual assessment of the ear canal and tympanic membrane. This is especially important as it relates to children who present with ear-related symptoms and in whom clinicians need to diagnose and treat acute otitis media and otitis media with effusion.<sup>66</sup> Most studies of interventions to remove cerumen impaction do not explicitly describe improved visualization of the tympanic membrane as an outcome, although ears may be described as “completely cleared.”<sup>12,67</sup> One exception is a study of emergency room patients aged 1 to 81 years who presented with suspected ear problems and in whom visualization of the tympanic membranes was partially or totally obscured by cerumen. After instillation of docusate sodium, followed by irrigation if necessary, there was full visualization 81% of the time.<sup>68</sup>

Additionally, as described in key action statement 2A, cerumen impaction can interfere with necessary audiometric and vestibular testing. Cerumen should be removed in this situation.

**STATEMENT 3B: NONINTERVENTION IF ASYMPTOMATIC: Clinicians should not routinely treat cerumen in patients who are asymptomatic and whose ears can be adequately examined.** *Recommendation against based on control groups in randomized trials and observational studies and a preponderance of benefit over harms.*

#### Action Statement Profile for Statement 3B

- Quality improvement opportunity: Avoidance of harm, efficient use of health care resources (National Quality Strategy domains: patient safety and efficient use of health care resources)
- Aggregate evidence quality: Grade C, control groups in randomized trials and observational studies
- Level of confidence in the evidence: Medium
- Benefits: Avoid unnecessary treatment with potential adverse events and costs
- Risks, harms, costs: Potential progression to impaction
- Benefit-harm assessment: Preponderance of benefit over harms
- Value judgments: The presence of cerumen is not in itself harmful, and it may not progress to impaction; in fact, it may resolve spontaneously. If it progresses, it can be managed at that time.
- Intentional vagueness: The word *routinely* was added to this statement to acknowledge that there may be

circumstances where cerumen removal may be offered anyway, as in a patient with hearing aids.

- Role of patient preferences: Substantial role for shared decision making. The patient may still opt for removal of the cerumen.
- Exceptions: Medical reasons for exceptions to this statement include, but are not limited to, history of recurrent cerumen impaction.
- Policy level: Recommendation against
- Differences of opinion: None

#### Supporting Text

The purpose of this statement is to affirm that cerumen that is not causing symptoms or impeding assessment can safely be left alone.

Cerumen is a naturally occurring product of the ear canal that serves as a self-cleaning agent with protective, emollient, and bactericidal properties.<sup>10</sup> The normal lateral migration of epithelium in the external auditory canal is responsible for the ear’s self-cleaning mechanism. Most cerumen is asymptomatic and does not impair necessary physical examination.<sup>3</sup> It is important that patients understand that cerumen does not always need to be removed.

Epithelial cells move off the tympanic membrane and then travel down the ear canal toward the meatus of the external canal. Cerumen migrates toward the entrance of the canal. Foreign bodies, such as dirt, dust, and other small particles, adhere to cerumen and are extruded with the cerumen when it is cast off from the canal.<sup>10</sup> This “conveyor belt” process is an ongoing process in most individuals.<sup>6</sup>

Since cerumen is naturally extruded from the ear canals of most people and spontaneous clearing of significant impactions occurs frequently, observation over time can be offered as reasonable management. There have only been limited studies investigating the outcome of observing cerumen in the ear canal. Keane et al performed a small randomized controlled study of the use of solvents to disperse cerumen in the impacted ears of general practice patients in Dublin.<sup>67</sup> After 5 days, 5% of patients in the control group demonstrated complete cleaning of the ear and 26%, moderate cleansing, when managed with observation alone without any intervention. In another study, developmentally delayed individuals in a residential facility who had 50% to 80% of their external canal occluded by cerumen but no related conductive hearing loss had no intervention and were examined after a year.<sup>11</sup> At the follow-up examination, 44% had no cerumen; 53% still had the same amount but no conductive hearing loss; and only 3% progressed to impaction with associated hearing loss.

Additionally, cerumen affects some but not all diagnostic studies of the ear and hearing. Specifically, cerumen does not appear to interfere significantly with temperature measurement based on infrared ear devices. In a prospective study of 333 patients in a Swiss emergency room, cerumen impaction was found in 73 of 666 ears examined (11% of ears). Ear temperature measurement increased only 0.2°C after the cerumen removal. This difference had no clinically significant effect on decision making.<sup>46</sup>

While symptomatic cerumen may require intervention, cerumen may not affect studies involving the ear. Specifically, intervention for cerumen is not necessary for temperature measurements.

**STATEMENT 3C. NEED FOR INTERVENTION IN SPECIAL POPULATIONS: Clinicians should identify patients with obstructing cerumen in the ear canal who may not be able to express symptoms (young children and cognitively impaired children and adults), and they should promptly evaluate the need for intervention.** *Recommendation based on cohort and observational studies with a preponderance of benefit over harm.*

### Action Statement Profile for Statement 3C

- Quality improvement opportunity: Efficient use of health care resources and coordination of care (National Quality Strategy domains: care coordination and efficient use of health care resources)
- Aggregate evidence quality: Grade C, cohort and observational studies
- Level of confidence in the evidence: High
- Benefits: Improved hearing and functional health status; improved evaluation of external auditory canal, tympanic membrane, and middle ear
- Risks, harms, costs: Potential overtreatment of cerumen that is asymptomatic; evaluation and treatment costs; substantial administrative burden in settings with a high prevalence of cognitively impaired individuals, such as nursing homes and institutional facilities
- Benefit-harm assessment: Preponderance of benefit over harm
- Value judgments: Importance of identifying and treating cerumen impaction in special populations
- Intentional vagueness: The term *young children* does not specify age but rather indicates children who are unable or too immature to express symptoms or who fail to disclose real symptoms out of fear of treatment. Additionally, the term promptly does not specify a time frame but allows for clinical judgment regarding how expedient the evaluation should be.
- Role of patient preferences: None for the patient but moderate for patient advocates
- Exceptions: None
- Policy level: Recommendation
- Differences of opinion: None

### Supporting Text

The purpose of this statement is to make providers aware of patient populations that may not be able to report symptoms of cerumen impaction but would benefit from evaluation and treatment.

Elderly patients, young children, and the cognitively impaired are at high risk for cerumen impaction and may be unaware of it or unable to express the symptoms associated with it. The hearing loss associated with cerumen impaction

may further impair cognitive function. Furthermore, cerumen may obstruct the examiner's view of the external auditory canal, tympanic membrane, and middle ear, limiting accurate diagnosis and treatment of pathology in these areas. It is important to educate these patients and their caregivers regarding cerumen impaction and its symptoms, as well as the potential risks and benefits of cerumen removal. Caregivers may be more able to report symptoms to providers than the patients themselves.

A higher incidence of cerumen impaction in these populations is well documented.<sup>11,15,18,19,69-72</sup> The specific reasons are not clear: they may be related to the size of the external auditory canal in children and the developmentally delayed, or they may stem from changes in the skin of the external auditory canal in elderly patients. A study of 107 children with Down syndrome who were referred to otolaryngologists showed that 39% had stenosis of the external auditory canal frequently complicated by cerumen impaction.<sup>73</sup> A longitudinal study of 117 developmentally delayed adult patients followed over a 12-year period demonstrated a high incidence of recurrent cerumen impactions in this population.<sup>11</sup> Data on recurrence rates are not available for children or elderly patients. Some elderly and developmentally delayed patients reside in nursing homes or institutions. Cerumen impaction rates appear higher for institutionalized patients.<sup>15,74</sup> Patients in these settings may also suffer more baseline cognitive impairment than similar, ambulatory populations.

Impaired cognitive function in the elderly may prevent them from recognizing hearing loss or other symptoms and may impair their ability to bring symptoms to the attention of caregivers. A study screening asymptomatic elderly patients admitted to nursing homes<sup>15</sup> and one screening 755 asymptomatic developmentally delayed athletes<sup>70</sup> found relatively high levels of cerumen impaction and significant hearing loss in these populations. Small children may also lack the maturity to recognize hearing loss or bring ear problems to the attention of their caregivers. Children may also underreport or deny symptoms due to fear of examiners or examination. A cross-sectional study of nearly a thousand 4- to 5-year-old black and India children attending preschools in South Africa found that conductive hearing loss from cerumen impaction caused >10% of children to fail hearing screening.<sup>75</sup>

No RCTs have compared hearing in patients in these populations who have or have not been evaluated and treated for cerumen impaction. A case-control study of 226 hospitalized elderly patients, with each patient acting as his or her own control, demonstrated an incidence of cerumen impaction of 35% and a statistically significant improvement in hearing among those patients who had an impaction removed.<sup>19</sup> A survey study of >14,000 elderly people in England found that 10% of people who initially failed a hearing screening passed after cerumen removal.<sup>76</sup> A small cohort study of elderly patients admitted to nursing homes found that 65% of patients had cerumen impaction and that removal of the cerumen resulted in a statistically significant improvement in hearing and cognitive function, as demonstrated by a Mini-Mental Status Examination.<sup>15</sup> However, a strong conclusion cannot be

made due to a small sample size (N = 29). In addition, there are no data on the impact of cerumen-induced hearing loss on cognitive function in children.

Cerumen removal in this group of patients can be challenging. Care must be taken to avoid harm. Use of an assistant may be adequate, but in rare circumstances sedation may be needed (see key action statement 10).

**STATEMENT 4. INTERVENTION IN HEARING AID USERS: Clinicians should perform otoscopy to detect the presence of cerumen in patients with hearing aids during a health care encounter.** *Recommendation based on cohort and observational studies with a preponderance of benefit over harm.*

#### Action Statement Profile for Statement 4

- Quality improvement opportunity: Effective use of health care resources and prevention of problems with hearing aid use in high-risk populations (National Quality Strategy domains: efficient use of health care resources and clinical processes/effectiveness)
- Aggregate evidence quality: Grade C, observational studies
- Level of confidence in the evidence: High
- Benefits: Prevent hearing aid dysfunction and associated repair costs
- Risks, harms, costs: Overtreatment of asymptomatic cerumen
- Benefit-harm assessment: Preponderance of benefit over harm
- Value judgments: Cerumen can have a disproportionate effect on patients with hearing aids due to their underlying hearing loss and the impact of the cerumen on the hearing aids, even if there is not an actual impaction.
- Intentional vagueness: The term *health care encounter* is somewhat vague but is intended to indicate any time that a patient with a hearing aid is assessed by a health care worker.
- Role of patient preferences: Small
- Exceptions: None
- Policy level: Recommendation
- Differences of opinion: None

#### Supporting Text

The purpose of this statement is to make clinicians aware of how hearing aids affect cerumen accumulation and impaction and how cerumen can impair the functioning of hearing aids.

The normal self-cleaning process of cerumen can be disturbed by the presence of objects such as hearing aids or ear plugs.<sup>10,77,78</sup> Perry suggested that the presence of foreign objects such as hearing aids and ear plugs can cause stimulation of cerumen glands, leading to excessive cerumen production and he termed this process “mechanical milking.”<sup>78</sup> Coupled with the obstruction of the lateral canal by the presence of the aid, hearing aid users are at increased risk for

cerumen impaction. Furthermore, the combination of cerumen impaction and hearing aid use may alter external auditory canal bacterial flora to include pathogens that can increase the risk of otitis externa.<sup>79-81</sup>

The clinician should examine patients with hearing aids for impacted cerumen during a health care encounter. Examination is accomplished by removing the hearing aid and inspecting the ear canal with a handheld otoscope or binocular microscope. If the patient has bilateral hearing aids, the second ear is examined after replacing the first hearing aid to facilitate communication. Users of hearing aids should visit a primary care physician or audiologist any time that a change in performance is noticed.

Cerumen impaction may change hearing aid performance. Irrespective of the type of hearing aid being worn, cerumen impaction can reduce the intensity of the sound reaching the tympanic membrane by as much as 10 to 15 dB in the mid- to high frequencies.<sup>77</sup> If hearing aid malfunction is suspected, then the patient should be referred to an audiologist for formal assessment of the hearing aid. In addition, even a partial impaction can change the resonance properties of the ear canal, reducing mid- and high-frequency perception.<sup>82</sup>

Current estimates from various hearing aid manufacturers indicate that 60% to 70% of all hearing aids sent for repair are damaged as a result of contact with cerumen.<sup>83</sup> If an in-the-ear instrument is utilized, cerumen can enter the vent or receiver. The resulting added mass of cerumen on the receiver diaphragm causes low-output distortion and loss of high-frequency response. A more insidious process occurs as the acidic compounds within the cerumen slowly deteriorate the diaphragm suspension, resulting in receiver failure.

Cerumen in the ear canal can cause the hearing aid to fit poorly and not seal properly. If the hearing aid fits poorly, sound produced by the aid passes around it and out of the ear canal, where it is picked up by the microphone and reamplified. A positive feedback loop is created, and audible high-pitched feedback results. Cerumen removal eliminates feedback due to excess cerumen.

The percentage of hearing aid users with impaction is higher than the general population. Additionally, the cerumen migration is disrupted by the aid, causing the cerumen to be trapped and accumulate in the canal. A management protocol<sup>84</sup> is described in **Table 5**.

**STATEMENT 5A. RECOMMENDED INTERVENTIONS: Clinicians should treat, or refer to a clinician who can treat, the patient with cerumen impaction with an appropriate intervention, which may include  $\geq 1$  of the following: cerumenolytic agents, irrigation, or manual removal requiring instrumentation.** *Recommendation based on RCTs and observational studies, with a preponderance of benefit over harm.*

#### Action Statement Profile for Statement 5A

- Quality improvement opportunity: Engage patient and family; promote the use of effective therapy (National Quality Strategy domains: patient and family engagement and clinical processes/effectiveness)



- Aggregate evidence quality: Grade B, RCTs with limitations and cohort studies
- Level of confidence in the evidence: High
- Benefits: Improved cerumen removal by using effective therapies and avoiding harm from ineffective or untested therapies
- Risks, harms, costs: Specific adverse effects related to treatments used; no cost associated with the decision to use appropriate therapy
- Benefit-harm assessment: Preponderance of benefit over harm
- Value judgments: Therapy should be effective and minimize harm
- Intentional vagueness: This does not specify one method as superior, as studies have not compared them head-to-head and all may be effective.
- Role of patient preferences: Large
- Exceptions: Irrigation and cerumenolytics should not be used in the setting of a nonintact tympanic membrane.
- Policy level: Recommendation
- Differences of opinion: None

### Supporting Text

The purpose of this statement is to encourage safe and effective methods managing impacted cerumen. Details of each treatment are enumerated in key action statements 6, 7, and 8.

**Appropriate Interventions for Cerumen Impaction.** In the symptomatic patient, the goal of intervention is to help alleviate or relieve the symptoms (pain, fullness, hearing loss, tinnitus, etc). In the asymptomatic patient with impacted cerumen, the goal is to allow visualization of the ear canal and the tympanic membrane or perform audiometric or vestibular evaluations. Several methods for achieving these goals are widely used. However, evidence in the literature that clearly identifies the superiority of one therapeutic option versus another is lacking.

Three effective therapeutic options are widely used: (1) irrigation, (2) cerumenolytic agents, and (3) manual removal requiring instrumentation. Combining  $\geq 1$  of these options on the same day or at intervals is routinely used in everyday practice.<sup>85</sup> There are no comparative randomized clinical trials addressing the relative effectiveness of the 3 methods.<sup>86</sup> **Table 8** gives an overview of these methods in the form of a shared decision grid for patients and caregivers.<sup>87</sup>

Irrigation (also referred to as *ear syringing*) involves flushing the wax out by a jet of warm water (ideally at body temperature). This is generally safe and effective but does carry the small risk of perforation of the eardrum.<sup>88</sup> Irrigations should be avoided in certain at risk populations (see key action statement 2B).

Cerumenolytics, or wax-softening agents, are used to disperse the cerumen and reduce the need for syringing or for manual removal of the impaction. Cerumenolytics can be used alone or in combination with irrigation or manual removal. A

Cochrane review demonstrated the effectiveness of cerumenolytic drops but did not find any significant difference among agents. In fact, none were superior to water.<sup>89</sup>

Manual removal includes the use of ear cures, probes, hooks, forceps, or microsuction. This method is generally safe and effective but can abrade the ear canal. If the suction device becomes partially occluded, it can generate excessive noise in the ear canal and potentially lead to tinnitus or hearing loss.<sup>90</sup>

These methods can also be combined to increase effectiveness. Irrigation or manual removal can be combined with softening the impacted cerumen. No direct comparison has been performed between (1) same-day, in-office softening followed by irrigation or manual removal and (2) home softening followed by irrigation and manual removal.

Since there is no demonstrated advantage of one method over another, the treatment method used should depend on (1) the available resources, (2) experience of the treating clinician with the available options, (3) the ease with which the canal can be cleared, and (4) shared decision making. Recently, Clegg et al<sup>91</sup> performed a systematic review and cost-effectiveness analysis of published articles from 2008 to 2010 on the effectiveness of softening and/or removing earwax in adults and children. They identified 24 studies that met their criteria of earwax removal with softening, irrigation, mechanical removal, and other methods and combinations of these methods. They determined that (1) softening by any agent was more effective than no softening for earwax removal and (2) removal by a nurse practitioner/professional was better than self-irrigation.

**Interventions Not Recommended to Treat Cerumen Impaction.** Interventions that are not appropriate for cerumen removal include home use of oral jet irrigators and cotton-tipped swabs.<sup>92</sup> Removing cerumen with an oral jet irrigator was described by Larsen.<sup>93</sup> Flared tip and OtoClear Tip are promoted as safer tips to eliminate overinsertion and direct the water away from the tympanic membrane, theoretically avoiding the risk of injury by reducing the buildup of pressure causing damage or pain. Research demonstrating the effectiveness of these home therapeutic options is lacking. Expert opinion favors the 3 clinician-administered methods discussed above as the most safe and effective options.

Expert opinion recommends against the use of cotton-tipped swabs to remove cerumen from the ear canal, although the evidence against it is sparse. The product label of one of the leading manufacturers of cotton-tipped swabs specifically notes that the product should not be placed into the ear canal. The cotton buds at the end of cotton-tipped applicators may separate, requiring removal as a foreign body.<sup>92</sup> One case report did report fatal otogenic meningitis and brain abscess due to retained cotton swabs.<sup>94</sup>

In a prospective study, Lee et al showed that complications do arise from self-cleaning of the external auditory canal.<sup>42</sup> Thirty-six percent of the patients cleaned their ears by introducing a foreign object into the ear. Unfortunately, the

**Table 8.** Shared Decision Grid for Patients and Caregivers for Cerumen Management.<sup>87</sup>

Frequently Asked Questions	Observation (KAS 3b)	Cerumenolytic Agents (KAS 6)	Irrigation (KAS 7)	Manual Removal (KAS 8)
Are there any age restrictions?	No	Yes—not recommended for ages <3 years and in patients with nonintact ear drums	No—but small children may be noncooperative	No—but small children may be noncooperative
What does it involve?	See provider periodically to examine the ear canal	Instill several drops of earwax-softening products once or twice daily for 3 to 5 days	Cleaning the ear canal with water to flush out the earwax	Earwax is removed by the clinician inserting a curette, forceps, or suction tip into the ear, dislodging the wax, and retracting it
How long does the treatment take?	Time to examine the ear canal	<5 minutes to instill drops	Should not take >30 minutes (includes preparation time)	The procedure takes a few minutes and does not need anesthesia
What are the benefits?	Reduce unneeded treatment	Noninvasive, done at home, avoid clinician visits	Immediate resolution of symptoms caused by the cerumen impaction; self-irrigation can also be done at home	Immediate resolution of symptoms caused by the cerumen impaction
What are the potential risks and side effects?	Small amount of cerumen could progress to impaction	None reported	Temporary dizziness, pain, and/or eardrum rupture	Trauma to the ear canal skin leading to bleeding or infection; discomfort from the instruments or noise of the suction; and/or rare tinnitus or hearing loss from the noise of the suction
What usually happens in the long term?	Nothing	Cerumen may reaccumulate and require additional treatment	Cerumen may reaccumulate and require additional treatment	Cerumen may reaccumulate and require additional treatment
Are there any special precautions?	None at this time	Should seek medical attention if excessive pain or discomfort or loss of hearing is noticed	Not recommended for patients with pressure equalization tubes, nonintact eardrum, and susceptibility to ear infection (see KAS 2B)	Cautious when treating patients who are taking blood thinners and susceptible to bleeding easily

Abbreviation: KAS, key action statement.

majority of the patients in that study were not willing to change their habits for a safer method of cleaning.

A nonrandomized comparison of earwax removal with a “do it yourself” ear vacuum kit versus the conventional manual method of removal by a clinician with a Jobson-Horne probe concluded that the probe is significantly more effective than an ear vacuum for the removal of earwax.<sup>95</sup>

The most popular alternative practice for cerumen removal is ear candling, also known as “ear coning” or “thermo-auricular therapy.” This is ineffective and potentially dangerous and should not be used.<sup>96</sup> See key action statement 5B for more information.

**STATEMENT 5B: CONTRAINDICATED INTERVENTION (EAR CANDLING/CONING): Clinicians should**

**recommend against ear candling/coning for treating or preventing cerumen impaction.** *Recommendation against based on RCTs and observational studies with a preponderance of benefit over harm.*

**Action Statement Profile for Statement 5B**

- Quality improvement opportunity: Reducing harm and avoiding ineffective treatments (National Quality Strategy domain: patient safety and clinical processes/effectiveness)
- Aggregate evidence quality: Grade C
- Level of confidence in evidence: Medium
- Benefits: Avoid ineffective therapy; avoid harms; cost savings; prevent delay of effective therapy
- Risk, harm, cost: None

- Benefit-harm assessment: Preponderance of benefit
- Value judgments: Strong consensus of the group to avoid potentially harmful and costly therapies with no proven benefit
- Intentional vagueness: None
- Role of patient preferences: None
- Exclusions: None
- Policy level: Recommendation against
- Differences of opinion: None

### Supporting Text

The purpose of this statement is to make practitioners and patients aware of the ineffectiveness and risks associated with ear candling/coning for cerumen removal.

Ear candling for cerumen removal uses a hollow candle that is burned with one end in the ear canal, with the intent of displacing cerumen. The procedure can be self-administered or performed by an assistant. The candles are made with beeswax, honey extract, essential oils, and organic linen.<sup>97</sup> A dark brown waxy substance purported to be cerumen plus external auditory canal debris is left in the stub of the candle. Ear candles have been used in children<sup>98</sup> and adults.<sup>97,99</sup>

Two main theories support candling: (1) the “chimney effect”—the burning candle creates a vacuum that draws wax out of the ear, along with debris and bacteria; (2) at the time of the candling, no earwax is drawn out, but the wax heats up, melts, and comes out of the ear over the following few days.<sup>99</sup> The former hypothesis has been assessed with tympanometric measurements in an ear canal model.<sup>96</sup> That study failed to demonstrate that ear candles produced negative pressure. In a limited clinical trial, 1 arm showed no removal of cerumen from the external auditory canal in 4 ears with cerumen impactions.<sup>96</sup> In another arm of this trial, 2 of 4 cerumen-free ears were noted to have new deposits after candling. Mass spectrography of candling residues showed that, not only are they composed of multiple alkanes found in candle wax, but they included none of the constituents of cerumen.<sup>96</sup>

The members of Northwest Academy of Otolaryngology–Head and Neck Surgery were surveyed about their patients’ use of ear candling and whether they had seen any complications from its use. Of 122 respondents, 40 were aware of its use by their patients, and 21 had treated ear injuries associated with ear candling.<sup>96</sup> Complications of candling include ear blockage,<sup>97</sup> ear canal burns,<sup>96</sup> tympanic membrane perforation,<sup>96,99</sup> conductive hearing loss,<sup>99</sup> otitis externa,<sup>96</sup> and hair fire.<sup>96</sup>

Because of risks of serious injuries, the Food and Drug Administration has issued a warning to consumers to not use ear candles.<sup>100</sup> The administration has advised that serious injuries can occur even when ear candles are used according to the manufacturer’s recommendations.

**STATEMENT 6. CERUMENOLYTIC AGENTS: Clinicians may use cerumenolytic agents (including water or saline solution) in the management of cerumen impaction.**  
*Option based on limited randomized trials, with a balance of benefit and harm.*

### Action Statement Profile for Statement 6

- Quality improvement opportunity: Encourage use of effective care; promote effective therapy (National Quality Strategy domain: clinical processes/effectiveness)
- Aggregate evidence quality: Grade C, individual treatment arms of randomized trials showing beneficial outcomes, 1 RCT suggesting better outcomes over no treatment
- Level of confidence in the evidence: High
- Benefits: Safe and effective removal of impacted cerumen
- Risks, harms, costs: Potential external otitis, allergic reactions, and otalgia; cost of cerumenolytic agents other than water or saline solution, cost of procedure if performed in an office setting
- Benefit-harm assessment: Balance of benefit and harm
- Value judgments: The panel values cost control and safety in view of limited data on absolute and comparative efficacy
- Intentional vagueness: None
- Role of patient preferences: Large role for shared decision making
- Exceptions: Medical reasons for exceptions to this statement include, but are not limited to, persons with a history of allergic reactions to any component, persons with infection of the ear canal or active dermatitis, and persons with a nonintact tympanic membrane
- Policy level: Option
- Differences of opinion: None

### Supporting Text

The purpose of this statement is to describe the option of cerumenolytic agents, which are topical compounds that disintegrate earwax, and to review the evidence regarding the safety and efficacy of this method for the treatment of impacted cerumen.

Topical therapy is commonly used to manage cerumen impactions either as a single therapeutic intervention or in combination with other techniques, including irrigation of the ear canal and manual removal of cerumen. Topical preparations exist in 3 forms: water based, oil based and nonwater, nonoil based (**Table 9**). Water and water-based agents have a cerumenolytic effect by inducing hydration and subsequent fragmentation of corneocytes within the cerumen. Oil-based preparations lubricate and soften cerumen without disintegrating cerumen.<sup>101</sup> The mechanism by which nonoil-, nonwater-based eardrops manage cerumen has not been defined by in vitro studies.<sup>102</sup>

Despite the high incidence of cerumen impaction, there is a paucity of well-controlled and homogeneous studies of high quality on the efficacy of commonly used cerumenolytics, either alone or in conjunction with subsequent irrigation for this condition. One systematic review and meta-analysis

**Table 9.** Topical Preparations.<sup>102</sup>

	Preparation	Active Constituents
Water based	Acetic acid	Aqueous acetic acid
	Cerumenex	Triethanolamine polypeptide oleate-condensate
	Colace	Docosate sodium
	Hydrogen peroxide	Hydrogen peroxide solution
	Sodium bicarbonate	Sodium bicarbonate
	Sterile saline solution	Water
Oil based	Almond oil	Almond oil
	Arachis oil	Arachis oil
	Earex	Arachis oil, almond oil, rectified camphor oil
	Olive oil	Olive oil
	Mineral oil/liquid petrolatum	Liquid petrolatum
Nonwater, nonoil based	Audax	Choline salicylate, glycerine
	Debrox	Carbamide peroxide (urea-hydrogen peroxide)

evaluated 15 preparations, including saline and plain water, and concluded that without syringing, there was weak evidence that both water- and oil-based eardrops were more effective than no treatment. Pooled data from this review suggest that longer treatment results in greater success in clearing of cerumen.<sup>102</sup> A second systematic review, including different agents and methods of cerumen removal, found weak evidence suggesting that use of a cerumenolytic agent either alone or prior to irrigation was more beneficial than either no treatment or irrigation alone in terms of the end result of clearing the cerumen impaction.<sup>103</sup> Another review found no benefit of one cerumenolytic agent over another but did suggest that use of a cerumenolytic followed by self-irrigation at home was the most cost-effective protocol, when compared with cerumenolytic plus professional irrigation or no treatment (the cost of no treatment was considered to be the hearing loss persisting when untreated).<sup>104</sup>

A Cochrane review of trials using water- and oil-based preparations, almost all of which used irrigation as a secondary treatment, concluded that using drops may be preferable to irrigation without drops but that no specific agent was superior to another and none were superior to the much more cost-effective use of either saline or water.<sup>89</sup>

In summary, the evidence shows that any type of cerumenolytic agent tends to be superior to no treatment but that no particular agent is superior to any other. In vitro studies support using a true cerumenolytic rather than an oil-based lubricant for disintegration of cerumen, with a longer period of treatment tending to be more efficacious.

### Precautions

Instilling cerumenolytic agents can result in discomfort, transient hearing loss, dizziness, and skin irritation. Studies evaluating cerumenolytics exclude patients with otitis externa; therefore, cerumenolytics should be avoided in patients with active infections of the ear canal. Many commercially available cerumenolytics contain possible skin irritants, and such agents should be applied for limited periods. The risk of a

local skin reaction in response to a cerumenolytic appears to be lowest with nonorganic solutions such as saline.

**STATEMENT 7. IRRIGATION: Clinicians may use irrigation in the management of cerumen impaction.** *Option based on RCTs with heterogeneity and with a balance of benefit and harm.*

### Action Statement Profile for Statement 7

- Quality improvement opportunity: Promote effective therapy (National Quality Strategy domain: clinical processes/effectiveness)
- Aggregate evidence quality: Grade B, 1 RCT verifying absolute efficacy but multiple treatment arms of comparative studies verifying benefit over cerumenolytic alone
- Level of confidence in the evidence: High
- Benefits: Resolve cerumen impaction
- Risks, harms, costs: External otitis, vertigo, tympanic membrane perforation, otalgia, temporal bone osteomyelitis; cost of supplies and procedure
- Benefit-harm assessment: Balance of benefit and harm
- Value judgments: Panel enthusiasm was tempered by the lack of appropriate head-to-head trials comparing irrigation with manual removal or cerumenolytics
- Intentional vagueness: None
- Role of patient preferences: Large
- Exceptions: Medical reasons for exceptions to this statement include, but are not limited to, patients with nonintact tympanic membrane, active dermatitis or infection of the ear canal and surrounding tissue, previous intolerance or adverse reaction to this technique, anatomic abnormalities of the ear canal, or history of surgery of the ear or ear canal (including ear tubes).
- Policy level: Option
- Differences of opinion: None

## Supporting Text

Irrigation is another option for managing the patient with impacted cerumen. The purpose of this statement is to describe the use of aural irrigations for removal of impacted cerumen and to summarize the evidence regarding the efficacy and potential risks of this intervention.

Aural irrigation is a widely practiced form of cerumen removal and can be performed with a syringe or electronic irrigator. While there are no randomized controlled clinical trials of aural irrigation versus no treatment, there is general consensus that aural irrigation is effective in removing cerumen. Manual irrigation performed with a large syringe typically made out of metal or plastic is the most commonly employed method in general practice. The water should be at close to body temperature to avoid caloric effects. Sorenson and Bonding assessed the pressure developed during routine ear syringing and found it safe for normal ears, although there is a risk of perforation when the tympanic membrane is atrophic.<sup>105</sup>

A standard oral dental jet irrigator, with or without a specially modified tip, is commonly used. Electronic irrigators specially designed for aural irrigation are also available. These irrigators claim to have controlled pressures and specially modified tips that make them safer than standard oral jet irrigators, but comparative trials are not available to verify this assertion. A study by Dinsdale et al suggests that standard oral jet irrigators are safe if used at low pressure settings and if the jet of water is directed at the ear canal wall and not longitudinally down the ear canal toward the tympanic membrane.<sup>88</sup> The OtoClear safe irrigation system was found to be safe and effective in a small sample of children.<sup>106</sup> A proprietary system for automated irrigation was found to be safe, effective, and well tolerated in children and could be utilized by trained nurses. However, long-term benefits as compared with no treatment were not evaluated in this study.<sup>107</sup>

Self-irrigation by the patient without health care provider involvement may be a cost-effective alternative to professional intervention. Patients given cerumenolytic drops and instructions for home irrigation with a bulb syringe had comparable outcomes and satisfaction to those treated in similar fashion by a health care provider.<sup>108</sup> Furthermore, at 2-year follow-up, the self-irrigation group had fewer return visits with complaints related to cerumen impaction than did the professionally irrigated group,<sup>109</sup> suggesting a potential economic benefit specific to self-irrigation. Additionally, 1 small study suggested that following clearing of cerumen impaction, weekly irrigation with 70% isopropyl alcohol resulted in fewer cases of recurrent impaction over a 2-month period.<sup>110</sup> This study, however, did not compare the use of alcohol with water, a potentially less irritating irrigation solution. The ability of all patients to do this at home, however, has not been demonstrated, and jet irrigators should be avoided for home use due to risk of damage to ear structures.<sup>111</sup>

Systematic reviews of the available evidence suggests that pretreatment (15 minutes before irrigation) with an otic drop, to soften wax, improves the efficacy of aural irrigation,

regardless of solution type. Therefore, saline and tap water may be as good as specially formulated products.<sup>22,89,102</sup>

**Hearing Outcomes.** In uncontrolled studies following aural irrigation of 28 ears with varying levels of occlusion, Mandel et al demonstrated that <5-dB improvement in hearing at all frequencies could be expected.<sup>106</sup> Other research suggests an average 5-dB increase in hearing after aural irrigation.<sup>9</sup> In contrast, a single-blind RCT found an average of 10-dB improvement in 34% of ears that had cerumen removed by aural irrigation versus only 1.6% of control ears.<sup>60</sup> Furthermore, hearing improvements up to 36 dB were observed among subjects in this study.

**Harms.** The main complications reported after aural irrigation are pain, injury to the skin of the ear canal with or without hemorrhage, and acute otitis externa. Commonly reported significant complications are tympanic membrane perforation (0.2%) and vertigo (0.2%).<sup>111</sup>

Complications were reported in  $\geq 1$  patients by 38% of 274 practitioners who performed aural irrigation for cerumen removal.<sup>9</sup> Most complications were either relatively minor or responded promptly to initial management by the treating practitioner. Adverse events included pain, tinnitus, vertigo, otitis media, otitis externa, and tympanic membrane perforation. Several authors have estimated that only 1 in 1000 episodes of aural irrigation resulted in a complication significantly severe to require specialist referral.<sup>9,25</sup> Tympanic membrane perforation with serious injury to the middle and inner ear is rare but has been reported on a number of occasions.<sup>9,24,88,112</sup>

**Modifying Factors.** Ear irrigation should not be performed in individuals who have a nonintact tympanic membrane or those who have had ear surgery, since the tympanic membrane may be thinned or atrophic and vulnerable to perforation. Since the eardrum is frequently not visualized due to cerumen impaction, a detailed history should be obtained prior to the decision for irrigation. If a small portion of the drum is visible and mobile with pneumatic otoscopy, it is safe to proceed. Aural irrigation should be avoided in individuals with anatomic abnormalities of the canal (congenital malformations, osteomas, exostoses, scar tissue, etc) that might trap water in the external auditory canal after irrigation.

A higher incidence of malignant otitis externa was found among diabetic patients following aural irrigation with tap water, suggesting that aural irrigation may have caused the disease in some of these individuals.<sup>49,51</sup> Consequently, aural irrigation, especially with water, should be performed with caution in diabetic patients. If patients with diabetes have cerumen removal by aural irrigation, they should be instructed to report the development of otorrhea and/or otalgia promptly. Consideration should be given to reacidifying the ear canal since the slightly acidic pH of the normal external auditory canal may be a significant factor in producing resistance to external otitis and/or malignant otitis externa.<sup>54</sup> This can be done with vinegar or acetic acid drops after treatment. Solutions containing alcohol should be avoided unless one

can be certain that the tympanic membrane is intact. Alcohol in the middle ear space is both painful and potentially ototoxic.

**STATEMENT 8. MANUAL REMOVAL: Clinicians may use manual removal requiring instrumentation in the management of cerumen impaction.** *Option based on case series and expert opinion with a balance of benefit and harm.*

#### Action Statement Profile for Statement 8

- Quality improvement opportunity: Promote effective therapy (National Quality Strategy domain: clinical processes/effectiveness)
- Aggregate evidence quality: Grade C, observational case series and expert opinion
- Level of confidence in the evidence: High
- Benefits: Removal of cerumen impaction under direct visualization
- Risks, harms, costs: Bleeding, laceration, tympanic membrane perforation, otalgia; procedural cost; equipment cost
- Benefit-harm assessment: Balance of benefit and harm
- Value judgments: Recommendation acknowledges widespread practice of manual removal, but this is tempered by the relative absence of evidence.
- Intentional vagueness: None
- Role of patient preferences: Large
- Exceptions: None
- Policy level: Option
- Differences of opinion: None

#### Supporting Text

The purpose of this statement is to describe manual removal as an option for cerumen impaction treatment.

Advantages of manual removal are that it is often quicker, allows direct visualization of the external auditory canal, and does not expose the ear to moisture. Manual removal requires adequate illumination, visualization, instrumentation, and competence in performing the procedure. Direct visualization of the ear canal throughout the process allows assessment of when removal of the cerumen impaction is complete.<sup>113</sup>

A handheld speculum or otoscope, a headlamp or head mirror, or the binocular microscope are all appropriate instruments for visualization. The binocular microscope offers the advantage of stereoscopic magnification.<sup>4</sup> Instruments used for removal include a metal or plastic curette loop or spoon, an alligator or cup forceps, a right-angled hook, a straight applicator with applied wisps of cotton wool, angulated suction tips (French size 3, 5, 7), and a Jobson-Horne probe.<sup>95</sup> Wax, which has a softer consistency, can sometimes be wiped out with cotton wool applied to an applicator or aspirated with a suction tip attached to a negative-pressure pump. The use of cerumenolytic agents during the week prior to the office visit can reduce potential side effects of suction removal, such as pain or vertigo.<sup>114</sup>

Manual removal of cerumen is often preferred in patients with abnormal otologic findings (eg, obstructing exostoses),

recent ear surgery, or systemic illness that may compromise immunity or make them more prone to infection (eg, diabetes). Patients with perforation of the tympanic membrane or with a patent pressure-equalizing tube are at risk for developing suppurative otitis media should irrigation or cerumenolytic agents enter the middle ear. The tympanic membrane may also be attenuated in patients who have had previous ear surgery, placing them at greater risk of a pressure-induced perforation from irrigation.

Adequate training, experience, and availability of appropriate equipment will minimize the risk of adverse events and maximize the likelihood of successful cerumen removal.

**Harms.** Trauma to the external auditory canal (including pain and/or bleeding), perforation of the tympanic membrane, and, rarely, infection have been reported. Suctioning the ear canal can produce noises that are quite loud and may startle the patient. Although no demonstrable shifts in auditory thresholds have been noted in a prospective controlled series,<sup>115</sup> practitioners should be aware that the noise levels generated during suctioning of the canal can reach levels that may be unsafe. Suctioning may create a cooling effect and elicit a caloric response from the inner ear, causing nystagmus and vertigo.

**STATEMENT 9. OUTCOMES ASSESSMENT: Clinicians should assess patients at the conclusion of in-office treatment of cerumen impaction and document the resolution of impaction. If the impaction is not resolved, the clinician should use additional treatment. If full or partial symptoms persist despite resolution of impaction, the clinician should evaluate the patient for alternative diagnoses.** *Recommendation based on RCTs with limitations (supporting a failure of clearance of cerumen in some cases) and with a preponderance of benefit over harm.*

#### Action Statement Profile for Statement 9

- Quality improvement opportunity: Ensuring effectiveness of treatment to optimize patient outcomes and ensuring accurate diagnosis of cause of symptoms (National Quality Strategy domain: clinical processes/effectiveness)
- Aggregate evidence quality: Grade C. Observation in treatment arms of several randomized trials show that retreatment is sometimes necessary and can be effective; first principles support evaluation for efficacy after treatment.
- Level of confidence in the evidence: High
- Benefits: Detect complications; encourage proper diagnosis; ensure effective therapy
- Risks, harms, costs: See sections on individual treatments; cost of additional treatment or evaluation
- Benefit-harm assessment: Preponderance of benefit over harm
- Value judgments: Importance of clinician assessment after treatment; avoid misdiagnosis

- Intentional vagueness: The term *additional treatment* does not specify what type of treatment. Additional treatment can include repeating the same treatment or trying an alternative method (ie, manual removal if irrigation was tried first or use of softening agents if not used initially)
- Role of patient preferences: Small
- Exceptions: None
- Policy level: Recommendation
- Differences of opinion: None

### Supporting Text

The purpose of this statement is to ensure that treatment for cerumen impaction is effective, that complications are recognized immediately, and that alternative diagnoses are sought if presenting symptoms are not resolved.

Trials indicate that in-office treatment of cerumen impaction is variably effective.<sup>102</sup> Recent trials showed the effectiveness of the various treatments ranging from 65% to 90%.<sup>110,114,116</sup> Even in manual removal with microsuction, nearly 10% of attempts at removal were unsuccessful.<sup>114</sup> With irrigation, the success rates were lower and lacked direct visualization of the cerumen being removed. Direct assessment is required to confirm effective treatment.

Additionally, symptoms of cerumen impaction—including hearing loss, tinnitus, fullness, itching, otalgia, and occasionally cough—may overlap with many other conditions. To ascertain whether symptoms were in fact due to cerumen, reevaluation of the patient is necessary after the impaction has been resolved. Outcome assessment requires (1) examination of the ear and (2) patient assessment for symptom resolution. Both these steps require collection and interpretation of clinical data, and depending on state laws governing scope of practice, the posttreatment evaluation may be performed by a physician, an audiologist, an advanced practice nurse, a physician assistant, or a registered nurse. The laws governing scope of practice for medical assistants vary by state and therefore should be referenced before delegating the posttreatment assessment to a medical assistant.<sup>117</sup>

Posttreatment evaluation to assess complications related to the removal procedure is important for patient safety and medicolegal purposes.<sup>118</sup> While the techniques for cerumen removal are generally safe, these procedures have been associated with otitis externa, bleeding, pain, dizziness, syncope, tinnitus, and tympanic membrane perforation.<sup>9,104</sup> For these reasons, the results of both the posttreatment otoscopic examination and symptom assessment should be documented in the medical record.

The impaction is resolved when (1) the clinician can examine the ear or perform the appropriate testing without the interference of cerumen and (2) associated symptoms have resolved. If cerumen has been adequately removed but symptoms persist, the clinician should consider alternative diagnoses: sensorineural hearing loss, conductive hearing loss due to other disorders (eg, serous otitis media, otosclerosis, cholesteatoma), otitis media, medication side effects, head and neck tumors, temporomandibular joint syndrome, upper respiratory infections, eustachian tube dysfunction, or disorders of the skin of the canal.

If the cerumen cannot be adequately removed to resolve symptoms or perform the desired testing, additional treatment should be prescribed (see key action statement 5A and supporting text). This may include repeating the initial treatment but with an alternative treatment method or strategy (eg, softening agents before repeating manual removal). If the treating provider cannot clear the impaction safely and without significant discomfort, he or she should refer the patient to a provider who has the necessary skills or equipment for proper treatment (see key action statement 10: referral and coordination of care).

**STATEMENT 10. REFERRAL AND COORDINATION OF CARE: If initial management is unsuccessful, clinicians should refer patients with persistent cerumen impaction to clinicians who have specialized equipment and training to clean and evaluate ear canals and tympanic membranes.** *Recommendation based on individual arms of randomized trials and preponderance of benefit over harm.*

### Action Statement Profile for Statement 10

- Quality improvement opportunity: Coordination of care and effective treatment (National Quality Strategy domains: care coordination and clinical processes/effectiveness)
- Aggregate evidence quality: Grade C, individual arms of randomized trials
- Level of confidence in evidence: High
- Benefits: Promote successful removal of cerumen impaction; timely coordination of care; avoidance of harm from repeated unsuccessful interventions; avoid patient and clinician frustration; avoiding misdiagnosis
- Risk, harm, cost: Cost of additional care; limited access to specialty care
- Benefit-harm assessment: Preponderance of benefit
- Value judgments: Skill and instruments will promote a better outcome. The level of care that can be rendered can be limited by the available equipment and training.
- Intentional vagueness: The specialized equipment and training are vague but may include access to binocular microscopy, suction, microinstruments, or the operating room. Type of training is not specified, but this refers to someone with advanced capabilities of removing cerumen. Unsuccessful treatment may entail a repeat visit or multiple treatments by the initial clinician to allow for use of softening agents or spontaneous improvement of impacted cerumen.
- Role of patient preferences: Small
- Exclusions: None
- Policy level: Recommendation
- Differences of opinion: None

### Supporting Text

The purpose of this statement is to encourage clinicians to refer patients with refractory cerumen impaction to another

practitioner with higher-level skills and equipment when initial attempts to resolve cerumen impaction are unsuccessful.

Initial management of cerumen impactions through irrigation, manual removal, or cerumenolytics is not always successful. The range of success in resolving cerumen impactions with irrigation has been reported to be 68% to 92%. The success rates for manual removal with a binocular microscope for visualization are around 90%, with no reported canal trauma or perforations in 1 study of 159 patients.<sup>107</sup> However, in a primary care or pediatric setting, visualization for manual removal is often provided by a handheld otoscope. No published studies have reported success rates of manual removal with a handheld otoscope for visualization, but they are likely to be considerably lower.<sup>104,107</sup> The success rates for cerumenolytics alone are lower still.

As detailed earlier in the guideline, when initial attempts are unsuccessful, an alternative strategy or combination of multiple treatments should be attempted (eg, adding a cerumenolytic and then repeating irrigation or manual removal). Cerumenolytics used as a softening agent may even improve the tolerability of subsequent attempts at cerumen removal.

When repeated attempts are made, complications occur, and patient intolerance may prevent further attempts. In 1 study, 38% of general practitioners reported having seen a complication related to irrigation, including tympanic membrane perforation, otitis externa, injury to the external ear canal, and otitis media.<sup>9</sup> Avoiding adverse outcomes and minimizing patient discomfort after initial attempts to treat a cerumen impaction requires recognizing when primary attempts are unsuccessful, (2) complications are encountered, (3) the patient is no longer tolerating efforts to clear the cerumen, or (4) at any point the treating clinician no longer feels comfortable making further (or even initial) attempts, he or she should refer the patient to a clinician with access to specialized equipment and with experience in treating refractory cerumen impactions.

Specialized equipment for cerumen removal consists of (1) a microscope or otoendoscope for visualization and (2) aural microsuction or otologic instruments for cerumen removal. Generally, these are available through an otolaryngologist, but there may be other clinicians with this equipment and the skills to use.

In rare instances, after multiple failed efforts to clear cerumen or for patients who are unable to tolerate removal, sedation or general anesthesia may be needed. Mild sedation or anxiolytics may be adequate for some patients. Cerumen removal with otomicroscopy under general anesthesia should also be considered for pediatric patients and patients with developmental delay who will not tolerate cerumen removal in the clinic. Specific situations that would warrant the use of general anesthesia include concern for significant abnormalities (ie, tympanic membrane perforation, cholesteatoma, and retained foreign body), persistent hearing loss in a speech-delayed or developmentally delayed child, and coordination of cerumen removal with hearing assessment under anesthesia (ie, brainstem auditory evoked response).

#### **STATEMENT 11. SECONDARY PREVENTION: Clinicians may educate/counsel patients with cerumen impaction or excessive cerumen regarding control measures.**

*Option based on survey and comparative studies with unclear balance of benefit vs harm.*

##### **Action Statement Profile for Statement 11**

- **Quality improvement opportunity:** Patient and family engagement (National Quality Strategy domain: patient and family engagement)
- **Aggregate evidence quality:** Grade C; observational studies, experimental pilot studies, and expert opinion
- **Level of confidence in the evidence:** High
- **Benefits:** Prevent development of cerumen impaction or recurrent cerumen impaction
- **Risks, harms, costs:** Time for counseling and potential risk of preventive measures if used
- **Benefit-harm assessment:** Balance benefit over harm
- **Value judgments:** Importance of prevention in managing patients with cerumen impaction
- **Intentional vagueness:** The term *excessive cerumen* is used to indicate when cerumen is present but not actively causing symptoms, to allow the clinician freedom to counsel patients who appear to be at risk for cerumen impaction even when the ear is not actually impacted.
- **Role of patient preferences:** Large, opportunities for shared decision making
- **Exceptions:** None
- **Policy level:** Option
- **Differences of opinion:** None

##### **Supporting Text**

The purpose of this statement is to inform clinicians of control measures that patients can use to prevent recurrence of cerumen impaction following removal in the office and to prevent an accumulation of cerumen from becoming impacted.

Although empirical evidence supporting measures to reduce the recurrence of cerumen impaction is limited, clinicians have the opportunity to counsel patients on the risks and potential benefits of specific control measures. Measures that may be beneficial in reducing cerumen impaction include (1) instilling prophylactic topical preparations, (2) irrigating the ear canal, (3) cleaning hearing aids, or (4) routine cleaning of the ear canal by a clinician. It has been suggested that patients with an increased propensity for cerumen production might benefit from regular ear care to reduce the risk of developing an impaction.<sup>10</sup> Patients can purchase wax-softening drops or home irrigation kits as part of an ear hygiene regimen to help prevent recurrence of cerumen occlusions.<sup>119</sup> Cerumen accumulation and impaction may be exacerbated by the use of hearing aids.<sup>37,39</sup> Thus, it is important to provide instructions on proper care and routine cleaning of aids (**Table 5**).

Choices regarding topical preparations and devices for irrigating the ears should be shared with the patient, allowing for



**Table 10.** Options to Help Reduce Earwax.

Secondary prevention choices	Alcohol or hydrogen peroxide drops or irrigation Topical earwax-softening agents Irrigation with bulb syringe or irrigation kits Checking of the ear canal for cerumen by clinician in hearing aid users Physically removing wax by health care provider
Not advised	Daily olive oil drops or sprays Ear candling Probing ears with foreign objects (eg, cotton-tipped swaps, pens/pen tops, paper clips)

substantial patient preference and discussion of cost factors in determining treatment options. Studies of preventive measures have shown mixed results. One study in 50 patients >50 years of age with bilateral occluding cerumen examined the effect of daily olive oil spray in the external ear canal to determine if this reduced cerumen accumulation.<sup>120</sup> Each patient had 1 treated ear and 1 control ear. Ear canal contents were weighed prior to any treatment and again at 8, 16, and 24 weeks. Treated ears actually had heavier contents than control ears. This may be the result of the added oil. A randomized prospective study evaluated the use of a prophylactic topical emollient preparation in preventing or reducing the recurrence of cerumen impaction.<sup>121</sup> Thirty-nine adults and children with completely impacted ear canals were randomly assigned to either an intervention group or a control group (regular care) after removal of the cerumen and were followed prospectively for 12 months. Cerumen impaction recurred in 1 or both ears in only 23% of intervention patients versus 61% of the control patients, a significant difference between groups. A high patient attrition rate, particularly in the intervention group, dampens enthusiasm for results of this study.

Self-irrigation is another option to reduce earwax accumulation. A randomized trial with 237 symptomatic patients with cerumen occlusions found that ear irrigation with bulb syringes significantly reduced self-reported symptoms. Fewer than half (49%) of treated patients needed reirrigation by the nurse for cerumen removal.<sup>108</sup> In a retrospective chart review<sup>109</sup> of these same 237 patients 2 years later, 73% of patients in the control group (ear drops only) had been treated in the office for episodes of earwax occlusion, compared with 60% of those in the intervention group (ear drops and irrigations with bulb syringes). This represents a statistically significant difference ( $P = .038$ ). In addition, patients in the self-treatment bulb syringe irrigation group required about half the rate of irrigation consultations by the nurse as compared with the control group.<sup>109</sup> Based on these 2 studies, patients may reduce symptoms from cerumen impaction and need for intervention by performing self-irrigations with bulb syringes at home.

In a prospective crossover pilot study, 20 adults with a history of cerumen impaction received cerumenectomy in the office and were then randomly assigned to 1 of 2 groups to evaluate the safety and efficacy of once-weekly ear irrigations with 70% isopropyl alcohol. Group 1 performed the weekly

irrigations on their ears for 2 months, followed by 2 months of no ear cleaning. Group 2 did the same protocol in reverse. At the end of 2 months, both groups were evaluated for cerumen occlusion. Those who had performed once-weekly ear irrigations had significantly less accumulation of cerumen than patients who did not. There was also a significant difference in cerumen occlusion when the weekly ear irrigations were stopped for 2 months.<sup>110</sup> Findings from this pilot study suggest that once-weekly ear irrigations with isopropyl alcohol may help prevent recurrence of cerumen occlusions. A larger trial is needed to confirm these results.

Currently, there is no standard protocol for self-irrigation of ears based on the efficacy and safety of irrigation solutions, delivery devices, or frequency of regimen. Studies evaluating the benefits as well as the harms associated with specific interventions designed to prevent or reduce cerumen impaction are very limited. The clinician may discuss the various methods for self-treatment of cerumen accumulation at home, including self-irrigation, use of ear drop softeners, and proper ear hygiene regimens. Patients interested in these approaches should be properly trained to do them safely. **Table 10** provides options to help reduce earwax.

## Implementation Considerations

The complete guideline is published as a supplement to *Otolaryngology–Head and Neck Surgery* to facilitate reference and distribution. A full-text version of the guideline will also be accessible free of charge at the [www.entnet.org](http://www.entnet.org), the AAO-HNSF website. Existing brochures and publications by the AAO-HNSF will be updated to reflect the guideline recommendations.

An anticipated barrier to diagnosis is distinguishing modifying factors for cerumen impaction in a busy clinical setting. This will be addressed with a laminated teaching card or visual aid summarizing important factors that modify management. Laminated cards will be available for purchase through Guideline Central.

An anticipated barrier to the “observation option” for non-impacted cerumen is patient and clinician reluctance to not intervene when cerumen is observed. This barrier can be overcome with educational pamphlets and information sheets that outline the favorable natural history of nonimpacted cerumen, the moderate incremental benefit of removal on clinical

outcomes, the potential adverse effects of treatment, and the benefits of cerumen for a healthy ear canal.

Prompt evaluation of special populations may be hindered by the high prevalence of cerumen impaction in these populations and additional treatment time that may be necessary in busy practice settings. Information sheets outlining the high prevalence and potential morbidity of cerumen impaction in these populations may increase awareness and willingness to manage this problem.

Performance of irrigation and instrument removal other than irrigation, when appropriate, may be hindered by access to equipment and by procedural cost. Last, successfully achieving an understanding of the lack of efficacy and potential harms of ear candling, a popular alternative therapy, will require patient and clinician access to education materials. Pamphlets may help in dispelling myths about comparative efficacy.

## Research Needs

While there is a body of literature from which these guidelines were drawn, significant gaps in our knowledge about cerumen impaction and its management remain. The guideline committee identified several areas where further research would improve the ability of clinicians to optimally manage patients.

1. Establish a universal definition of cerumen impaction to make comparisons of management strategies more meaningful.
2. Assess the natural history of cerumen impactions by performing observational studies in untreated populations, including the elderly, children, and developmentally delayed patients.
3. Conduct studies assessing the role of preventive measures, such as emollients and ear hygiene, on the development of cerumen impactions.
4. Assess the various methods of cerumen removal, either as single interventions or combined interventions, through well-designed large-scale RCTs.
5. Determine the efficacy of manual removal of cerumen through prospective studies.
6. Assess comparative impact of different cerumenolytic agents through well-designed clinical trials.
7. Evaluate the efficacy of prophylactic topical antibiotics in preventing otitis externa when local trauma occurs during cerumen removal.
8. Conduct a financial analysis comparing the various methods of cerumen management
9. Determine the relative efficacy of cerumenolytic agents and irrigation for adult, elderly, and pediatric patients and for patients at high risk for complications related to cerumen removal due to underlying conditions (ie, diabetes, coagulopathies)
10. Evaluate the impact of cerumen removal on the resolution of symptoms, such as itching, hearing loss, pain, fullness, tinnitus, and vertigo, through prospective clinical studies.
11. Establish that studies evaluating cerumen removal should document adverse events
12. Assess variation in outcomes for cerumen removal relative to the type of health care provider managing the patient (ie, nurse, physician assistant, physician, medical assistant)
13. Conduct financial analyses of the relative costs for cerumen management when performed by different types of health care providers

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## Disclosures

**Competing interests:** Bopanna B. Ballachanda, chief of Audiology and consultant for Audiology Management Group; Jesse M. Hackell, shareholder of Pfizer and GSK, expert witness, medical malpractice consultant; Helene J. Krouse, AAO-HNSF journal editor, spouse on AAO-HNSF Board of Directors, Sohn research funding; Erika A. Woodson, consultant for Oticon Medical, speaker honoraria for CitiGroup; Eugene R. Cunningham Jr, salaried employee of AAO-HNSF.

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