

- 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.⁹⁷ 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 children⁹⁸ and adults.^{97,99}

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.⁹⁹ The former hypothesis has been assessed with tympanometric measurements in an ear canal model.⁹⁶ 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.⁹⁶ In another arm of this trial, 2 of 4 cerumen-free ears were noted to have new deposits after candling. Mass spectroscopy 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.⁹⁶

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.⁹⁶ Complications of candling include ear blockage,⁹⁷ ear canal burns,⁹⁶ tympanic membrane perforation,^{96,99} conductive hearing loss,⁹⁹ otitis externa,⁹⁶ and hair fire.⁹⁶

Because of risks of serious injuries, the Food and Drug Administration has issued a warning to consumers to not use ear candles.¹⁰⁰ 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.¹⁰¹ The mechanism by which nonoil-, nonwater-based eardrops manage cerumen has not been defined by in vitro studies.¹⁰²

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