Primary Care Based Ear Irrigation

Service Specification No.	
Service	Primary Care Based Ear Irrigation
Commissioner Lead	NHS Lincolnshire Integrated Care Board
Period	1st April 2023 to 31st March 2024
Date of Review	March 2023

1. Population Needs

1.1 National Context and Evidence Base

A build-up of earwax in the ear canal can cause hearing loss and discomfort, contribute to infections and lead to stress, social isolation and depression. Moreover, earwax can prevent adequate clinical examination of the ear, delaying investigations and management; GPs cannot check for infection and audiologists cannot test hearing and fit hearing aids if the ear canal is blocked with wax. Excessive earwax is common, especially in older adults and those who use hearing aids and earbud-type earphones. In the UK, it is estimated that 2.3 million people each year have problems with earwax sufficient to need intervention (The National Institute for Health and Care Excellence).

Earwax is usually treated initially with ear drops. However, if this is unsuccessful, the wax can be removed using irrigation (flushing the wax out using water) or microsuction (using a vacuum to suck the wax out under a microscope). There are few studies comparing these different techniques in terms of effectiveness, efficiency and adverse events. Ear syringing, where a manual syringe pumps water into the ear, is potentially harmful and should not be used.

The care pathway information detailed below is drawn from the NICE Clinical Knowledge Summary (CKS) for Earwax Management, July 2016. The full document is available at http://cks.nice.org.uk/earwax.

1.2 Local Context

Lincolnshire's Integrated Care System and Integrated Care Board

The NHS Lincolnshire Integrated Care System (ICS) was created on 1 July 2022 following an amendment of the Health and Social Care Act 2006.

The ICS is a partnership that brings together providers and commissioners of NHS services across Lincolnshire with local authorities and other local partners (such as the voluntary sector), to collectively plan health and care services to meet the needs of their population.

The 4 aims of the ICS are:

- improve outcomes in population health and healthcare
- tackle inequalities in outcomes, experience, and access
- enhance productivity and value for money
- help the NHS support broader social and economic development

NHS Lincolnshire Integrated Care Board (ICB) is the statutory body within Lincolnshire ICS responsible for the provision of health services, in accordance with the Health and Care Act 2022.

Lincolnshire ICB will use its resources and powers to collaboratively tackle complex challenges, including:

- improving the health of children and young people
- supporting people to stay well and independent
- acting sooner to help those with preventable conditions
- supporting those with long-term conditions or mental health issues
- caring for those with multiple needs as the population ages
- getting the best from collective resources so people get care as quickly as possible

<u>Lincolnshire ICB statistics</u>

- Lincolnshire ICB has 82 practices
- The total registered population is 813,240 (as of January 2023)
- The registered population live in 7 different lower tier Local Authorities
- As of 2021, the male average life expectancy in Lincolnshire (78.3 years) is slightly lower than the national average (78.7 years). The average Lincolnshire life expectancy for females is 82.8 years, which is the same as the national average
- The 2021 overall premature mortality rate in Lincolnshire (deaths <75 years per 100,000) is 366.3, which is slightly higher than the national figure of 363.4
- The average level of deprivation in England as of 2019 was 21.7. Lincolnshire ICB as a whole is slightly less deprived than this, at 20.2. However, there are pockets of deprivation across the county that are within the national 20% most deprived areas (mainly around coastal and inner urban areas)

2. Outcomes

2.1 NHS Outcomes Framework Domains & Indicators

Domain 1	Preventing people from dying prematurely	n/a
Domain 2	Enhancing quality of life for people with long-term conditions	n/a
Domain 3	Helping people to recover from episodes of ill-health or following injury	Yes
Domain 4	Ensuring people have a positive experience of care	Yes
Domain 5	Treating and caring for people in a safe environment and protecting them from avoidable harm	Yes

2.2 Local Defined Outcomes

The purpose of this specification is to commission a community based service providing ear irrigation services to patients aged 16 years and over that is clinically effective, appropriate, convenient, easy to access and to:

- provide a basic level of aural care to the registered population
- reduce referrals to secondary care

This approach is in line with the current Sustainability and Transformation Programme which aims to provide better access to services, earlier diagnosis, avoidance of unnecessary hospital attendance and integrated care.

3. Scope

3.1 Aims and Objectives of Service

For patients to receive high quality efficient services locally, with reduced waiting times and a high degree of responsiveness.

To provide clinically effective management of earwax (including safe removal) for patients (aged 16 and over) that conforms to a recognised quality assurance tool.

The key principles of the service are:

- Compliance with established clinical guidelines and good practice
- To improve standards of care
- To increase the availability of care closer to home, improving patient experience
- Provide person-centred care and devices tailored to patient need
- Ensure that NHS resource is used economically and wisely for the benefit of the local population.

Expected outcomes of the service:

- Personalised care for all patients accessing the service
- Improved quality of life for patients measured through high levels of satisfaction from patients accessing the service
- Improved adherence to current clinical guidance and a resultant reduction in the need for secondary care intervention.

3.2 Service Description

3.2.1 When to Remove Earwax

1. If earwax is totally occluding the ear canal and hearing loss is present
2. If the tympanic membrane is obscured by wax but needs to be viewed to establish a diagnosis.
3. If the person wears a hearing aid, wax is present and an impression needs to be taken of the ear canal for a mould, or if wax is causing the hearing aid to whistle.

3.2.2 How to Remove Earwax

1. Explain that removal of earwax may not necessarily relieve the symptoms (for example hearing loss may be a sensorineural loss and not due to impacted wax).
2. Prescribe ear drops for 3–5 days initially, to soften wax and aid removal.
    - Olive oil, or almond oil drops can be used 3-4 times daily for 3-5 days (do not prescribe almond oil ear drops to anyone who is allergic to almonds).
    - Sodium bicarbonate 5%, sodium chloride 0.9%. (Sodium chloride 0.9% is not available as a proprietary ear drop product. However, sodium chloride 0.9% nasal drops can be prescribed for use in the ear (off-label use)).
    - Do not prescribe drops if you suspect the person has a perforated tympanic membrane.
    - Warn the person that instilling ear drops may cause transient hearing loss, discomfort, dizziness and irritation of the skin.
3. If symptoms persist, consider ear irrigation, providing that there are no contraindications.
4. If irrigation is unsuccessful, there are three options:
    - Advise the person to use ear drops for a further 3–5 days and then return for further irrigation.
    - Instill water into the ear. After 15 minutes irrigate the ear again.
    - Refer to an Ear Nose and Throat specialist for removal of wax.
5. Advise anyone who has had earwax removed to return if they develop otalgia or significant itching of the ear, discharge from the ear (otorrhoea), or swelling of the external auditory meatus, as this may indicate infection.

3.2.3 Removal Methods not Recommended

1. Advise people against inserting anything in the ear. Cotton buds, matchsticks and hair pins can:
    - Damage the wall of the canal and increase the likelihood of otitis externa.
    - Cause the wax to become impacted by pushing it further into the canal.
    - Perforate the tympanic membrane.
2. Advise that the use of ear candles has no benefit in the management of earwax removal and may result in serious injury.
    - Ear candling should never be used: a hollow candle is burned with one end in the ear canal. The intention is to create a negative pressure which draws the earwax out of the ear canal.

3.2.4 When to Refer

1. Refer before irrigation if:
    - The person has (or is suspected to have) a chronic perforation of the tympanic membrane.
    - There is a past history of ear surgery.
    - There is a foreign body, including vegetable matter, in the ear canal.
    - There is a visible tympanic membrane perforation.
    - Ear drops have been unsuccessful, and irrigation is contraindicated.
2. Refer after irrigation if irrigation is unsuccessful
3. Seek immediate advice from an Ear Nose and Throat specialist if severe pain, deafness, or vertigo occurs during or after irrigation.
4. Refer or seek urgent advice if infection is present and the external canal needs to be cleared of wax, debris, and discharge.
5. If the person continues to experience hearing loss after wax removal arrange an audiogram.

3.2.5 Managing Recurrent Earwax

1. Decide on the most appropriate treatment taking into account the person's wishes, previous successful treatment and any contraindications.
2. Treatment options include ear drops, irrigation, or referral for manual removal of earwax.

3. To prevent wax becoming impacted, advise that regular use of ear drops may be helpful.
    - Explain that there is no evidence to suggest the best type of ear drops or how frequently they should be used.
    - Experts suggest using either sodium bicarbonate, sodium chloride, olive or almond oil ear drops. The suggested frequency of use varied from daily to once a fortnight.
    - It is not known if such treatment is effective, and the person may need to return for repeat wax removal.

3.2.6 Ear irrigation: Contraindications, Cautions and Warnings

1. Do not use ear irrigation to remove wax for people with:
    - A history of any previous problem with irrigation (pain, perforation, severe vertigo).
    - Current or past perforation of the tympanic membrane.
    - Grommets in place.
    - A history of any ear surgery (except extruded grommets within the last 18 months, with subsequent discharge from an Ear Nose and Throat department).
    - A mucus discharge from the ear (which may indicate an undiagnosed perforation) within the past 12 months.
    - A history of a middle ear infection in the previous six weeks.
    - Cleft palate, whether repaired or not.
    - Acute otitis externa with an oedematous ear canal and painful pinna.
    - Presence of a foreign body, including vegetable matter, in the ear. Hygroscopic matter, such as peas or lentils, will expand on contact with water making irrigation more difficult.
    - Hearing in only one ear if it is the ear to be treated, as there is a remote chance that irrigation could cause permanent deafness.
    - Confusion or agitation, as they may be unable to sit still.
    - Inability to cooperate, for example young children and some people with learning difficulties.
2. Use ear irrigation with caution in people with:
    - Vertigo, as this may indicate the presence of middle ear disease with perforation of the tympanic membrane.
    - Recurrent otitis media with or without documented tympanic membrane perforation, as thin scars on the tympanic membrane can easily be perforated.
    - An immunocompromised state, especially older people with diabetes, as there is an increased risk of infection from iatrogenic trauma to the external auditory canal in this group of people.
3. Careful instrumentation should be employed in people who are taking anticoagulants due to increased bleeding risk.
4. Warn people with a history of recurrent otitis externa or tinnitus that ear irrigation may aggravate their symptoms.

3.2.7 Ear Irrigation: How to Irrigate an Ear

1. Use an electronic ear irrigator. This should have a variable pressure control so that irrigation can begin at the minimum pressure.
    - The use of a metal syringe for the irrigation of the ear canal is not recommended as there is a risk of causing damage to the ear, including the tympanic membrane and the oval and round windows. The design of the syringe, combined with the inability to control water pressure, increases the risk of ear damage. It is also difficult to disinfect after use [NHS Quality Improvement Scotland, 2006].
2. Prepare equipment as per local guidelines and manufacturer's instructions. This will include a fresh speculum and jet tip for each person. Protect the person's

clothing with a towel or waterproof covering. Ask the person to hold the water receiver under their affected ear.

3. Ensure that the person is sitting comfortably and that you are sitting at the same level. Young children should sit on an adult's knee with their head held in place. Use a good light source, preferably with a head lamp or head mirror, throughout the procedure.
4. Ensure that the temperature of water used for irrigation is around body temperature.
5. Pull the pinna upwards and outwards (downwards and backwards in children) to straighten the ear canal.
6. Angle the jet tip so that the flow of the water is along the top of the posterior wall. Compare the perimeter of the canal to a clock face: for the left ear direct the fluid towards 1 o'clock, and for the right ear direct the fluid towards 11 o'clock.
7. Inspect the ear canal periodically with the auriscope and monitor the solution running into the receiver to determine whether wax is coming out.
8. If the person complains of dizziness or pain, stop the procedure.
9. In general, use no more than 500ml of water per ear in any one irrigating procedure.
10. Following irrigation, examine the ear with an auriscope to check that the wax has been removed and the tympanic membrane is intact. Look for old, healed perforations. Inspect the canal for otitis externa. Follow local protocols regarding dry mopping.
11. Seek immediate advice from an Ear Nose and Throat specialist if severe pain, deafness, or vertigo occur during or after irrigation, or if a perforation is seen following the procedure.

3.2.8 Ear Irrigation Complications

1. The following have been reported:
    - Failure of wax removal
    - Otitis externa
    - Perforation of the tympanic membrane
    - Damage to the external auditory meatus
    - Necrotizing (malignant) external otitis is a rare infection, occurring primarily in immunocompromised people, especially older people with diabetes mellitus, and is often initiated by iatrogenic trauma to the external auditory canal
    - Pain
    - Vertigo
    - Otitis media due to water entering the middle ear when there is a previous perforation
    - Exacerbation of pre-existing tinnitus
    - Serious injury to the middle and inner ear (rare)
2. Bleeding (usually self-limiting).
3. Nausea, vomiting, and vertigo may result from temperature variations of the irrigating fluid.

3.2.9 Follow-Up

Advise anyone who has had earwax removed to return if they develop earache or significant itching of the ear, discharge from the ear (otorrhoea), or swelling of the external auditory meatus, as this may indicate infection.

3.3 Population Covered

Patients must be temporarily or permanently registered with a General Practice within the geographical boundary of Lincolnshire ICB.

3.4 Any Acceptance and Exclusion Criteria and Thresholds
None specific. Patients should be managed in accordance with the guidance outlined in this specification, including any referred to documents and guidance.

3.5 Interdependence with other Services/Providers
The service is an element of the ICB's Ear, Nose and Throat pathway, which includes primary, community and secondary care elements. The Provider must ensure effective relationships with all other services within the pathway including but not limited to:

- Onward referrals to be made by the patient's registered GP practice
- Information sharing protocols

The service forms part of a system-wide ENT service of partnership working between:

- GPs
- Primary health care teams,
- Audiology services and ENT departments
- The voluntary and community sector
- Independent health care providers.

3.6 Days/Hours of Operation
The service must be available to patients over a minimum of five days per week.

4. Applicable Service Standards

4.1 Applicable National Standards (eg NICE)
No specific national directives are in place regarding the management of earwax.

NICE Clinical Knowledge Summaries (July 2016) provide best practice guidance:
https://cks.nice.org.uk/earwax#!scenario.
https://cks.nice.org.uk/earwax#!scenario:1

Hearing loss in adults (assessment and management) guidance is currently being reviewed by NICE and should be updated in 2018. Guidance is also currently being reviewed by the British Society of Audiology and should be updated in 2018.

4.2 Applicable standards set out in guidance and/or issued by a competent body (e.g., Royal Colleges)

- National Community Hearing Association Guidance 2015-18
- 'Common Principles of Rehabilitation for Adults with Hearing – and/or Balance-Related Problems in Routine Audiology Services' British Society of Audiology (2012)
- 'Shaping the Future: Strengthening the Evidence to Transform Audiology Services' NHS Improvement Agency (2010)
- 'Provision of Services for Adults with Tinnitus: a Good Practice Guide' Department of Health (2009)
- British Academy of Audiology Guidelines for Referral to Audiology of Adults with Hearing Difficulty (2009)
- 'Provision of Adult Balance Services: a Good Practice Guide' Department of Health (2009)
- Transforming Adult Hearing Services for Patients with Hearing Difficulty – A Good Practice Guide', Department of Health, (2007)

4.3 Applicable Local Standards
Agreement to this specification places on the Provider an obligation to provide the specified service at the level of service, days and hours of operation and at the locations specified. Any variation can be made only with the agreement of the Commissioner. The Provider must plan for and put in place robust contingency arrangements for known or possible events which may include:

- Staff sickness

- Staff turnover
- Maternity
- Annual leave or other types of special leave.

The Provider may only suspend or restrict service for more than one day after agreement with the Commissioner. Agreement to suspension or restriction will be for a period of no greater than 21 days from the application to the Commissioner but may be renewed.

Whilst unexpected staff absence cover over the first twenty-four hours will be challenging to cover, the provider must ensure that any absence which is in excess of twenty-four hours in duration will be robustly covered such that the usual level of service commissioned resumes without delay. The arrangements to cover the staff absence will be communicated effectively to practices affected and to the commissioners.

Agreement and renewal will only take place if the Provider has demonstrated that they have made reasonable but unsuccessful efforts to substitute staff and resources from other areas of their operation, or failing that, by obtaining staff and resources from a third party. In an emergency, the Provider may unilaterally suspend or restrict the service for only 24 hours.

The provider must at all times comply with 'Code of Practice For The Promotion of NHS-Funded Services' and must ensure that the commissioning body has signed off any marketing materials before these are used or launched.

Use of the phrase 'NHS services provided here' is the preferred advertising mechanism.

4.4 System Resilience
It is expected that periods of expected high demand which could lead to the variation, suspension or restriction of the service provided shall be planned for accordingly, e.g., this may include winter pressure planning. The provider will be expected to actively contribute toward the commissioner-led System Resilience Plan, where required. Providers are strongly encouraged to have contingency plans in place with other local providers for suitably qualified and experienced staff to perform this service in the event that their own staff is not available.

4.5 Professional Standards and Codes of Conduct
1. Providers must be registered with the regulatory body appropriate to their profession and must adhere to the professional standards and codes of practice.
2. Staff involved in the delivery of this service will be appropriately trained and competent in the provision of the services offered.
3. The services provided and scope of this service will be reviewed with staff as part of the annual appraisal process.
4. The service provider must provide evidence to the ICB that their healthcare professionals have the appropriate knowledge, skills, experience, qualifications and competency to provide the service. This must include but would not be limited to the following requirements:
    - Enhanced Disclosure and Barring Service checks have been completed
    - Where applicable staff will be fully registered with the appropriate professional body
    - All staff will be able to provide evidence of their continuing professional development post qualification.

4.6 Reporting and Audit
The provider must ensure that details of the patient's monitoring as part of this service are included in his or her lifelong record. If the patient is not registered for primary medical services with the provider of this service, the provider must send this information to the patient's registered GP for inclusion in their lifelong medical record.

Reporting to include:

- Total number of treatments undertaken
- Number of patients subsequently referred to ENT
- Number of patients referred to a specialist through advice and guidance
- Number of patients referred to ENT for wax removal due to contraindications
- Number of patients referred back to GP for onwards referral to ENT, post irrigation
- Number of patients undergoing second or subsequent irrigation procedure

Providers should record all the required information detailed on the Minimum Data Set (MDS) which will inform a quarterly report. The required reporting template can be found in Schedule 6A of the contract

It is recommended that the practice use the following codes when recording the delivery of this enhanced service.

Procedure	READ codes	SNOWMED codes
Irrigation of ear	Xa8Od	66363008

The provider must also provide an annual report to commissioners highlighting any results of research conducted and information gathering which will lead to improvements in practice and/or efficiencies in service delivery.

The provider is encouraged to participate and present any clinical research supporting the further development of this service and improvements for patient care.

4.7 Patient Satisfaction

In order to ensure patients are satisfied with the ear irrigation service, the ICB will undertake a rolling programme of questionnaires that providers will need to distribute to patients. When the provider needs to take part, they will be supplied with a number of paper questionnaires and pre-paid envelopes. Patients will return their questionnaires directly to the ICB and the provider will ensure they are encouraged to complete them. The ICB will ensure the provider receives the resulting data analysis for their information, as well as a copy of an annual overview.

5. Applicable Activity and Quality Reporting Requirements

5.1 Applicable Quality Requirements

Practices which take part in the scheme must demonstrate that service provision is of high quality, evidence based, safe and effective, with robust governance systems and safeguards in place, staff have received appropriate training and equipment is maintained to the highest standard. Practices may be required to provide commissioners with assurance that services provided are within the criteria of the contract general conditions, service conditions and particulars.

The Service Provider will notify the ICB Quality Services Team, Cross O'Cliff Court, Bracebridge Heath, Lincoln, LN4 2HN directly or by email licb.clinicalriskincidents@nhs.net of all serious incidents. These must be reported by the service provider within one working day of the information becoming known to them.

The service provider will participate in a review of any serious incidents notified to the Head of Quality Services and demonstrate that any learning from the incident is acted upon to minimise future risk.

5.2 CQUIN goals will not be applied.

6. Location of Provider Premises

Service delivery should be from the registered GP Practice, where the GP Practice is a Provider of the service. Alternative service provision locations should be agreed with Lincolnshire ICB.

Where a service provider is providing this service for a population covering several practices, agreement should be reached with the commissioner as to where these services will be located, in order to ensure equitable access to all patients.

The service may be provided as a home-based service in accordance with the registered provider's normal home-based services policies/guidance.

The provider's premises must meet the clinical requirements to provide primary care and ear irrigation services as advised in clinical guidance. The premises must be kept clean and safe for use and should portray an image of high quality and professional services at all times.

It is a requirement that all providers have a fully operational NHS N3 (secure) connection and will be required to utilise appropriate NHS IT systems such as NHS mail, NHS SUS, e-Referrals etc. All relevant staff must have their own smartcard.

7. Finance Schedule

Please refer to Schedule 4 (finance schedule) for tariffs

Payment will be based on the impact and saving on secondary care referrals achieved through contracting with the 'provider' on either a population basis or a practice list basis.

8. References

- NICE Clinical Knowledge Summary – Earwax (March 2021) https://cks.nice.org.uk/earwax
- NHS Quality Improvement Scotland - Ear Care Best Practice Statement (May 2006) http://www.healthcareimprovementscotland.org/previous_resources/best_practice_statement/ear_care.aspx
- NHS Wales Policy and Procedure for Ear Irrigation (2020) https://gov.wales/ear-wax-management-primary-and-community-care-pathway-html