HTE 10079 Hearing Aids for Adults with Hearing Loss Existing Use Assessment

Final Protocol

Produced by: CEDAR (Centre for Healthcare Evaluation, Device Assessment, and Research).

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1. Decision problem

The technologies included in this Existing Use Assessment are hearing aids. Table 1 summarises the decision problem to be addressed in this assessment. Further detail on each element can be found in the published scope for the assessment.

Table 1. Summary table of the decision problem

Item	Description

Population(s)	Adults with hearing loss who could benefit from a hearing aid.
	If the evidence allows, the following subgroups may be considered:
	• Severity of hearing loss:
	  ○ Mild (21 – 40 dB)
	  ○ Moderate (41 – 70 dB)
	  ○ Severe (71 – 95 dB)
	  ○ Profound (>95 dB)
	• Age
	• Sex
	• Socioeconomic status
	• Ethnicity

Intervention(s)	Hearing aids which meet core technology requirements and have one or more additional or innovative features that are available on the NHS, including: BTE, RITE.
Comparators	Hearing aids that meet core technology requirements and lack most or all of the additional innovative features being evaluated.
Setting	Primary, community and secondary care.

Outcomes eligible for inclusion	Intermediate outcomes:
	• Measures of adherence and use, for example:
	  ○ Hearing aid uptake rates
	  ○ Daily wearing time
	  ○ Progression in usage over time (via data logging)
	  ○ Proportion of patients continuing to wear hearing aids
	Clinical outcomes:
	• Aided speech in noise testing using QuickSIN
	• Aided threshold testing using functional gain testing
	• Objective signal-based indices such as the Hearing Aid Speech Perception Index (HASPI) and the Hearing Aid Speech Quality Index (HASQI)
	• Understanding speech in complex listening situations using Abbreviated Profile of Hearing Aid Benefit global score (APHAB-Global), Words-in-Noise (WIN) test

	• Intervention-related adverse events such as pain, discomfort, dissatisfaction with sound quality • Device related issues such as discomfort, feedback (whistling), difficulty with insertion, battery changes, cleaning, and volume adjustment Patient-reported outcomes: • Hearing-specific health related quality of life using validated self-reporting tools such as the Glasgow Hearing Aid Benefit Profile (GHABP) or the Client-Orientated Scale of Improvement (COSI). • Health related quality of life • Wellbeing • Revised Hearing Handicap Inventory (RHHI) • Listening ability, including music • Communication ability • Impact on social factors, such personal relationships and participation restrictions • Impact on partner and family Costs and resource use: • Cost of hearing aids and associated lifecycle costs • Cost of treating adverse events • Number of appointments for hearing aid fitting and repairs/reviews • Waiting times for hearing aid fitting and repairs/reviews • Costs of storage and transport of hardware • Costs of audiologist time including appointment, training • Cost of other resource use including health care professional appointments or visits (primary, community and secondary care), time for fitting and adjusting hearing aids, time for training Measures of environmental sustainability such as battery waste, e-waste generation, carbon footprint, device lifespan and replacement rates A user preference assessment will be conducted to determine the preferences of hearing aid users when choosing a hearing aid.
Economic analysis	A health economic model will be developed comprising a cost utility or cost-comparison analysis. Costs will be considered from an NHS and Personal Social Services perspective. Sensitivity and scenario analysis should be undertaken to address the relative effect of parameter or structural uncertainty on results. The time horizon should be long enough to reflect all important differences in costs or outcomes between the technologies being compared.

1.1 Objectives

Existing use assessments support procurement and commissioning decisions, promote effective use of NHS resources and improve care, through assessing a group of similar technologies that are already in established use in the NHS.

The objective of this existing use assessment is to determine if price variation between hearing aids available on the NHS is justified by differences in user or system outcomes. The overall research question the assessment will aim to answer is:

- Is there any value added by continuous improvements or incremental innovation in features of hearing aids that could justify variation in price to the NHS?

The following activities are proposed to address the research question:

Clinical effectiveness:

- Identify and assess the most relevant evidence to the decision problem, focusing on available innovative features, rather than specific devices.
- Highlight any equalities issues not described in the scope.
- Briefly outline the limitations of all evidence identified.

Cost effectiveness:

- Identify and assess relevant economic information.
- Identify and assess additional evidence to inform the economic modelling.
- Develop economic models to determine value for money of each feature where sufficient evidence is available.
- Report available model parameters and any key limitations.

User preference:

- Collect, analyse and report information on factors beyond clinical and cost-effectiveness which affect user preference when selecting a digital hearing aid.

2. Evidence review methods

An independent search for the most relevant evidence will be conducted by the EAG. Evidence that is most relevant to the scope will be identified using a combination of published evidence from databases, evidence provided by device manufacturers, and real-world evidence e.g. registry data. The EAG will adopt rapid review methods, guided by the Cochrane Rapid Review Methods Guidance (Garritty et al., 2024) and consistent with NICE HealthTech programme manual (NICE, 2025a).

Inclusion criteria

Table 2 outlines the inclusion and exclusion criteria considered for the evidence identified. If a large volume of evidence is identified, certain evidence may be prioritised for inclusion (see Section 2.2). This assessment will only consider hearing aids listed under the Hearing Aids and Custom Ear Moulds framework on NHS Supply Chain. As per the published scope, this assessment will not consider hearing implants such as bone conducting hearing implants, middle ear implants, cochlear implants and auditory brainstem implants, as these devices are listed under a separate framework on NHS Supply Chain. Hearing aid accessories or a comparison between air conduction hearing aids and bone conduction hearing aids will also not be considered for this assessment.

Table 2. Inclusion and exclusion criteria

	Inclusion Criteria	**Exclusion Criteria**
Population	Adults with hearing loss who could benefit from a hearing aid.	Children and young people aged <18 years.
Intervention	Hearing aids which meet core technology requirements and have one or more additional or innovative features that are available on the NHS, including: BTE, RITE.	Hearing aids which are not available on NHS Supply Chain, such as those provided over-the-counter or directly to the consumer. Hearing implants, hearing aid accessories or other hearing systems.
Comparators	Hearing aids that meet core technology requirements and lack most or all of the additional features being evaluated.	Hearing implants, hearing aid accessories or other hearing systems.

Setting	Primary, community and secondary care.	
Outcomes	Only those included in the scope.	Evidence will be excluded if no relevant outcomes are reported. If a subsection of outcomes are relevant to the scope, these alone will be reported.
Study design	• Systematic reviews and meta-analyses. • Randomised controlled trials (RCTs). • Non-randomised comparative studies. • Observational studies (retrospective and prospective).	• Narrative/non-systematic reviews. • Case reports.
Publication type	• Full-text publications • Conference abstracts and proceedings (provided they contain sufficient detail on methods and relevant outcomes) • Unpublished reports submitted by companies (provided they contain sufficient detail on methods and relevant outcomes).	Studies only reported in conference abstracts and proceedings may be excluded if there is a large volume of relevant full-text publications available.

2.1 Search strategy

Searches will be developed in Medline ALL (Ovid) by an experienced Information Specialist. Search terms will include free-text terms and controlled terms from databases (e.g. MeSH). Searches will be structured around device terms and innovative features as detailed in the published scope. The search strategy will be peer-reviewed by a second Information Specialist. A draft search strategy is available in Appendix A. The search strategy will be translated to each database.

The following bibliographic databases will be searched:

- Medline ALL (Ovid)
- Embase (Ovid)

- Cochrane Database of Systematic Reviews (CDSR)
- Cochrane Central Register of Controlled Trials (CENTRAL)
- International HTA database (INAHTA)
- Epistemonikos
- Database of Abstracts of Reviews (DARE, via CRD)
- NHS Economic Evaluation Database (NHS EED, via CRD)

The following clinical trials registries will be searched for ongoing trials:

- ClinicalTrials.gov
- International Clinical Trials Registry Platform (ICTRP)

Where possible, the EAG will identify additional studies from the information companies provided to NICE. To identify studies that have not been retrieved by the database searches, company websites will be searched for relevant publications.

Depending on the volume of evidence available from database searches, supplementary searches may be conducted. This may comprise of citation tracking of studies included in the evidence review, asking experts about known studies on the topic, identifying studies from the instructions for use documents, and searching stakeholder websites.

2.2 Study selection

Retrieved references will be imported into EndNote and deduplicated, after which they will be imported into the online screening tool Rayyan, where deduplication will be completed and records screened. Titles and abstracts of identified studies will be screened by one reviewer and a minimum of 20% of excludes will be checked by a second reviewer against the pre-specified inclusion and exclusion criteria. The AI screening tool available within Rayyan will not be used and all decisions will be made by the review team. Full-text articles of eligible studies will be obtained and screened by one reviewer with final inclusions and a random 20% of exclusions checked by a second reviewer. A list of studies excluded at the full text stage, with reasons for their exclusion, will be presented in an appendix in the report.

Where a large volume of evidence is identified, a pragmatic approach to study selection may be taken, in line with the Technical Support Document 27: Prioritising studies and outcomes for NICE HealthTech literature reviews (Carroll et al., 2025). Prioritisation of studies to be included may be based on factors such as study design, sample size, availability of relevant patient-focused outcomes, length of follow-up, and extent of generalisability to a UK population. Clinical experts may be consulted to inform these decisions. Any decisions made and approaches taken by the EAG will be flagged with the NICE team for discussion and presented transparently in the final report.

2.3 Data extraction strategy

Where available, the following data will be extracted from studies: study information (i.e., author, year), study design, intervention characteristics (i.e., digital hearing aid name, type, key features), comparator, participant characteristics (i.e., demographics, indication), outcomes relevant to the decision problem, and cost and resource data if relevant to a UK setting. Data will be extracted into a standardised table by a single reviewer and checked by a second reviewer.

2.4 Quality assessment strategy

Critical appraisal of key studies included in the clinical evidence review will be conducted using the JBI Critical Appraisal Tools. When there is a large number of studies, critical appraisal may be prioritised for studies considered key for decision making, particularly those providing data used for economic models, in accordance with the with NICE HealthTech programme manual (NICE, 2025a). A narrative summary of the key strengths and limitations of the evidence will be presented in the final report. This summary will highlight potential biases in individual studies for example, relevance to scope, potential confounding, and will discuss how these impact on the certainty of the results.

In line with NICE's real-world evidence framework (NICE, 2022), an assessment of the suitability and quality of real-world evidence will be conducted using the Data Suitability Assessment Tool (DataSAT).

2.5 Methods of synthesis and analysis

Meta-analysis may be considered to pool effect size associated with digital hearing aids with particular features from published literature. However, the EAG acknowledges that the evidence may not be suitable for meta-analysis due to anticipated diversity in the conduct and reporting of relevant studies, and the features-based nature of this assessment. Checks on heterogeneity or consistency will be performed to determine if meta-analysis will be appropriate and credible.

Where meta-analysis is not considered appropriate, relevant clinical outcome data identified will be presented in a suitable tabular format, accompanied by brief narrative synthesis highlighting any evidence of differences in clinical effectiveness or quality of life that can credibly be attributed additional features of digital hearing aids or incremental innovation.

3. Economic analysis methods

The economic analysis will be performed in line with the NICE reference case, where sufficient clinical evidence is available. The perspective of NHS and Personal Social Services will be undertaken. Costs will be expressed in 2025 prices and where applicable, costs will be inflated using NHS Cost Inflation Index (NHSCII). If a time horizon longer than one year is used, all costs and outcomes will be discounted at 3.5% per annum.

The economic analysis will compare costs and outcomes of different innovative features of the hearing aids. The devices will be based on those currently available through NHS Supply Chain. Device costs will be derived based on prices from NHS Supply Chain, using a weighted average by volume of sales for each feature group, where possible. The number of feature groups to be assessed in the economic analysis will depend on the available evidence in the EAG evidence review. If appropriate, quality-adjusted life years (QALYs) will be the primary outcome in the economic analysis. The time horizon will reflect the expected replacement interval for hearing aids. The incremental cost-effectiveness ratio (ICER) for each feature group will be estimated as incremental cost per additional QALY gained. Using the NICE willingness-to-pay threshold, the net monetary benefit will be calculated.

Economic evidence will be identified from literature identified from the EAG main search strategy and information submitted in companies' Requests for Information (RFIs).

3.1 Model development

If the available evidence is sufficient to inform a cost-utility analysis, a probabilistic analysis will be undertaken as the base case, to determine the cost-effectiveness between different feature groups of the hearing aids and the comparator. The comparator will be hearing aids that meet core technology requirements and do not include most or all the additional innovative features. In this analysis, a Monte Carlo simulation will be performed by random sampling a set of model inputs from the assigned distributions. The range or 95% confidence interval (95% CI) for each input will be identified from published literature, where possible. The model will be repeated for typically 1,000 to 10,000 iterations. Using the costs and outcomes generated from these iterations, a cost-effectiveness scatterplot and cost-effectiveness acceptability curves will be presented. Where there is insufficient data to allow modelling of features, a cost comparison model will be considered to assess costs between feature groups.

A pragmatic search for any existing economic models will be undertaken, prioritising models used in NICE guidance. If unavailable, this may expand to literature. The existing models will be evaluated for suitability for this assessment. Where no suitable model is available, a new model will be developed in Microsoft Excel or R. The model structure and outcomes to be included in the model will be based on the evidence identified in the EAG evidence review, company RFIs, clinical and user expert advice and findings from the user preference assessment. Expert opinions will be sought to ensure the model reflects NHS practice. All assumptions applied in the economic model will be clearly stated, and all model inputs and data sources will be reported. Additional targeted searches will be conducted to inform model parameters, along with expert opinion as needed.

Costs will be considered from an NHS and Personal Social Services perspective, consistent with the methods and data sources recommended in NICE reference case. Costs and resource use in the model may include:

- Cost of hearing aids and associated lifecycle costs
- Costs of treating adverse events
- Number and costs of appointments for hearing aid fitting, reviews/repairs
- Staff time and costs for training, appointments and support
- Waiting times for appointments resulting from the different innovative features if available data are sufficient
- Costs of storage and transport of hardware
- Cost of other resource use including health care professional appointments or visits (primary, community and secondary care)

For utility or disutility values to inform the economic model, these values will be identified from NICE guidance and a targeted literature search. Where appropriate, sensitivity analyses will be undertaken to examine the impact of different utility values.

Environmental sustainability across feature groups will be explored. If evidence allows, lifecycle costs will include factors such as battery waste, device lifespan and replacement rates. Additional evidence on environmental outcomes will be presented separately if available.

Deterministic analysis will also be performed using the point estimate of each model input, and results will be reported. Deterministic sensitivity analyses will be undertaken to identify the key cost drivers and to explore the impact of uncertainty, where possible. Deterministic sensitivity analyses may include one-way sensitivity analysis and scenario analysis. Subgroup analyses may be performed for different patient subgroups if sufficient evidence is available to do so. Where applicable, threshold analysis may be conducted to identify the price range where the innovative feature is considered as value for money.

To validate the EAG model, the model will be reviewed and checked by a second health economist independently. This will include checking model calculations used

in calculating model inputs, patient transitioning in the model and the resulting total and incremental costs and QALYs. All model inputs will be checked against their original source, and model inputs will be varied to check if the results are consistent with existing expectations.

4. User preference assessment

In parallel to the clinical evidence review and economic analysis, the EAG will perform a user preference assessment to identify criteria related to features of the technology or its performance (preference criteria) that influence the preferences of users. Users are people whose experience with the technologies would allow them to make informed choices between different options. For this assessment, there are expected to be 2 groups of users: audiologists and people with hearing loss who use or have experience using hearing aids.

Two virtual workshops will be held, and 2 email exercises will be performed by the EAG as part of the user preference assessment (Table 3).

Table 3: Summary of user preference assessment activities.

User preference activity	Purpose
Workshop 1	Identify and define key factors (criteria) that are important to them when selecting a hearing aid.
Email exercise 1	Determine an average rank for each criterion identified, in order of most to least important, using the simple multi-attribute rating technique (SMART).
Email exercise 2	Establish the weight (relative importance) of each criterion, using the swing weighting technique (which may include weighing only the top 10 ranked criteria).
Workshop 2	Define “performance rules” which can describe how each criterion can be measured.

The above steps will generate a performance matrix table which will include the most important criteria to users and how users would measure ‘success’ in these criteria. This performance matrix may guide the EAG in where to focus the clinical evidence review and may be used to guide the health economic model or assess if additional scenario analyses are needed. Findings from the user preference assessment will be

presented in the EAG assessment report, alongside results of the clinical evidence review and health economic modelling.

5. Handling information from the companies and other stakeholders

All data submitted by the companies in evidence and information requests by NICE, or data submitted by other stakeholders will be considered by the EAG if received by 27/02/2026. Information arriving after this date will not be considered. If the data included in the information provided meets the inclusion criteria for the review, they will be extracted and quality assessed following the procedures outlined in this protocol. The EAG may seek clarification or additional information from companies and other stakeholders where necessary. All correspondence between the EAG and companies will happen through NICE.

Any 'commercial in confidence' data provided by a company and specified as such will be highlighted in blue and underlined in the assessment report. Any 'academic in confidence' data provided by a company, and specified as such, will be highlighted in yellow and underlined in the assessment report. If confidential information is included in the economic model, the EAG will provide a copy of the model with 'dummy variable values' for the confidential values (using non-confidential values).

The EAG will ensure any personal information (e.g. contact details) of participants in the user preference activities will be kept confidential and not shared with other participants.

6. Competing interests of authors

None.

7. References

Carroll C, Cooper K, Harnan S et al. (2025) Technical Support Document 27: Prioritising studies and outcomes for NICE HealthTech literature reviews. Sheffield Decision Support Unit

Garritty C, Hamel C, Trivella M et al. (2024) Updated recommendations for the Cochrane rapid review methods guidance for rapid reviews of effectiveness. BMJ 384: e076335

Németh B, Molnár A, Bozóki S et al. (2019). Comparison of weighting methods used in multicriteria decision analysis frameworks in healthcare with focus on low- and middle-income countries. Journal of comparative effectiveness research, 8(4), 195–204.

NICE (2025a) NICE HealthTech Programme Manual (PMG48). Available from: Introduction | NICE HealthTech programme manual | Guidance | NICE

NICE (2025b) NICE technology appraisal and highly specialised technologies guidance: the manual (PMG36). Available from: Introduction | NICE process and methods | Guidance | NICE

NICE (2022) NICE real-world evidence framework (ECD9). Available from: Overview | NICE real-world evidence framework | Guidance | NICE

Appendix A: Draft search strategy

Ovid MEDLINE(R) ALL <1946 to January 13, 2026>

1 Hearing Aids/ 10750

2 ((hear or hearing) adj3 aid*).tw. 12685

3 1 or 2 15780

4 digital.tw. 234775

5 3 and 4 617

6 "behind the ear".tw. 639

7 (receiver adj3 canal).tw. 29

8 (receiver adj3 ear).tw. 30

9 (receiver adj3 (ear or canal)).tw. 53

10 ((contralateral or bicontralateral or "bi contralateral") adj2 "routing of sound").tw. 21

11 ((BTE or RITE or RIC or CROS) and hear*).tw. 490

12 BiCROS.tw. 23

13 or/6-12 1072

14 5 or 13 1623

15 ((advance* or adaptive) adj2 "noise manag*").tw. 8

16 "context aware".tw. 1464

17 (AI or "artificial intelligen*" or (machine adj2 learn*)).tw . 273004

18 speech in noise processing.tw. 30

19 (beamform* or binaural).tw. 8630

20 (bluetooth or auracast or streaming or "public broadcast*").tw. 9744

21 (app or apps or mobile* or smartphone*).tw. 217337

22 Recharge*.tw. 11388

23 (charg* adj3 (batter* or wireless or desktop)).tw. 1596

24 (frequenc* adj2 lower*).tw. 24043

25 ((wireless or remote) adj3 (microphone* or accessor*)).tw. 175

26 ("two way" or "2 way" or "hands free").tw. 35034

27 ("sound generator*" or mask*).tw. 117252

28 ("water resistan*" or waterproof or "water proof" or splashproof or "splash proof").tw. 3974

29 innovati*.tw. 297430

30 (teleaudiology or "tele audiology").tw. 118

31 (remote adj3 (manage* or control*)).tw. 5347

32 (translat* adj3 language*).tw. 2782

33 biometric*.tw. 12608

34 (Hearables or wearables).tw. 3545

35 or/15-34 983956

36 14 and 35 284

37 exp animals/ not humans.sh. 5414436

38 36 not 37 283

39 limit 38 to english language 267