Supporting Access to New Indications for Cochlear Implants: Health Technology Assessment (HTA) Challenges and Insights

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Presenter Disclosure Information

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Current Situation

• First new CI indications since ~2000
  – ElectroAcoustic Stimulation (EAS)
  – Single-Sided Deafness (SSD; also, asymmetric hearing loss)
  – Expanded Indications (EI) for CI

• Recent bilateral CI Health Technology Assessments (HTA) experiences highlighted significant gaps in evidence quality and outcomes data consistency

• Need evidence base for regulatory approvals AND for HTAs that determine reimbursement access

• Apply insights gained from recent CI HTA experience to improve HTA success for new indications
What Are HTAs?

• Assessment of available evidence (literature) on selected intervention
  – High quality studies – remove biases
  – Safety and effectiveness – proven patient outcomes
  – Cost-effectiveness – good value for money spent
• Used by public and private payers to determine which interventions cover (patient access)
Where Have CI HTAs Been Done?

- Global: UK, France, Spain, Netherlands, New Zealand, etc.

  ![NICE](image)

- US: Public and Private entities

- State:

  - Each HTA adds to reference body for next assessment
  - Each HTA is critical for future access to CI
Why HTAs?

Balance: deliver better care, improve population health & manage/lower costs

Healthcare Triple Aim

Population health
(Clinical outcomes)

Experience of care
(Satisfaction, QoL)

Per capita cost
(Cost-effectiveness)
How Is an HTA Done?

• Select technologies for evaluation
• Formulate key questions
• Perform literature search and assessment (for selected period)
• Publish assessment report
• Receive public comments and update assessment
• Conduct public meeting
• Obtain panel decision (coverage, coverage with limits, no coverage)
• Publish & implement final decision
HTA and New Technologies

HTAs evaluate whether new technologies demonstrate one or more of the following:

• Lower costs – reduce length of stay (LOS), OR suite time, etc.
• Improve patient outcomes – quicker recovery, less invasive, better result, etc.
• Improve quality and safety – lower infection rate, etc.
HTA and CI: Challenges

• Expensive device; does not lower hospital, provider costs
• Already has high quality & safety; incremental improvements
• Principal advances are improved patient outcomes; however, need more sensitive quality of life measures for deafness, CI
• Small population; small study sizes
• Variances in study procedures and reported measures/conditions; difficult to compare data across studies
HTA and CI: Top Recommendations

1. Consider outside stakeholders (e.g., HTA reviewers)
2. Include references to seminal studies (often precede review period) to address first-time key questions
3. Develop publication strategies to support access to new indications (independent of brand)
4. Develop QoL and Functional Benefit instruments for CI
Summary and Call to Action

• Leverage insights from previous HTA challenges to improve HTA success for new CI indications
• Highlight use of clinical publications by payers for coverage decisions that determine patient access
• Urge stakeholder collaboration to develop solid evidence to support patient access to new indications for CI
• Begin process NOW...takes time to implement