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

Tom Walsh, MBA
Director, Business Strategy and Health Policy
Tom Walsh
Employee, Advanced Bionics
Current Situation

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

• Health Technology Assessment (HTA) experiences with bilateral CI 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 previous CI HTA experiences to improve HTA success for new indications
What Are HTAs?

• Rigorous 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:**

  ![Logos](image)

- 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

Population health (Clinical outcomes)

Healthcare Triple Aim

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 selection (for assessment review 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
HTAs evaluate whether new technologies demonstrate one or more of the following:

<table>
<thead>
<tr>
<th>Objective</th>
<th>Measure</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lower costs</td>
<td>Reduce length of stay (LOS), OR suite time, etc.</td>
</tr>
<tr>
<td>Improve patient outcomes</td>
<td>Quicker recovery, less invasive, better result, etc.</td>
</tr>
<tr>
<td>Improve quality and safety</td>
<td>Lower infection rate, fewer readmissions, etc.</td>
</tr>
</tbody>
</table>
HTA and CI: Challenges

• Expensive device; does not lower hospital, provider costs
• Already has high quality & safety; incremental improvements
• CI innovations have 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
1. Consider outside stakeholders’ use of your publications (e.g., HTA reviewers)

2. Include references to seminal studies (often precede review period) to address first-time key questions

3. Collaborate to develop publication strategies that support access to new indications (independent of brand)

4. Develop QoL and Functional Benefit instruments for CI to ensure appropriate comparison with other technologies
Summary and Call to Action

- Leverage insights from previous HTA challenges to improve HTA success for emerging CI indications
- Highlight payer use of clinical publications for coverage decisions that determine patient access
- Urge stakeholder collaboration to develop solid evidence and appropriately sensitive QoL and Functional Benefit instruments to support patient access to new indications for CI
- Begin process NOW…takes time to implement