

Expansion of Cochlear Implant Criteria

Robert J. Yawn, MD, MBA, FACS

Associate Professor of Otolaryngology and Neurosurgery

University of Tennessee Health Science Center, Memphis, TN

Disclosures

- No financial relationships to disclose

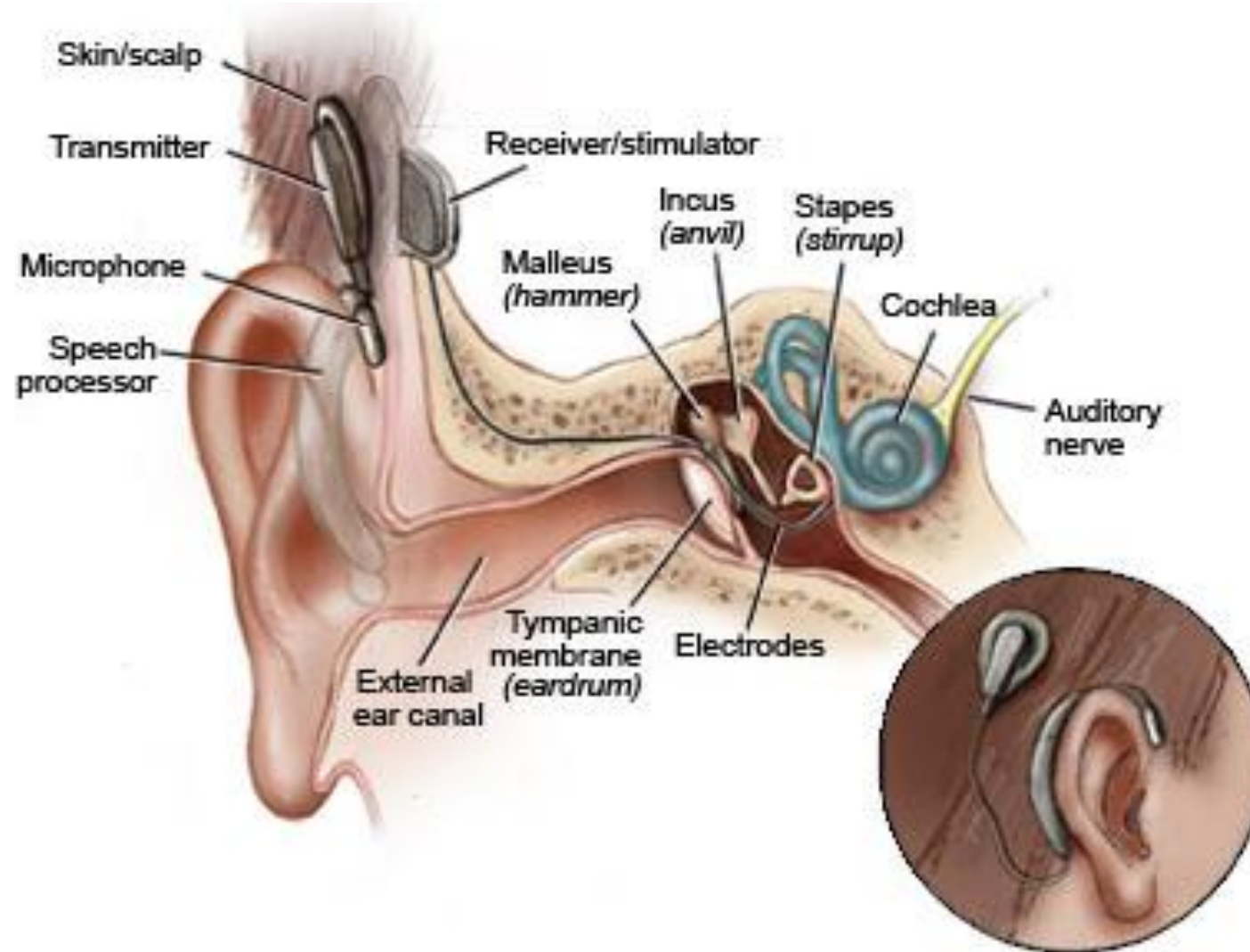
Overview

- Cochlear Implants
 - Introduction/Device Overview
 - History/Discovery
 - Initial Audiologic Criteria
 - Current State of Affairs:
 - Manufacturer Criteria
 - Medicare
 - Commercial Insurance
 - Medicaid
 - Evidence for Expansion of Modern Criteria
 - Unique Scenarios
 - Single-Sided Deafness (SSD)
 - Retrocochlear Pathology/Vestibular Schwannoma

Parts of a CI

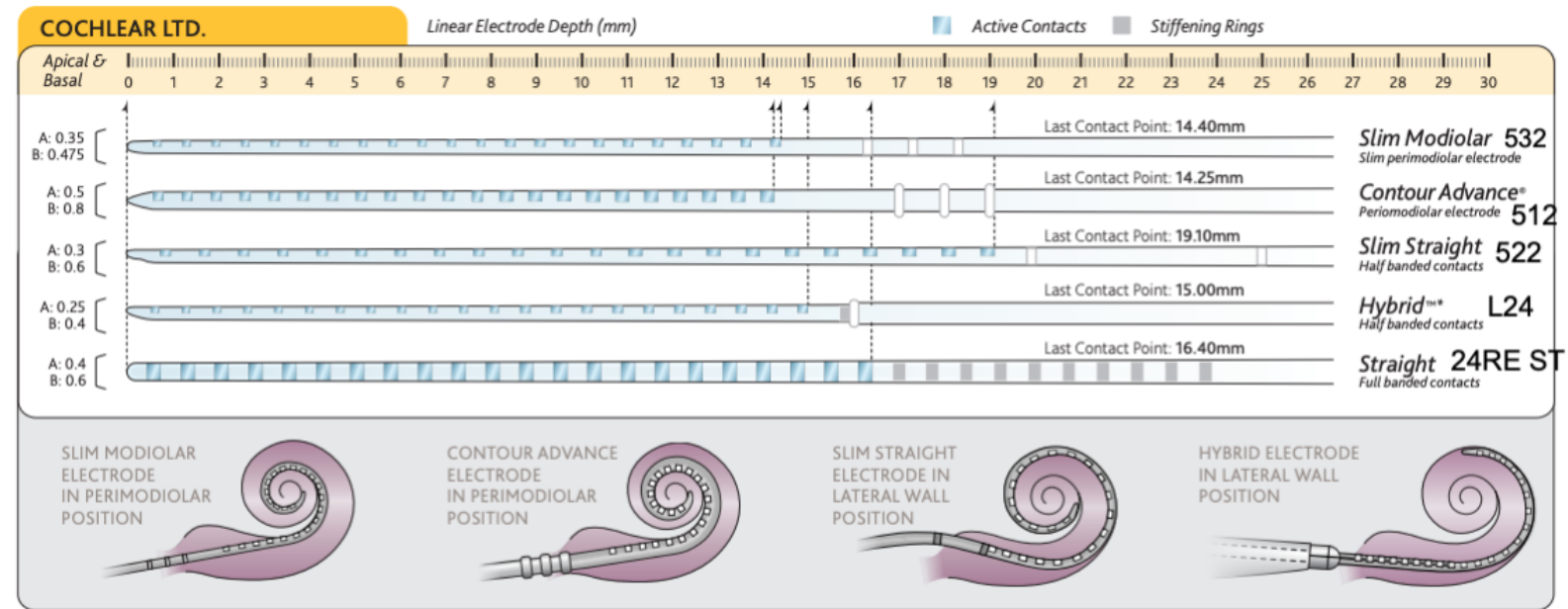


How does a CI work?



Cochlear

- CI 1032
- CI 1022
- CI 1012

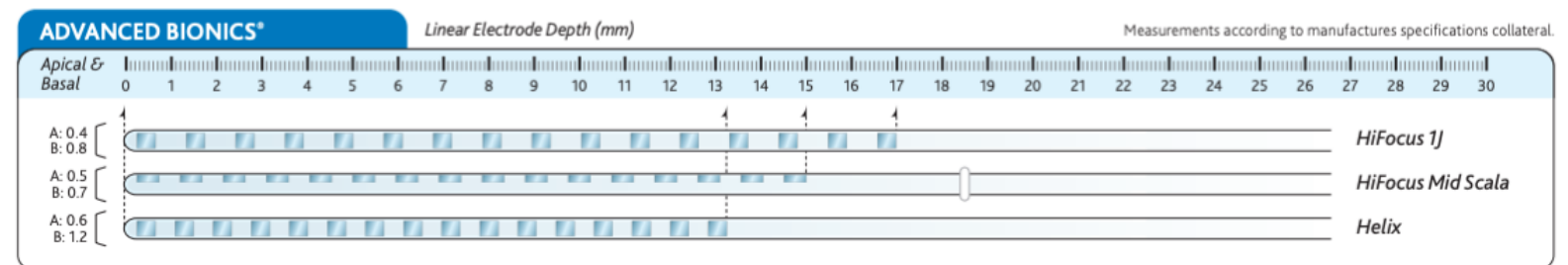
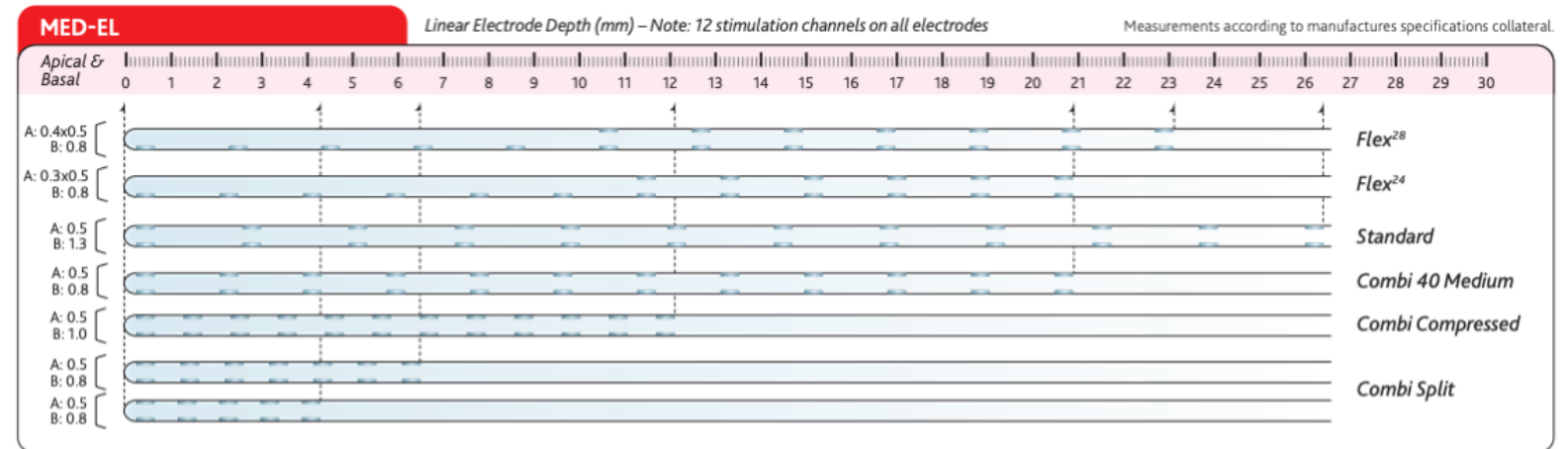


Advanced Bionics (AB)

- Slim J
- Mid-Scala

Med-EL

- Flex 20/24/28 (mm)
- Flexsoft



History of Cochlear Implantation

- 1748- Benjamin Wilson used static electricity from a Leyden Jar to stimulate hearing in a deaf woman.
- Alessandro Volta conducted similar experiments in 1800s but discontinued due to patient discomfort.
- 1957- French physicists Djourno and Eyries used an electrical stimulator to stimulate the auditory nerve directly and the patient had sound awareness for several weeks.



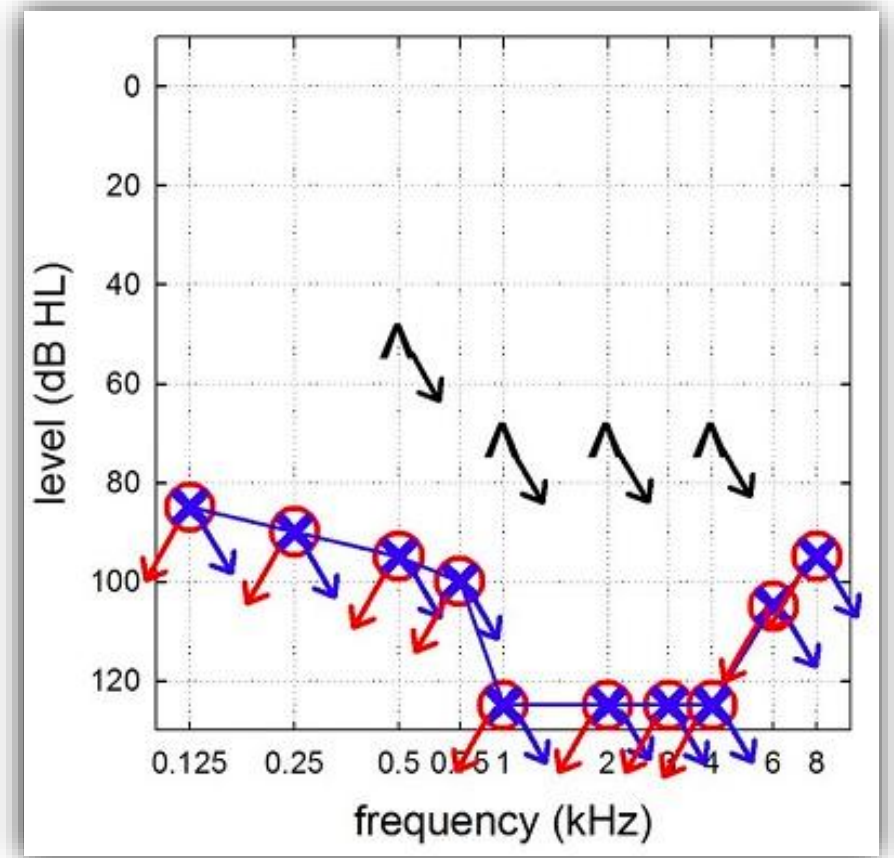
History of Cochlear Implantation

- William House is considered the father of neurotology.
- Implanted the first “cochlear Implant” in 1961.
- First 3M-House single-channel cochlear implant FDA approved for adults on 11/29/1984.
- Nucleus 22 multiple channel cochlear implant FDA approved 10/31/1985.



Initial Criteria for Cochlear Implantation

- Profound bilateral sensorineural hearing loss (SNHL)
- Post-lingually deafened
- No benefit from hearing aids
- 0% performance on open-set speech testing



Who Determines Cochlear Implant Labeling?

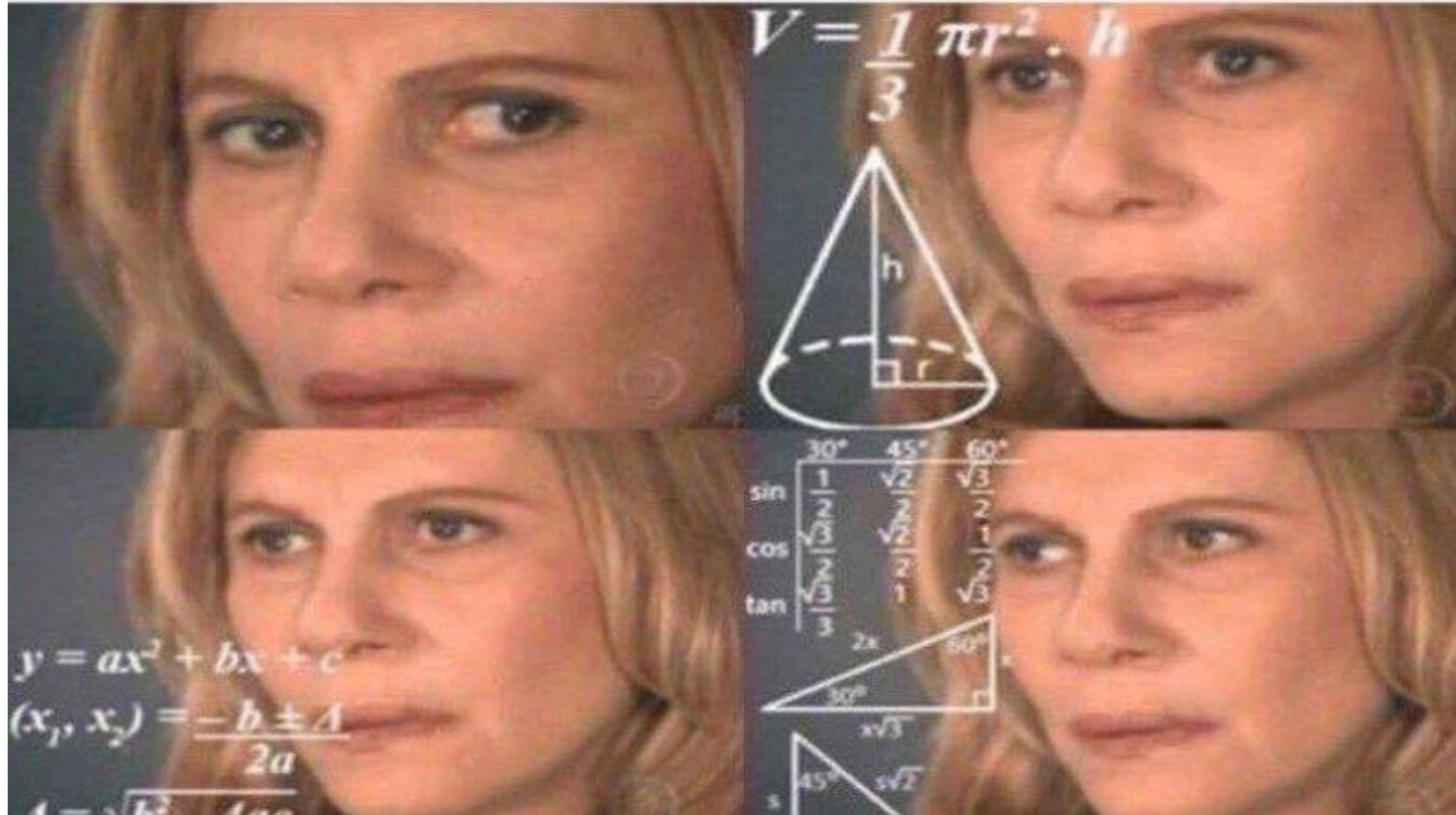
- **Industry** does, NOT the FDA.
- Manufacturer approaches the FDA with intent to complete a clinical trial.
- FDA either approves or does not approve the request for trial.
- Trial is completed
- If acceptable, the FDA grants premarket approval (PMA) for commercial release of the device and associated 'labeled criteria'.
- Because of this, each FDA-approved device by the three cochlear implant companies active in the US **have different criteria**.
- Medicare adopts criteria based on assumed best practice for coverage.
- Commercial insurance companies' guidelines may or may not follow the approved criteria.

Table 1 FDA-approved Labeling for Adults for Current Cochlear Implant Systems

Device	Audiometric indications	Speech recognition indications
Advanced Bionics HR90K Ultra 3D	Severe to profound, bilateral sensorineural hearing loss (>70 dB HL)	$\leq 50\%$ for open-set sentence recognition (HINT sentences)
Cochlear Profile and Profile Plus	Moderate to profound hearing loss in the low frequencies and profound (≥ 90 dB HL) hearing loss in the mid to high frequencies	$\leq 50\%$ in the ear to be implanted ($\leq 60\%$ in the best-aided condition) on recorded tests of open-set sentence recognition
Cochlear Hybrid—L24	Thresholds ≤ 60 dB HL through 500 Hz and ≥ 70 dB HL for 2,000 Hz	$\leq 60\%$ CNC word recognition in the ear to be implanted, $\leq 80\%$ CNC word recognition in the contralateral ear
MED-EL Synchrony and Synchrony 2	Bilateral severe to profound sensorineural hearing loss (pure tone average ≥ 70 dB HL)	$\leq 40\%$ in best-aided listening condition on recorded tests of open-set sentence recognition (HINT sentences)
MED-EL Synchrony and Synchrony 2 EAS	Thresholds ≤ 65 dB HL through 500 Hz and ≥ 70 dB HL for 2,000+	$\leq 60\%$ CNC word recognition in the ear to be implanted and in the contralateral ear
MED-EL Synchrony and Synchrony 2 for single-side deafness	Thresholds ≥ 90 dB HL in the ear to be implanted and normal hearing or mild sensorineural hearing loss in the other ear	$< 5\%$ CNC word recognition in the ear to be implanted
MED-EL Synchrony and Synchrony 2 for asymmetric hearing loss	Thresholds ≥ 90 dB HL in the ear to be implanted and mild to moderately severe sensorineural hearing loss in the other ear, with a difference of at least 15 dB in pure tone averages between ears	$< 5\%$ CNC word recognition in the ear to be implanted
Oticon Neuro System	Severe to profound hearing loss (pure tone average ≥ 70 dB HL at 500, 1,000, and 2,000 Hz)	50% or less on HINT sentences in quiet or noise, in the best-aided listening condition

Abbreviations: CNC, Consonant–Nucleus–Consonant; HINT, hearing in noise test.
Source: Adapted from Gifford et al.⁹

Confused Yet?



So... How do we decide when to implant?

- FDA governs the CI industry but does **not govern the decisions of individual clinicians.**
- *“good medical practice and the best interests of the patient require that physicians use legally available drugs, biologics, and devices according to their best knowledge and judgment. If physicians use a product for an indication not in the approved labeling, they have the responsibility to be well informed about the product, to base its use on firm scientific rationale and on sound medical evidence, and to maintain records of the product’s use and effects”*

Who gets implanted?

- If a patient receives a cochlear implant who does not meet the FDA approved indications, it is referred to as **“off-label” use**.
- **78% of respondents** at a recent American Neurotology Society meeting reported performing **at least one cochlear implant for an off-label indication** within the 2 years prior to survey completion.
- This discrepancy indicates that current clinical best practice **differs** from current labeling.
- Decision making often depends therefore on **insurance coverage and approval**.

Medicare Indications

- **These indications should be followed very strictly for patients that are being implanted with Medicare coverage.**
- The Centers for Medicare and Medicaid Services (CMS) is a federal program that determines how products will be reimbursed through Medicare.
- Medicare covers people 65yo and older, people younger than 65 with certain disabilities, and individuals of all ages with end-stage renal disease.
- The FDA focuses on safety and effectiveness, while CMS determines if coverage is reasonable and necessary
- Therefore, FDA approval doesn't guarantee CMS coverage, and CMS coverage may extend to technologies that the FDA hasn't yet approved.

Current CMS Guidelines for coverage

- Bilateral Pre or Postlinguistic deafness
- Moderate-to-profound hearing loss with limited amplification benefit
- Test scores **of $\leq 40\%$ correct in best aided condition** using tape-recorded tests of open-set sentence recognition.
- CI can be performed under CMS guidelines between 40%-60% as long as patient is enrolled in a CMS or FDA approved clinical trial.
- Guidelines are intentionally vague with respect to noise.
- The American Cochlear Implant Alliance has submitted a formal request with CMS for expansion of criteria to include adults $<60\%$

What About Medicare Advantage Plans?

- Medicare Advantage (Part C) plans are required to at least cover the same services related to CI as Part A and Part B.
- Part C plans usually require PREAUTHORIZATION
- This can be useful as plans may approve a request to provide CI in patients that are in the "gray zone" that fall outside of traditional Medicare Criteria

Coverage by Private Insurance

- Private insurance coverage is variable, but frequently follows CMS decisions.
- More than 90% of private employer health insurance plans and managed care provide benefits for CI.
- Indications vary and may differ from FDA labeling.
- Option for appeal if initially denied.
- Typically benefits are reviewed annually which may allow private insurance more flexibility in changing coverage benefits compared to Medicare and FDA.
- If in doubt, submit Cochlear Implant Evaluation and documentation for approval.

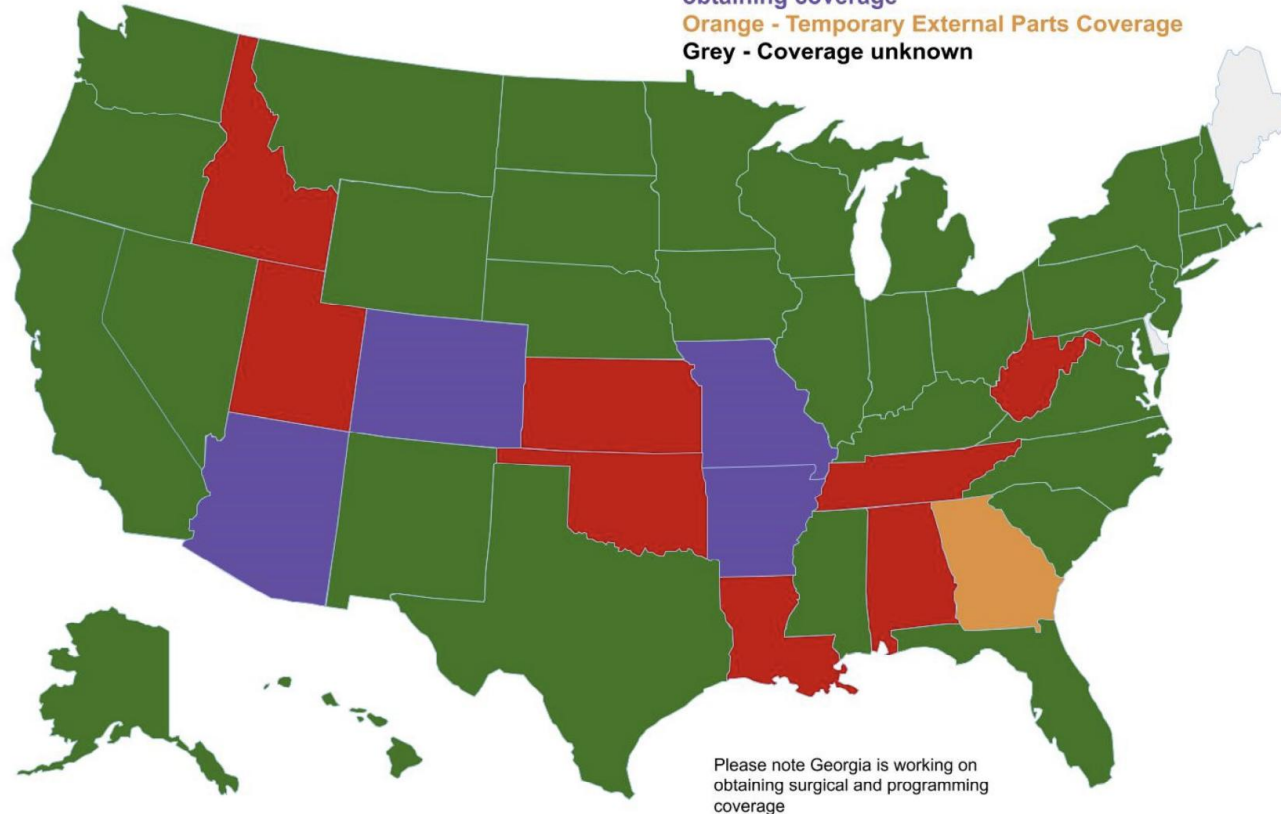
Medicaid Coverage

- Joint federal/state program that covers medical costs for individuals who meet income criteria.
- Federal government has general rules but each state sets its own criteria for inclusion.
- **Medicaid must cover for any health issue or disability that can interfere with a child's ability to develop in a typical manner.**
- For **children**, generally CI surgery/audiology/rehab/devices are **covered in all 50 states** with slight variation on specifics.
- For adults coverage varies significantly from state to state.

Medicaid Coverage for Adults

Medicaid Adult CI Coverage As of January 2024

Green - States with full coverage for adults
Red - States with no coverage
Purple - States with ACIA Champs working on obtaining coverage
Orange - Temporary External Parts Coverage
Grey - Coverage unknown



Evidence for Expansion

- Multiple clinical trials have shown **significant improvements** in patients with greater residual hearing on cochlear implant testing.
- Some cochlear implant test batteries (HINT/Az-Bio sentence) have **ceiling effects limiting their usefulness** in appropriate evaluation and monitoring of progress with CI
- Clinics are moving towards **CNC words and CNC phonemes** as these tests are generally harder and can identify patients with meaningful hearing loss that are not benefitting from amplification.
- **How much noise** do we use when evaluating candidacy?
- Current screening guidelines **60/60 rule**.
- In the US, CMS significantly influences downstream trends from other coverage sources.

Unique Scenarios: Single Sided Deafness

- Increasing attention has been paid to patients with asymmetric HL or SSD. These patients historically have not had access to CI due to good hearing in the contralateral ear.
- Studies have shown:
 - Improved speech recognition in the implanted ear
 - Better performance in noise
 - Modest improvement in sound localization
 - Tinnitus reduction
 - Improvements in QoL

Single-Sided Deafness

- On July 22, 2019 MED-EL received FDA approval for usage in patients 5 years and older with single-sided deafness and asymmetric hearing loss.
- Cochlear received FDA approval on January 11, 2022 for the same indications.
- These approvals have increased commercial insurance coverage for these patients but it is still **not included under Medicare coverage.**

Unique Scenarios: Retrocochlear Pathology

- As a part of clinical trials, some academic centers have begun performing simultaneous cochlear implantation and vestibular schwannoma removal.
- This is not FDA approved and only a part of clinical trials, as retrocochlear pathology (i.e. vestibular schwannoma) is a contraindication to cochlear implantation according to the FDA.
- Significant challenges exist including preservation of cochlear nerve function during tumor resection, and magnet placement interfering with tumor surveillance.

Take Home Points

- FDA labeling, CMS guidelines, and commercial insurance guidelines do not always overlap.
- Screening for patients should be performed based on the 60/60 rule if dissatisfied with hearing aid performance.
- **STRICT ADHERENCE TO CMS GUIDELINES FOR PATIENTS WITH MEDICARE A/B**
- CMS criteria may change based on advocacy
- State advocacy is necessary for certain states to expand Medicaid coverage.
- With commercial insurance, always ok to “shoot your shot” with preauthorization after CI-workup.

Thank You

