Title of Rule: Revision to the Medical Assistance Act Rule concerning Unilateral Cochlear Implants, Section 8.200.3.D.1.2.e.iii-iv
Rule Number: MSB 23-05-05-A
Division / Contact / Phone: Health Policy Office / Erica Schaler / 303-866-5927

STATEMENT OF BASIS AND PURPOSE

1. Summary of the basis and purpose for the rule or rule change. (State what the rule says or does and explain why the rule or rule change is necessary).

   The proposed rule adds unilateral cochlear implants to the list of covered cochlear implants in the speech, language, and hearing section of the physician services rule for pediatric members that meet Federal Drug Administration (FDA)-approved age guidelines. The current rule covers bilateral cochlear implants for pediatric members, but not unilateral cochlear implants. Bilateral and unilateral cochlear implants are covered under Early and Periodic Screening, Diagnosis and Treatment (EPSDT) for pediatric members aged 20 and under, the proposed rule references the EPSDT authority for this coverage.

2. An emergency rule-making is imperatively necessary

   ☐ to comply with state or federal law or federal regulation and/or
   ☐ for the preservation of public health, safety and welfare.

   Explain:

3. Federal authority for the Rule, if any:

   42 CFR 440.110(c) (2023)

4. State Authority for the Rule:

   Sections 25.5-1-301-303, 25.5-5-202(l)(I), C.R.S. (2023);

Initial Review **11/09/23** Final Adoption **12/08/23**
Proposed Effective Date **01/30/24** Emergency Adoption

DOCUMENT #03

Title of Rule: Revision to the Medical Assistance Act Rule concerning Unilateral Cochlear Implants, Section 8.200.3.D.1.2.e.iii-iv
Rule Number: MSB 23-05-05-A
Division / Contact / Phone: Health Policy Office / Erica Schaler / 303-866-5927

REGULATORY ANALYSIS

1. Describe the classes of persons who will be affected by the proposed rule, including classes that will bear the costs of the proposed rule and classes that will benefit from the proposed rule.

   Pediatric members who require unilateral cochlear implants will benefit from the proposed rule as these implants are now a covered benefit. Providers of cochlear implants will now be able to receive reimbursement for medically necessary cochlear implants provided to pediatric clients with unilateral hearing loss. The Department will bear the cost of the proposed rule.

2. To the extent practicable, describe the probable quantitative and qualitative impact of the proposed rule, economic or otherwise, upon affected classes of persons.

   This rule has a quantitative impact on the Department as the new coverage of cochlear implants for pediatric members with unilateral hearing loss will increase from zero to an undetermined number of claims that will be reimbursed for these devices/services. This rule has a qualitative impact on Pediatric members who will now be able to receive medically necessary unilateral cochlear implants as a covered Medicaid benefit.

3. Discuss the probable costs to the Department and to any other agency of the implementation and enforcement of the proposed rule and any anticipated effect on state revenues.

   The cost to the Department of the proposed rule is estimated to be $3,040,000, annually. This rule will not result in costs to any other agency.

4. Compare the probable costs and benefits of the proposed rule to the probable costs and benefits of inaction.

   The probable cost of the proposed rule is provided in the response to question #3 above. The benefit of the proposed rule is coverage of cochlear implants for pediatric members with unilateral hearing loss. The cost of inaction is continuing lack of coverage for cochlear implants for pediatric members with unilateral hearing loss. The only benefit to inaction would be the program cost savings of denying coverage of cochlear implants to pediatric members with unilateral hearing loss.

5. Determine whether there are less costly methods or less intrusive methods for achieving the purpose of the proposed rule.

There are no less costly methods or less intrusive methods to expand coverage of unilateral cochlear implants to pediatric members.

6. Describe any alternative methods for achieving the purpose for the proposed rule that were seriously considered by the Department and the reasons why they were rejected in favor of the proposed rule.

   There are no alternative methods for expanding coverage of unilateral cochlear implants to pediatric members.

8.200 PHYSICIAN SERVICES

8.200.3. BENEFITS

8.200.3.D Physician Services

Note: 8.200.3.D.1 Podiatry Services was moved to §8.810 01/2015.

2. Speech – Language and Hearing Services

[SECTIONS 8.200.3.D.2.a-d UNAFFECTED BY THIS RULE CHANGE, REMAIN AS-IS]

e. COVERED SERVICES

[SECTIONS 8.200.3.D.2.e.i-ii UNAFFECTED BY THIS RULE CHANGE, REMAIN AS-IS]

iii. Audiology Services

1. Audiological benefits include identification, diagnostic evaluation and treatment for ~~children~~ members 20 and under with hearing loss, neurologic, dizziness/vertigo, or balance disorders. Conditions treated may be either congenital or acquired.

2. Assessment – Service may include testing or clinical observation or both, as appropriate for chronological or developmental age, for one or more of the following areas, and must yield a written evaluation report.

a. Auditory sensitivity (including pure tone air and bone conduction, speech detection and speech reception thresholds).

b. Auditory discrimination in quiet and noise.

c. Impedance audiometry (tympanometry and acoustic reflex testing).

d. Hearing aid evaluation (amplification selection and verification).

e. Central auditory function.

f. Evoked otoacoustic emissions.

g. Brainstem auditory evoked response.

h. Assessment of functional communicative skills to enhance the activities of daily living.

i. Assessment for cochlear implants (for ~~clients~~ members age~~s~~ 20 and under).

j. Hearing screening.

k. Assessment of facial nerve function.

l. Assessment of balance function.

m. Evaluation of dizziness/vertigo.

3. Treatment **–** Service may include one or more of the following, as appropriate:

a. Auditory training.

b. Speech reading.

c. Augmentative and alternative communication training including training on how to use cochlear implants for members~~clients~~ ages 20 and under. Adults with chronic conditions may qualify for augmentative and alternative communication services when justified and supported by medical necessity to allow the individual to achieve or maintain maximum functional communication for performance of Activities of Daily Living.

d. Purchase, maintenance, repairs and accessories for approved devices.

e. Selection, testing and fitting of hearing aids for ~~children~~ members 20 and under with bilateral or unilateral hearing loss; and auditory training in the use of hearing aids.

f. Purchase and training on Department approved assistive technologies.

g. Balance or vestibular therapy.

iv. Cochlear Implants ~~– Unilateral~~

1. Bilateral and unilateral ~~C~~cochlear implants ~~may be indicated~~are covered for ~~clients~~ members aged ~~12 months through~~ 20 years and under in accordance with Section 8.280. ~~t~~The following prior~~e~~-authorization criteria must be met:

a. ~~Six months of age or older~~Food and Drug Administration (FDA)-approved cochlear implant guidelines for age.The proposed use of the device must be in accordance with FDA guidelines applicable to the member's age.

~~b. Limited benefit from appropriately fitted binaural hearing aids (with different definitions of "limited benefit" for~~

~~children 4 years of age or younger and those older than 4 years) and a 3-6 month hearing aid trial.~~

b~~e~~. Bilateral and unilateral hearing loss with unaided pure tone average thresholds of 6~~7~~0 dB or greater.

c~~d~~. Minimal speech perception may be measured using recorded standardized stimuli-speech discrimination scores of 50-60% or below with optimal amplification at 1000, 2000 and 4000 Hz.

d~~e~~. Family support and motivation to participate in a post-cochlear aural, auditory and speech language rehabilitation program.

e~~f~~. Assessment by an audiologist and otolaryngologist experienced in cochlear implants.

f~~g~~. ~~Bi lateral, unilateral, and hybrid/Electric Acoustic Stimulation cochlear implantation considered on a case-bycase basis.~~

fg~~h~~. No medical contraindications.

gh~~i~~. Up-to-date-immunization status as determined by the Advisory Committee on Immunization Practices (ACIP).

h.

i~~j~~. Replacement of an existing cochlear implant for all ages is a benefit ~~when the currently used component is no longer functional and cannot be repaired~~ when the currently used internal or external component is no longer functioning and cannot be repaired. For members age 20 and younger, please see 8.280 for additional guidance. ~~Age 20 and younger, please see 8.280 for additional guidance.~~

[SECTIONS 8.200.3.D.2.e.v UNAFFECTED BY THIS RULE CHANGE, REMAIN AS-IS]

[SECTIONS 8.200.3.D.2.f-g UNAFFECTED BY THIS RULE CHANGE, REMAIN AS-IS]