Anthem

Clinical UM Guideline

Subject: Prefabricated External Infant Ear Molding Systems
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Description

This document addresses the use of prefabricated external infant ear molding systems to treat external ear malformations and deformations. There are several systems currently available, including EarWell® (Beacon Medical LTD., Batavia, IL) and InfantEar™ (TalexMedical, LLC, Malvern PA).

Note: Please see ANC.00008 Cosmetic and Reconstructive Services of the Head and Neck for additional information.

Medically Necessary: In this document, procedures are considered medically necessary if there is a significant functional impairment AND the procedure can be reasonably expected to improve the functional impairment.

Reconstructive: In this document, procedures are considered reconstructive when intended to address a significant variation from normal related to accidental injury, disease, trauma, treatment of a disease or congenital defect.

Note: Not all benefit contracts/certificates include benefits for reconstructive services as defined by this document. Benefit language supersedes this document.

Cosmetic: In this document, procedures are considered cosmetic when intended to change a physical appearance that would be considered within normal human anatomic variation. Cosmetic services are often described as those that are primarily intended to preserve or improve appearance.

Clinical Indications

Medically Necessary:

Prefabricated external infant ear molding systems are considered **medically necessary** when the following criteria are met:

A. Initiation of treatment occurs when the individual is 8 weeks of age or younger; **and**
B. Treatment is intended to improve a significant functional impairment (for example, impairment of hearing).

Reconstructive:

Prefabricated external infant ear molding systems are considered **reconstructive** when the following criteria are met:

A. Treatment is intended to address a significant variation from normal; **and**
B. At least one of the following criteria (1 or 2) are met:
    1. Individual is 8 weeks of age or younger when treatment is started; **or**
    2. Individual has cryptotia and is 6 months of age or younger when treatment is started.

Cosmetic and Not Medically Necessary:

Prefabricated external infant ear molding systems are considered **cosmetic and not medically necessary** in the absence of a significant functional impairment or significant variation from normal.

Coding

The following codes for treatments and procedures applicable to this guideline are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

When services may be Medically Necessary or Reconstructive when criteria are met:

CPT	
	For the following CPT codes **when specified as application of an external ear molding system**:
29799	Unlisted procedure, casting or strapping
69399	Unlisted procedure, external ear
HCPCS	
	For the following HCPCS codes **when specified as supply of a prefabricated external ear molding system**:
A4649	Surgical supply miscellaneous
E1399	Durable medical equipment, miscellaneous
ICD-10 Diagnosis	
	All diagnoses, including but not limited to the following:
Q17.1	Macrotia
Q17.3	Other misshapen ear
Q17.5	Prominent ear
Q17.8	Other specified congenital malformations of ear
Q17.9	Congenital malformation of ear, unspecified

Note: if CPT code 21086 (Impression and custom preparation; auricular prosthesis) or HCPCS code L8045 (Auricular prosthesis,

provided by a non-physician) are used to describe application or supply of an external ear molding splint system, the criteria in this document will apply.

When services are Cosmetic and Not Medically Necessary:
For the procedure codes listed above when medically necessary or reconstructive criteria are not met, or when the code describes a procedure designated in the Clinical Indications section as cosmetic and not medically necessary.

Discussion/General Information

Ear anomalies are categorized as malformations (partial or complete absence of skin and cartilage) or deformations (misshapen cartilage with no underlying skin or cartilage deficiencies). Auricular deformations make up the majority of congenital ear anomalies (Anstadt, 2016). Approximately 30% of infant ear deformities will self-correct or experience spontaneous improvement within the first few weeks of life. Malformations generally do not improve spontaneously over time (Bhatti, 2021; Burns, 2023). Given the fact that there is no reliable system to predict which cases will self-correct and the short window of opportunity in which the ear tissue is malleable, non-surgical treatment should be initiated as soon as possible in affected infants. Surgical correction has been used as a method of correction for more severe cases or when non-surgical treatment is not an option. Surgery cannot take place until after age 5, when the ear has reached at least 90% of its adult size.

Ear molding has been used as a method of normalizing the shape of the ear by applying direct, continuous pressure. Appropriate ear molding needs to meet several clinical criteria. Anstadt (2016) lists the following criteria “should be delicate enough to reduce the risk of pressure ulcers, should be nonirritating to the skin to reduce risk of dermatitis, should be malleable to achieve the optimal ear shape …”. Reshaping of auricular deformities using non-surgical ear molding techniques are possible due to the malleability of infant ear cartilage. The type and severity of the anomaly appears to be a factor in the success rate. The age at treatment initiation is also very important; treatment initiated at 3 weeks of age or younger have generally reported better outcomes with shorter treatment periods. After 6 to 8 weeks, there is a recognized loss of pliability and increased stiffness in the infant cartilage (Daniala, 2023). Molding materials such as foam, tape wires, feeding tubes, tape, wax, and putty vinyl polysiloxane impression material have been used for non-surgical correction (Anstadt, 2016). Several prefabricated kits are available, including the Earwell and InfantEar systems.

Age at treatment initiation

Ideally, treatment is initiated in early after birth. Within this time period, the increased malleability of cartilage is thought to be related to the high levels of circulating maternal estrogen. Estrogen levels typically peak within a few days following birth and then begin to decline by 6 weeks of age. When treatment is begun within 3 weeks postpartum, there is a success rate of 90% or greater. When treatment is initiated within 6 weeks, positive results of greater than 70% are reported (Daniali, 2017; Mohammadi, 2016; Nigam, 2020; Roby, 2023; Wu, 2022). Treatment initiated at an earlier age generally require a shortened treatment period (Doft, 2015; van Wijk, 2009). Given this, use of prefabricated external infant ear molding systems is considered in accordance with generally accepted standards of medical practice when initiation of treatment occurs in individuals 8 weeks of age or younger.

Wu and colleagues (2022) examined the safety and effectiveness of EarWell Ear Correction Kit in the treatment of congenital auricle malformation. The meta-analysis included a mix of 12 retrospective and prospective studies. A total of 1027 ears were included in the analysis. The effective rate for correcting congenital auricle malformation was 89.1%; higher rates were reported when therapy was initiated earlier in life. The efficacy of therapy was reported at higher than 80% if initiated within 6 months of birth. The incidence of complications was reported at 11.4% and consisted mainly of skin lesions and dermatitis. This meta-analysis consisted of single arm retrospective and prospective studies and is associated with high heterogeneity. The authors noted that 9 of the 12 studies were from China and noted that further verification would be needed to determine whether the study results could be applied to individuals from other countries.

In 2022, Saba and associates conducted a systematic review and meta-analysis to assess the efficacy of ear molding therapy. The meta-analysis included 15 studies and 2508 ears, primarily involving ear deformities rather than malformation. The studies included prefabricated devices and non-fabricated devices. There was a high level of heterogeneity among of the studies. However, the results showed higher success when treatment was initiated at 3 weeks of age or younger. Reported complications (eczema, excoriation, infection, irritation, rash, and ulceration) were minor and transient. The analysis concluded that ear molding is safe and effective when used to treat congenital ear anomalies in appropriate populations.

Functional Impairment

The outer ear consists of the several cartilaginous structures which serve to direct sound waves into the external auditory ear canal and the tympanic membrane (Sánchez López de Nava, 2023). Hearing may be affected when there are abnormalities of the auditory ear canal or tympanic membrane and repair of these structures can improve hearing. Neonatal hearing loss can result from transient or permanent conductive, permanent sensorineural, auditory neuropathy, and mixed defects. Hearing loss in infancy can lead to delayed language development, difficulties with behavior and psychosocial interactions, and poor academic achievement. Significant functional hearing impairment in an infant may result from a physical structure or absence of a physical structure that is causing hearing loss of at least 15 decibels in the affected ear(s).

Ear molding is considered reconstructive when it is intended to address a significant variation from normal related to accidental injury, disease, trauma, treatment of a disease or congenital defect. When no reconstructive indication is present, ear molding is considered cosmetic if there is no functional impairment.

Cryptotia

In cryptotia, the cartilaginous framework of the ear is typically normal, but the upper third of the ear lies under the skin. Some cartilage deformities of the upper ear may also be present. Non-surgical ear molding beyond 8 weeks has been shown to be beneficial in this population (Saba, 2022; Xu, 2023; Zhou, 2019). Unlike in most ear deformities which are aimed at cartilage remodeling, correction of cryptotia involves the expansion of the retroauricular skin to cover the embedded cartilage. The outer ear supports eyeglass hearing aid or mask wear; ideally, the anatomic landmarks of the ears should align with each other to allow for symmetric or near symmetric of the device being supported (Susarla, 2022).

Chia and colleagues (2021) describe a non-surgical treatment modality of cryptotia in 5 infants aged 1 day to 7 months. All infants (n=5) were initially treated with 2 weeks of continuous medical distraction to unbury the auricle using the EarWell Infant Ear Correction System. The placement of the retractor was customized to address the inherent helical constriction and expand the helix. Infants under the age of 6 weeks at the age of initiation (n=2) were treated with an additional 2 weeks of helical molding to correct any residual deformities. All infants were evaluated by 2 blinded plastic surgeons and rated as having good to excellent results. At 1 year, all helices remained retracted. The authors explained why non-surgical molding was effective in older infants, noting:

> Our 2-stage approach addresses the two key pathologies of cryptotia. Unburying of the auricle is addressed in the first stage with the sustained distraction of the buried auricle out of the temporal skin pocket for 2 weeks. It is

postulated that the excessively developed intrinsic transverse or oblique auricular muscles result in cryptotia. The aim is to stretch the skin and auricular musculature and also initiate distraction histogenesis. This stage, unlike the second stage, is independent of cartilage pliability and, hence, the patient's age. It can be performed in older infants, provided the auricle is retractable, suggesting that the auricular muscles have not undergone fibrosis.

Prefabricated Systems

Success has been reported with non-prefabricated splinting systems with efficacy rates and complication rates comparable to the prefabricated kits (Anstadt, 2016; Chang, 2017; Manji, 2020; Mohammadi, 2016; Woo, 2017). Lennon and associates (2018) note that a benefit of the custom-made molds is that the materials are familiar, easily available and may be better able to address conchal bowl and inferior rim/lobular anomalies. Prefabricated devices are more convenient, and some devices may have the ability to mold ears both laterally and medially, and more rigid fixation may allow for improved treatment of more complex ear lesions.

Definitions

Anotia: Malformation in which the external ear is absent.

Constricted ear: A group of deformities in which there is an abnormal chondrocutaneous distribution of the superior helix. These deformities include lidded ear, lop ear and cup ear.

Cryptotia: Malformation in which the ear cartilage is partially located under the temporal scalp skin. Cryptotia is caused by the improper fusion of the cartilage of the ear and the overlying skin in utero.

Deformation: Misshapen cartilage with no underlying skin or cartilage deficiencies.

Functional impairment: Significant functional impairment may include physical, social, emotional, and psychological impairments or potential impairments. Examples of limits on normal physical functioning include problems with hearing, communication, respiration, eating, swallowing, visual impairments, skin integrity, distortion of nearby body parts, obstruction of an orifice. The cause of the functional impairment may be pain, structural integrity, congenital anomalies, or other factors.

Helical Rim Deformities: Deformity which affects the anatomic semicircular contour of the outer rim.

Malformation: Partial or complete absence of skin and cartilage.

Microtia: Malformation in which the external ear is underdeveloped.

Prominent ear: Deformity in which the auriculocephalic angle (projection of the ear from the mastoid process) exceeds the normal 20 to 30 degrees or upper ear protrusion greater than approximately 2cm in the matured ear.

Stahl ear: Deformity which affects the upper third of the ear, characterized by the presence of an extraneous third crus in the auricular cartilage.

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EarWell
InfantEar

Earbuddies® (Earbuddies, London, England)

The use of specific product names is illustrative only. It is not intended to be a recommendation of one product over another, and is not intended to represent a complete listing of all products available.

History

Status	Date	Action
New	02/15/2024	Medical Policy & Technology Assessment Committee (MPTAC) review. Initial document development.

Federal and State law, as well as contract language, and Medical Policy take precedence over Clinical UM Guidelines. We reserve the right to review and update Clinical UM Guidelines periodically. Clinical guidelines approved by the Medical Policy & Technology Assessment Committee are available for general adoption by plans or lines of business for consistent review of the medical necessity of services related to the clinical guideline when the plan performs utilization review for the subject. Due to variances in utilization patterns, each plan may choose whether to adopt a particular Clinical UM Guideline. To determine if review is required for this Clinical UM Guideline, please contact the customer service number on the member's card.

Alternatively, commercial or FEP plans or lines of business which determine there is not a need to adopt the guideline to review services generally across all providers delivering services to Plan's or line of business's members may instead use the clinical guideline for provider education and/or to review the medical necessity of services for any provider who has been notified that his/her/its claims will be reviewed for medical necessity due to billing practices or claims that are not consistent with other providers, in terms of frequency or in some other manner.

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