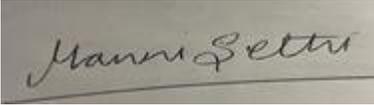


**Prior Authorization Review Panel
MCO Policy Submission**

A separate copy of this form must accompany each policy submitted for review.
Policies submitted without this form will not be considered for review.

Plan: Keystone First	Submission Date: 7/1/2024
Policy Number: ccp.1544.13	Effective Date: 7/2024 Revision Date: June 1, 2024
Policy Name: Frenuloplasty for ankyloglossia	
Type of Submission – Check all that apply: <input checked="" type="checkbox"/> New Policy <input type="checkbox"/> Revised Policy* <input type="checkbox"/> Annual Review – No Revisions <input type="checkbox"/> Statewide PDL	
*All revisions to the policy <u>must</u> be highlighted using track changes throughout the document. Please provide any clarifying information for the policy below: New Policy	
Name of Authorized Individual (Please type or print): Manni Sethi, MD, MBA, CHCQM	Signature of Authorized Individual: 

Frenuloplasty for ankyloglossia

Clinical Policy ID: CCP.1544.13

Recent review date: 6/2024

Next review date: 10/2025

Policy contains: Ankyloglossia; breast feeding; frenuloplasty; laser; speech.

Keystone First- CHIP has developed clinical policies to assist with making coverage determinations. Keystone First- CHIP's clinical policies are based on guidelines from established industry sources, such as the Centers for Medicare & Medicaid Services (CMS), state regulatory agencies, the American Medical Association (AMA), medical specialty professional societies, and peer-reviewed professional literature. These clinical policies along with other sources, such as plan benefits and state and federal laws and regulatory requirements, including any state- or plan-specific definition of "medically necessary," and the specific facts of the particular situation are considered by Keystone First- CHIP, on a case by case basis, when making coverage determinations. In the event of conflict between this clinical policy and plan benefits and/or state or federal laws and/or regulatory requirements, the plan benefits and/or state and federal laws and/or regulatory requirements shall control. Keystone First- CHIP's clinical policies are for informational purposes only and not intended as medical advice or to direct treatment. Physicians and other health care providers are solely responsible for the treatment decisions for their patients. Keystone First- CHIP's clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, Keystone First- CHIP will update its clinical policies as necessary. Keystone First- CHIP's clinical policies are not guarantees of payment.

Coverage policy

Frenuloplasty is clinically proven and, therefore, may be medically necessary to surgically correct a functional limitation caused by ankyloglossia (American Academy of Otolaryngology-Head and Neck Surgery [Messner, 2020]; American Academy of Pediatric Dentistry, 2023).

Limitations

Frenuloplasty is investigational/not clinically proven and, therefore, not medically necessary for the following indications (American Academy of Pediatric Dentistry, 2023; Messner, 2020):

- For dental or orthodontic purposes, such as mandibular prognathism or fitting of partial or complete dentures.
- To prevent a future feeding or speech disorder in an infant with little or no restriction in tongue mobility.
- Treatment for sleep apnea.
- The absence of a functional limitation.

Relative contraindications to infant frenuloplasty include neuromuscular disorder, hypotonia, retrognathia, micrognathia, and coagulopathy (Messner, 2020).

Alternative covered services

Lactation, speech pathology, or oral hygiene advice or consultation.

Background

Ankyloglossia is a congenital anatomic malformation in which a shortened sublingual frenum (fibrous tissue band connecting the underside of the tongue to the floor of the mouth) restricts tongue movement. Ankyloglossia is described classically as anterior, where the frenulum attaches at or close to the tongue tip. Posterior ankyloglossia has been described as frenulum that inserts into the posterior, less visible portion of the tongue or as submucosal tethering of the tongue. The etiology of ankyloglossia is unknown (Becker, 2023).

Diagnosis relies on clinical assessment. Validated tools for diagnosing clinically relevant ankyloglossia are lacking, and the severity or degree of ankyloglossia is not easily defined. There is no consensus on the use of available objective tools. For example, Coryllos Lingual Frenulum Classification System addresses the type of frenulum but not functionality or criteria for ankyloglossia, whereas the Hazelbacker Assessment Tool for Lingual Frenulum Function and the Bristol Tongue Assessment Tool have attempted to include functionality and ankyloglossia scoring. Regardless of the evaluation tool used, a diagnosis of ankyloglossia must demonstrate restricted tongue movement caused by the lingual frenulum exclusively (Becker, 2023; Messner, 2020).

Severity can range from mild (a thin flexible membrane) to complete tethering by a robust rope-like band of tissue. Prevalence is 7% and 4% for males and females, respectively (Hill, 2021). Increases in breastfeeding rates, lactation specialists, and a widening definition and awareness of ankyloglossia may contribute to the rising prevalence of ankyloglossia diagnoses in recent years, but the potential for overdiagnosis and overtreatment may also exist (Becker, 2023; Messner, 2020).

In the majority of patients in whom ankyloglossia is an incidental finding, the best management is observation and reassurance (Becker, 2023). Surgical treatment is reserved for cases of medical necessity where a functional limitation exists. There are three types of surgical procedures to correct ankyloglossia: frenotomy; frenectomy; and frenuloplasty. Frenuloplasty refers to an extensive incision of the lingual frenulum with a repositioning of the tissue (e.g., horizontal to vertical or z-plasty), and usually requires general anesthesia (Messner, 2020).

Findings

Guidelines

The American Academy of Otolaryngology-Head and Neck Surgery applied Delphi methodology to derive clinical consensus statements and identify continued areas of controversy related to the diagnosis, management, and treatment of ankyloglossia and upper lip tie in children. While most of the published literature on ankyloglossia treatment has focused on infants with breastfeeding difficulty, there is limited evidence supporting the indications and outcomes for frenuloplasty in older children and adolescents (Messner, 2020).

Ankyloglossia in older children may present with speech and dentition concerns, mechanical limitations, and associated social implications. Studies correlating ankyloglossia and speech articulation difficulties are of low quality and yielded conflicting results. Many studies failed to adequately describe and standardize the use of speech therapy in subjects. There is no method to predict which children with ankyloglossia will require treatment. No randomized trials have been conducted to determine whether frenuloplasty leads to definitive improvement in these outcomes or which frenuloplasty technique (e.g., cold versus laser or 4-flap z-frenuloplasty versus horizontal-to-vertical frenuloplasty) is superior (Messner, 2020).

For frenuloplasty, there is strong consensus that (Messner, 2020):

- Ankyloglossia does not typically affect speech.

- In an older child, a consultation with a speech pathologist is encouraged before undergoing frenotomy/frenuloplasty for speech concerns.
- Older children with ankyloglossia may experience social and mechanical issues (difficulty licking, difficulty keeping teeth clean, lower central incisor diastema, sense of social embarrassment); some of these children may experience improved quality of life after frenotomy/frenuloplasty.
- There is no maximum age for a patient undergoing frenotomy/frenuloplasty.
- There is not a preferred surgical procedure for correction of ankyloglossia in the older child.

The American Academy of Pediatric Dentistry (2023) acknowledges a lack of strong evidence to inform the timing, indication, and type of surgical intervention for ankyloglossia. The Academy supports frenuloplasty, frenulotomy, or frenectomy for speech or feeding limitations on an individual basis. The decision to treat ankyloglossia will depend on the presence of a functional limitation, as the majority of patients in whom ankyloglossia is an incidental finding will require no treatment.

Evidence reviews

One systematic review identified one poor-quality randomized controlled trial (n = 16) that compared two frenuloplasty approaches for treatment of children (mean age = six years) with a tight frenulum affecting articulation or intelligibility. Both 4-flap Z-frenuloplasty or horizontal-to-vertical frenuloplasty significantly improved articulation as judged by trained speech-language pathologists, but did not improve objective fluent speech scores (Chinnadurai, 2015).

A systematic review of 35 studies of variable quality found that conventional, laser, and Z-plasty procedures can improve breast feeding outcomes, but the superiority of one frenuloplasty procedure over another could not be determined. The evidence supporting an association between ankyloglossia, tongue mobility, and speech outcomes following these procedures remains inconclusive (Khan, 2020).

Another systematic review of two randomized controlled trials and two surgical case series found z-frenuloplasty and 4-flap frenuloplasty were superior to simple frenotomy for addressing ankyloglossia-related breast feeding and speech limitations in children after three months of age. The two-flap z-plasty and four-flap technique yield greater absolute improvements in tongue mobility and speech metrics when compared with the traditional horizontal-to-vertical frenuloplasty. Reoperation rates were lower with frenuloplasty than with traditional frenotomy. As frenuloplasty procedures require general anesthesia, the authors recommended performing frenulotomy early in infancy to correct breast feeding problems, reserving frenuloplasty for later in childhood (Shekher, 2021).

Two systematic reviews found insufficient evidence to determine the effects of lingual frenuloplasty on obstructive sleep apnea (Bussi, 2022; Correa, 2022). Both authors agree that alteration in the lingual frenulum can interfere with anatomical structures in the upper airway, leading to alterations in respiratory, suction, chewing, and speech functions. Adequate surgical release along with myofunctional therapy may improve function and quality of life, including sleep quality. Prospective trials are needed using objective assessment of obstructive sleep apnea and validated outcome measures to correlate presence of ankyloglossia and obstructive sleep apnea and to quantify the impact of surgical interventions on treating or preventing obstructive sleep apnea.

A systematic review of 16 low-quality studies assessed the association between ankyloglossia, surgical intervention, and speech articulation. There was no clear correlation between ankyloglossia and speech disorders. The outcomes for 4-flap Z-frenuloplasty or simple frenotomy on speech articulation were comparable. The authors called for well-designed clinical studies (Wang, 2022). To that end, Arena (2022) highlighted the benefit of using validated tongue assessment tools in non-infants when evaluating treatment effectiveness in research and clinical practice.

References

On April 18, 2024, we searched PubMed and the databases of the Cochrane Library, the U.K. National Health Services Centre for Reviews and Dissemination, the Agency for Healthcare Research and Quality, and the Centers for Medicare & Medicaid Services. Search terms were “ankyloglossia” (MeSH), “frenuloplasty,” “tongue-tie,” and “speech impediment.” We included the best available evidence according to established evidence hierarchies (typically systematic reviews, meta-analyses, and full economic analyses, where available) and professional guidelines based on such evidence and clinical expertise.

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Policy updates

6/2024: initial review date and clinical policy effective date: 7/2024

