Clinical Policy Title: Frenectomy for ankyloglossia

Clinical Policy Number: 11.03.03

Effective Date: October 1, 2014
Initial Review Date: April 16, 2014
Most Recent Review Date: May 18, 2016
Next Review Date: May 2017

Policy contains:
- Frenectomy.
- Ankyloglossia.

Related policies:
None.

ABOUT THIS POLICY: Prestige Health Choice has developed clinical policies to assist with making coverage determinations. Prestige Health Choice’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 Prestige Health Choice 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. Prestige Health Choice’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. Prestige Health Choice’s clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, Prestige Health Choice will update its clinical policies as necessary. Prestige Health Choice’s clinical policies are not guarantees of payment.

Coverage policy

Prestige Health Choice considers the use of sublingual frenectomy to be clinically proven and, therefore, medically necessary under the following conditions:

- Recession in gingival tissue adjacent to lower anterior teeth.
- Tongue tip cannot extend upward to posterior alveolar ridge and/or molars, or to the anterior alveolar ridge and/or incisors.
- Significant dysfunction in feeding, speaking or maintaining oral hygiene, documented by:
  - Type of feeding difficulty (with height and weight records for impact on growth).
  - Speech/language pathologist evaluation for articulation and/or disorder.
  - Oral hygiene issues with failed attempts to resolve.

Limitations:
Coverage determinations are subject to benefit limitations and exclusions as delineated by the state Medicaid authority. The Florida Medicaid website can be accessed at http://ahca.myflorida.com/Medicaid/.

Sublingual frenectomy performed for dental or orthodontic purposes is not covered:
- Mandibular prognathism.
- Fitting of partial or complete dentures.

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 and thus normal newborn feeding or speech. Severity can range from mild (a thin flexible membrane) to complete tethering by a robust rope-like band of tissue. Criteria for diagnosis are accordingly variable, as are prevalence estimates.

Frenectomy is a surgical procedure by which the abnormal frenum is restructured to permit a closer approximation of normal tongue motion, to fit dentures or for orthodontic purposes. It is performed on patients of all ages, usually with local anesthesia on an outpatient basis.

There are three types of surgical procedures to correct ankyloglossia, including frenectomy, frenotomy and frenuloplasty. In addition to the standard surgical procedure of frenectomy, physicians have the option of using Nd:Yap, which employs a laser to correct ankyloglossia. Frenectomy can involve use of one or two hemostats, a groove director or a laser (Junqueira 2014).

Searches

Prestige Health Choice searched PubMed and the databases of:
- UK National Health Services Centre for Reviews and Dissemination.
- Agency for Healthcare Research and Quality's National Guideline Clearinghouse and other evidence-based practice centers.
- The Centers for Medicare & Medicaid Services (CMS).

We conducted searches on April 26, 2016. Searched terms were: "sublingual frenectomy (MeSH)," "ankyloglossia (MeSH)" and "speech impediment."

We included:
- **Systematic reviews**, which pool results from multiple studies to achieve larger sample sizes and greater precision of effect estimation than in smaller primary studies. Systematic reviews use predetermined transparent methods to minimize bias, effectively treating the review as a scientific endeavor, and are thus rated highest in evidence-grading hierarchies.

- **Guidelines based on systematic reviews.**

- **Economic analyses**, such as cost-effectiveness, and benefit or utility studies (but not simple cost studies), reporting both costs and outcomes — sometimes referred to as efficiency studies — which also rank near the top of evidence hierarchies.

**Findings**

Lingual frenectomy is a safe and successful procedure, supported by moderate quality evidence for difficulties with breastfeeding, speech articulation and oral hygiene in patients of all ages. There is no evidence to support its use to modify mandibular prognathism or other malocclusion conditions, or to fit dentures. Post-operative symptoms and relapses are highly uncommon (Olivi 2012).

However, not nearly enough evidence, including lack of randomized control trials, exists comparing patient outcomes after frenectomy, frenotomy and frenuloplasty (Suter 2009). There is some evidence that use of a laser device (Er:YAG) may have potential advantages over conventional techniques (De Santis 2013). One study actually concluded that Nd:YAP had advantages over diode, another form of laser treatment, such as the fact that most Er:YAG patients did not require local anesthesia (Aras 2010).

Ferrés-Amat (2016) described a protocol followed in 101 patients in which frenectomy was performed and followed post-operatively. After the surgical intervention, the degree of ankyloglossia was reported as improved in 96 percent of the participants (95% CI: 90%, 98%). The authors emphasized the importance of myofunctional training to commence one week before the surgical intervention so that the patients learn the exercises without pain.

**Summary of clinical evidence:**

<table>
<thead>
<tr>
<th>Citation</th>
<th>Content, Methods, Recommendations</th>
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</thead>
<tbody>
<tr>
<td>Ferrés-Amat (2016)</td>
<td>Key points:</td>
</tr>
<tr>
<td>Multidisciplinary management of ankyloglossia in childhood. Treatment of 101 cases. A protocol.</td>
<td>Prospective study of 101 patients undergoing frenectomy for ankyloglossia due to the shortness of either the lingual frenulum or the genioglossus muscles or both. After the surgical intervention, the degree of ankyloglossia was improved in 97 (96%) of the participants (95% CI: 90%, 98%). The preferred surgical technique for moderate-severe ankyloglossia was frenectomy and lingual plasty. Rehabilitative myofunctional training began one week before the surgical intervention so that the patients learned the exercises without pain.</td>
</tr>
<tr>
<td>Junqueira (2014)</td>
<td>Key points:</td>
</tr>
<tr>
<td>Citation</td>
<td>Content, Methods, Recommendations</td>
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<td>----------------------------------------------</td>
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</tbody>
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| Surgical techniques for the treatment of ankyloglossia in children: a case series. | - Comparison of frenotomy/frenectomy results using 1–2 hemostats, groove director, laser:  
  - All techniques successful in treating ankyloglossia.                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| Webb (2013)                                  | **Key points:**                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
| The effect of tongue-tie division on breastfeeding and speech articulation: a systematic review. | - Effects on breastfeeding and speech articulation:  
  - Twenty studies (15 observational; five RCTs).  
  - Objective improvements in breastfeeding, milk production, infant weight gain; subjective in maternal pain and satisfaction.  
  - Recurrent tongue-ties requiring reoperation were the only adverse events.                                                                                                                                                                                                                                                                                                                                                                           |
| North Carolina Division of Medical Assistance (2012) | **Key points:**                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
| Surgery of lingual frenum.                   | - Surgery of lingual frenum:  
  - Recession in gingival tissue adjacent to lower anterior teeth.  
  - Tongue tip cannot extend upward to posterior alveolar ridge and/or molars, or to the anterior alveolar ridge and/or incisors.  
  - Significant dysfunction in feeding, speaking or maintaining oral hygiene, documented by:  
    - Type of feeding difficulty (with height and weight records for impact on growth).  
    - Speech/language pathologist evaluation for articulation disorder.                                                                                                                                                                                                                                                                                                                                 |
| American Academy of Pediatric Dentistry (2010) | **Key points:**                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
| Guideline on pediatric oral surgery.         | - Pediatric oral surgery:  
  - Frenectomy/frenuloplasty may be indicated to facilitate breastfeeding although supporting evidence is limited and a classification system for ankyloglossia in newborns is lacking on non-invasive measures such as lactation counseling. Support should be tried first.  
  - Insufficient evidence for any impact of ankyloglossia on development of mandibular prognathism or role of frenectomy in correcting.                                                                                                                                                                                                                                                                 |
| Aras (2010)                                  | **Key points:**                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
| Comparison of diode laser and Er:YAG lasers in the treatment of ankyloglossia. | - Comparing outcomes using diode laser and Er:YAG laser:  
  - Included 16 patients.  
  - No differences with pain, charring or speaking on first and seventh days post-op.  
  - Er:YAG patients had more pain in the first three hours post-op.  
  - Most Er:YAG patients didn’t need local anesthesia (all diode patients did).                                                                                                                                                                                                                                                                                                                                 |
| Suter (2009)                                 | **Key points:**                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
| Ankyloglossia: facts and                      | - Treatment options for Ankyloglossia:                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
myths in diagnosis and treatment. Considered 64 articles. Frenectomy, frenotomy, frenuloplasty are main surgical treatment options. Ankyloglossia lacks uniform definition and classification, making comparisons between studies almost impossible. No specific surgical method is preferable.


Key points:
- Breastfeeding:
  - Evidence does not suggest any major safety concerns.
  - Frenectomy for breastfeeding should be performed only by registered health care providers trained and credentialed for the procedure.
  - Further trials documenting impact on long-term breastfeeding success are needed.

Glossary

Ankyloglossia — A congenital anomaly commonly known as tongue tie that decreases mobility of the tongue tip and is characterized by a shortened lingual frenulum (membrane connecting the bottom of the tongue to the floor of the mouth).

Frenectomy — Surgical procedure restructuring the abnormal frenum, restoring normal tongue motion.

References

Professional society guidelines/other:


Peer-reviewed references:


Clinical trials:


CMS National Coverage Determination (NCDs):

No NCDs identified as of the writing of this policy.

Local Coverage Determinations (LCDs):

No LCDs identified as of the writing of this policy.
**Commonly submitted codes**

Below are the most commonly submitted codes for the service(s)/item(s) subject to this policy. This is not an exhaustive list of codes. Providers are expected to consult the appropriate coding manuals and bill accordingly.

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<thead>
<tr>
<th>CPT Codes</th>
<th>Description</th>
<th>Comments</th>
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<tbody>
<tr>
<td>41010</td>
<td>Frenotomy.</td>
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<tr>
<td>41115</td>
<td>Frenectomy, lingual.</td>
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<td>Frenulectomy.</td>
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<th>Comments</th>
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<tbody>
<tr>
<td>Q38.1</td>
<td>Ankyloglossia.</td>
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