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 1, 2018
Next Review Date: May 2019

Related policies:
None.

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

Coverage policy

AmeriHealth Caritas considers the use of sublingual frenectomy to be clinically proven and, therefore, medically necessary to correct a functional limitation associated with the following conditions (Becker, 2018; Pennsylvania Department of Human Services, 2016; American Academy of Pediatric Dentistry, 2015; Devishree, 2012; National Institute for Health and Care Excellence, 2005):

- An aberrant frenal attachment is present, which causes a midline diastema.
- A flattened papilla with the frenum closely attached to the gingival margin is present, which causes a gingival recession and a hindrance in maintaining oral hygiene.
- An aberrant frenum with an inadequately attached gingiva and a shallow vestibule is present.

Limitations:

Sublingual frenectomy performed for dental or orthodontic purposes is not medically necessary. This includes sublingual frenectomy performed for:

- 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 (Becker, 2018). 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 (Devishree, 2012).

The decision to treat ankyloglossia will depend on medical necessity, as, in the majority of patients in whom ankyloglossia is an incidental finding, the best management is observation and reassurance (Becker, 2018). There are three types of surgical procedures to correct ankyloglossia, including frenectomy, frenotomy, and frenuloplasty. Frenotomy is a simple procedure with few side effects and can be performed in an outpatient setting. Frenuloplasty requires general anesthesia and is rarely performed.

Frenectomy involves the complete surgical removal of the frenum, including its attachment to the underlying bone, to permit a closer approximation of normal tongue motion, to fit dentures, or for orthodontic purposes (Devishree, 2012). It is performed on patients of all ages, usually with local anesthesia on an outpatient basis. In addition to the standard scalpel technique, providers have the option of using lasers (neodymium-doped yttrium aluminum garnet [Nd: YAP]) or electrosurgery. Frenectomy can involve use of one or two hemostats, a groove director, or a laser (Junqueira, 2014).

**Searches**

AmeriHealth Caritas 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 March 22, 2018. Searched terms were: "ankyloglossia" (MeSH) and free text terms “frenectomy” 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**

Removal of a pathological frenum may be indicated when (Devishree, 2012):

- An aberrant frenal attachment is present, which causes a midline diastema.
- A flattened papilla with the frenum closely attached to the gingival margin is present, which causes a gingival recession and a hindrance in maintaining oral hygiene.
- An aberrant frenum with an inadequately attached gingiva and a shallow vestibule is present.

Linguinal frenectomy is a safe and successful procedure, supported by moderate-quality evidence for difficulties with breast feeding, 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 randomized controlled trials, exists comparing patient outcomes after frenectomy, frenotomy, and frenuloplasty (Suter, 2009). There is some evidence that use of a laser device (erbium-doped yttrium aluminium garnet laser [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, in 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 percent confidence interval: 90 percent to 98 percent). The authors emphasized the importance of myofunctional training to commence one week before the surgical intervention so that patients learn the exercises without pain.

**Policy updates:**

A systematic review (Delli, 2013) noted that the maxillary frenum is highly associated with a number of syndromes and developmental abnormalities. For example, a hypertrophic frenum may be involved in the etiology of the midline diastema. An injured frenum in combination with other traumas and doubtful history might point to child abuse. On the other hand, the causes of gingival recession due to the maxillary frenum and the involvement of hyperplastic frena in the pathogenesis of peri-implant diseases remain undefined. A superiority of laser treatment over conventional surgical methods of frenectomy was not demonstrated.

In 2018, we identified one updated guideline. The American Academy of Pediatric Dentistry (2015) acknowledges a lack of strong evidence to inform the timing, indication, and type of surgical intervention.
for ankyloglossia, and recommends frenectomy for functional 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 (Becker, 2018). We modified the coverage statement to include more detailed indications (Devishree, 2012) and a requirement of a functional limitation.

**Summary of clinical evidence:**

<table>
<thead>
<tr>
<th>Citation</th>
<th>Content, Methods, Recommendations</th>
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<tbody>
<tr>
<td><strong>American Academy of Pediatric Dentistry (2015)</strong>&lt;br&gt;Management considerations for pediatric oral surgery and oral pathology</td>
<td><strong>Key points:</strong>&lt;br&gt;- Ankyloglossia has been associated with breast feeding difficulties among neonates, limited tongue mobility and speech difficulties, malocclusion, and gingival recession.&lt;br&gt;- Systematic reviews acknowledge that the frenectomy procedure improves breast feeding and maternal nipple pain when provided in conjunction with support of other allied health care.&lt;br&gt;- Further evidence is needed to determine the benefit of surgical correction of ankyloglossia and its relation to speech pathology, as there are many children and individuals with ankyloglossia who do not suffer from speech difficulty.&lt;br&gt;- Frenuloplasty, frenotomy, or frenectomy may be successful in addressing functional limitations.</td>
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<td><strong>Delli (2013)</strong>&lt;br&gt;Facts and myths regarding the maxillary midline frenum and its treatment: A systematic review of the literature</td>
<td><strong>Key points:</strong>&lt;br&gt;- A systematic review noted that the maxillary frenum is highly associated with a number of syndromes and developmental abnormalities.&lt;br&gt;- A hypertrophic frenum may be involved in the etiology of the midline diastema.&lt;br&gt;- An injured frenum in combination with other traumas and doubtful history might point to child abuse.&lt;br&gt;- Causes of gingival recession due to the maxillary frenum and the involvement of hyperplastic frena in the pathogenesis of peri-implant diseases remain undefined.&lt;br&gt;- A superiority of laser treatment over conventional surgical methods of frenectomy was not demonstrated.</td>
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<td><strong>Webb (2013)</strong>&lt;br&gt;The effect of tongue-tie division on breastfeeding and speech articulation: A systematic review</td>
<td><strong>Key points:</strong>&lt;br&gt;- Effects on breast feeding and speech articulation:&lt;br&gt;  - Relevant studies, 1966 – June 2012.&lt;br&gt;  - Twenty studies (15 observational, five randomized controlled trials).&lt;br&gt;  - Objective improvements in breast feeding, milk production, and infant weight gain; subjective improvements in maternal pain and satisfaction.&lt;br&gt;  - Recurrent tongue-ties requiring reoperation were the only adverse events.</td>
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<td><strong>UK National Institute for Health and Clinical Excellence (2005)</strong>&lt;br&gt;Division of ankyloglossia (tongue-tie) for breastfeeding</td>
<td><strong>Key points:</strong>&lt;br&gt;- Evidence does not suggest any major safety concerns.&lt;br&gt;- Frenectomy for breast feeding should be performed only by registered health care providers trained and credentialed for the procedure.&lt;br&gt;- Further trials documenting impact on long-term breast feeding success are needed.</td>
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References

Professional society guidelines/other:


Peer-reviewed references:


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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<tr>
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<td>Frenotomy</td>
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<tr>
<td>41115</td>
<td>Frenectomy, lingual.</td>
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