

Cigna Medical Coverage Policy



Subject **Distraction Osteogenesis (DO)
for Craniofacial Deformities**

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Coverage Policy

Coverage for distraction osteogenesis is dependent on benefit plan language, may be subject to the provisions of a cosmetic and/or reconstructive surgery benefit and may be governed by state and/or federal mandates. Under many benefit plans, distraction osteogenesis is not covered when performed solely for the purpose of altering appearance or self-esteem or to treat psychological symptomatology or psychosocial complaints related to one's appearance. Please refer to the applicable benefit plan language to determine the terms, conditions and limitations of coverage.

If coverage for distraction osteogenesis is available, the following conditions of coverage apply.

Cigna covers distraction osteogenesis as medically necessary for the correction of a congenital or acquired craniofacial deformity when BOTH of the following are met:

- **ONE of the following craniofacial deformities is present:**
 - micrognathia in infants and children that is accompanied by airway obstruction (e.g., Pierre Robin sequence, Treacher Collins or Stickler syndromes)
 - mandibular deficiency that requires lengthening of more than 10 mm
 - lengthening a short mandibular ramus (stretching of the pterygomasseteric sling)
 - hemifacial microsomia in children with sufficient bone length to anchor an internal or external distraction device (e.g., Pruzansky Grade I and IIa type mandibular deformity)
 - syndromic craniosynostosis (e.g., Apert, Crouzon, or Pfeiffer syndromes)
- **ONE of the following functional impairments is present:**
 - persistent difficulties with mastication and swallowing after causes such as neurological or metabolic diseases have been excluded

- malnutrition, significant weight loss, or failure-to-thrive secondary to facial skeletal deformity
- speech dysfunction directly related to a jaw deformity as determined by a speech and language pathologist
- airway obstruction, such as obstructive sleep apnea, documented by polysomnogram where conservative treatment such as continuous passive airway pressure (CPAP) or an oral appliance has been attempted and failed despite patient compliance

Cigna does not cover distraction osteogenesis for EITHER of the following because it is considered not medically necessary for these indications:

- in preparation for dental implants or orthodontic care
- for the sole purpose of improving individual appearance and profile

General Background

Distraction osteogenesis (DO) may be employed as an early alternative to craniofacial and orthognathic surgery for the correction of craniofacial anomalies. The technique of DO creates a controlled fracture (corticotomy) in a bony structure and then separates the bony segments in a controlled and gradual manner. This process induces the formation of new bone in between the distracted segments. Craniofacial surgery utilizing DO is generally considered to be medically necessary when performed to treat a significant deformity that causes significant functional impairment, even though it is sometimes used for cosmetic purposes.

DO can be performed using internal or external devices. Internal devices have the advantage of not requiring big and bulky hardware sitting external to the face and can at times be applied with no skin incision (except for a small puncture site). The degree of control over the vectors of distraction is limited with internal devices. The external devices allow for three-dimensional distraction and better control of the vectors of distraction, but they are bulky and can be obtrusive. Pin migration scars can be significant as well.

In general, craniofacial anomalies may be congenital in nature (i.e., present at birth) or acquired, resulting from trauma, bone growth disturbance, or maxillary and/or mandibular neoplastic or degenerative processes. In these syndromes, abnormal growth of the jaw bones can lead to severe functional impairments such as airway obstruction, obstructive sleep apnea, malnutrition, failure to thrive, persistent inability to adequately masticate or persistent speech dysfunction (The American Association of Oral and Maxillofacial Surgeons [AAOMS], 2003). The severity of functional impairments correlates to the degree of upper and lower jaw deformity. Treatment of these conditions has been managed with such interventions as endotracheal airway support, nasopharyngeal intubation, tracheostomy, appliances that support the soft palate, uvulopalatopharyngoplasty (UPPP), and temporary tongue/lip adhesions.

The most common application site of DO in the craniofacial skeleton is the mandible. It is also used for maxillary advancement and in the upper face and cranial vault. The primary indications for mandibular DO include severe bone deficiency, including those with associated malocclusion, masticatory dysfunction, temporomandibular ankylosis, failed costochondral grafts for reconstruction of the mandibular ramus, obstructive apnea, and apertognathia. Congenital syndromes and recognized anomalies associated with these problems can include Treacher-Collins syndrome, Crouzon's syndrome, Apert's syndrome, Goldenhar's syndrome, hemifacial microsomia, Pierre Robin sequence, Stickler syndrome, and orofacial-digital syndrome. Although DO has an important place in mandibular reconstruction, DO is contraindicated in post-radiation bone (Robinson, 2005).

Standard treatment for maxillary and mandibular deficiencies includes craniofacial surgery, orthognathic surgery, dental extraction and orthodontic correction. During craniofacial surgery, osteotomies of the mandible, maxilla, and/or craniofacial bones are performed, and the bones are realigned and maintained in place using plates, screws, and wires. Orthognathic surgery involves only the mandible and maxilla.

The advantages of craniofacial DO are numerous. It allows for skeletal lengthening and advancement in three dimensions. The process is gradual, allowing the skin-soft tissue envelope to adapt to and accommodate the skeletal movement. DO is operatively less involved and requires less operative time (generating less blood loss)

than the techniques it is replacing. As a result, it can be done in young children and infants (Baskin and Tatum [Otolaryngology: Head and Neck Surgery], 2005).

Complications specific to the distraction process include: device failure; injuries to various branches of the facial nerve; pin-site infection with external or semi-buried devices; nonunion and premature fusion; complications specific to the osteotomy (e.g., neurovascular or dental injuries); and psychosocial issues related to the recovery (length of treatment time and patient's physical appearance). DO is more involved postoperatively than standard surgery. The role that the patient or parent assumes with the treatment includes having the distraction devices activated two or more times a day for one or more weeks and frequent office visits to ensure compliance and to allow for equipment adjustments (Patel, 2006; Robinson, 2005). Initial post distraction outcomes are generally good, however some individuals, such as syndromic patients, respond unpredictably. Relapse, compromised adaptation and defective post-distraction growth cannot always be prevented (Peltomaki, 2009).

U.S. Food and Drug Administration (FDA)

The U.S. Food and Drug Administration (FDA) approved several Class II distraction devices for use. Some of these include the KLS-Martin™ intraoral distractor (manufactured by Karl Leibinger GMBH, Muhleim, Germany), the TRAK™ intraoral mandibular distraction device (manufactured by Medicon, E.G., Tuttlingen, Germany), the Logic™ and the Spectrum™ mid-face distractor (manufactured by Osteomed L.P., Addison, TX) and the ACE™ alveolar distractor (manufactured by ACE Surgical Supply Co., Inc., Brockton, MA).

Literature Review

Evidence in the medical literature evaluating DO for the correction of craniofacial deformities consists of case reports (Malagoni, et al., 2000; Akizuki, et al., 2000; Cavaliere and Buchman, 2002; Fukuda, et al., 2004; Rbio-Bueno, et al., 2005) both prospective and retrospective case series (van Strijen, et al., 2000; Li, et al., 2002; Imola, et al., 2002; Denny, et al., 2004; Kofod, et al., 2005; Denny and Amm, 2005; Cascone, et al., 2005; Shetye, et al., 2006; Mitsukawa, et al., 2006; Meling, et al., 2006; Genecov, et al., 2009), a meta-analysis (Ow and Cheung, 2008) and published reviews (Swennen, et al., 2001; Lakhani, et al., 2003; Zim, 2007; Taylor, et al., 2014; Tahiri, et al., 2014). Much of the evidence focuses on repair of congenital deformities rather than acquired. In a majority of clinical studies the populations were small with short-term follow-up; diagnosis among study groups varied, but generally included microsomia, micrognathia, syndromal craniosynostosis, facial bone fractures and other maxillofacial mandibular defects. Follow-up times vary but range from the immediate postoperative period to five years post-surgery; few studies have reported outcomes extending beyond five years. When used early for the correction of hemifacial microsomia in particular, additional distraction procedures are often required (Nagy, et al., 2009).

Overall, evidence in the peer reviewed published scientific literature supports the clinical effectiveness of DO for correction of craniofacial deformities. Depending on individual age and condition, distraction rate, length of treatment and degree of correction vary. Nonetheless, DO has proved useful for correction of severe bone deficiencies and deformities of the mandible. Reported clinical outcomes include prevention of tracheostomies, relieved symptoms of sleep apnea, improvement in mandibular occlusion, improvement in facial asymmetry and retrognathia and improved upper airway status. For some conditions, DO is emerging as the preferred method of treatment in the growing child. It is the preferred method of treatment for mandibular lengthening when there is more than 7 mm of horizontal overjet, when there is an anterior open bite, when there is a history of temporomandibular joint (TMJ) symptoms or instability, or when repeat surgery is indicated for relapse (Robinson, 2005).

Professional Societies/Organizations

The American Association of Oral and Maxillofacial Surgeons (AAOMS) published their statement regarding the use of DO for the correction of maxillofacial deformities in July 2003. They indicated this technique should be used when it would be more efficient or effective than other available treatment modalities. Examples of these indications include:

- When a degree of improvement unavailable with other techniques would be produced (i.e., a superior result), DO is indicated.
- There is a severe deficiency of either jaw with early correction indicated (e.g., an infant with Pierre Robin sequence with mandibular deficiency so severe that tracheostomy is required and advancement of the mandible is the only way to correct an obstructive situation).

- There is a severe mandibular deficiency requiring lengthening of the mandible of greater than 10 mm. Growth modifications via orthodontics generally produces no more than 5 mm differential growth and conventional orthognathic procedures become more difficult and less predictable when greater than 8–10 mm of advancement is needed.
- There is a need for lengthening a short mandibular ramus. The nature of distraction osteogenesis is well-suited for stretching of the pterygomasseteric sling, which is not easily overcome by conventional procedures.

Other possible applications include:

- A narrow mandible which must be widened. According to the AAOMS, there has been little success in widening the mandible with conventional surgery prior to the advent of distraction. Distraction techniques offer a better way to address this problem.
- Widening of the maxilla is needed in an adult. However, the AAOMS also states that surgically assisted palatal expansion, which is analogous to distraction osteogenesis, has been utilized to overcome this problem for decades with very desirable and stable results.
- There is alveolar deficiency. The AAOMS indicate that there is limited documentation within the literature that describes successful vertical augmentation using this technique as a stand-alone procedure.

The AAOMS also state that no extensive long-term data exist that document the precise role of distraction osteogenesis in the care of routine maxillofacial deformities. It is important that detailed basic research in this area be continued, and long-term data be collected and published. DO should be used only when superior results can be achieved as compared to conventional techniques (AAOMS, 2003). A more recent update to this position statement was not located.

Summary

There is evidence in the published peer-reviewed literature supporting the clinical effectiveness of distraction osteogenesis (DO) as an early alternative to conventional medical and surgical interventions for the treatment of severe craniofacial deformities. DO has been used for patients with a variety of functional impairments including: airway obstruction, obstructive sleep apnea, malnutrition, failure to thrive, persistent inability to adequately masticate or persistent speech dysfunction. The procedure can be performed alone or in combination with other standard techniques to address these conditions.

Coding/Billing Information

Note: 1) This list of codes may not be all-inclusive.

2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

CPT® Codes	Description
20690	Application of a uniplane (pins or wires in 1 plane), unilateral, external fixation system
20692	Application of multiplane (pins or wires in more than one plane), unilateral, external fixation system (e.g., Ilizarov, Monticelli type)
20693	Adjustment or revision of external fixation system requiring anesthesia (eg, new pin[s] or wire[s] and/or new ring[s] or bar[s])
20694	Removal, under anesthesia, of external fixation system
20696	Application of multiplane (pins or wires in more than 1 plane), unilateral, external fixation with stereotactic computer-assisted adjustment (eg, spatial frame), including imaging; initial and subsequent alignment(s), assessment(s), and computation(s) of adjustment schedule(s)
21100	Application of halo type appliance for maxillofacial fixation, includes removal (separate procedure)
21110	Application of interdental fixation device for conditions other than fracture or dislocation, includes removal

21195	Reconstruction of mandibular rami and/or body, sagittal split; without internal rigid fixation
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***Current Procedural Terminology (CPT®) ©2013 American Medical Association: Chicago, IL.**

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