



Medical Coverage Policy

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Distraction Osteogenesis (DO) for Craniofacial Deformities

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Overview

This Coverage Policy addresses distraction osteogenesis for craniofacial deformities.

Coverage Policy

Coverage for corrective and reconstructive surgery including distraction osteogenesis for craniofacial deformities varies across plans. Refer to the customer's benefit plan document for coverage details.

Distraction osteogenesis is considered 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)
 - maxillary hypoplasia due to nonsyndromic cleft lip and palate (CLP)
- **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 positive airway pressure (CPAP) or an oral appliance has been attempted and failed despite patient compliance

Distraction osteogenesis is considered NOT medically necessary:

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

General Background

According to the American Association of Oral and Maxillofacial Surgeons (AAOMS), distraction osteogenesis (DO) is a surgical technique in which new bone formation is induced by gradual separation of bony segments by means of an appliance in conjunction with an osteotomy. The steps and the basic technique of distraction osteogenesis are:

- Osteotomy phase. An osteotomy or corticotomy with placement of a device either internally or externally across the bony segment.
- Latency phase. This is a period of time in which the healing process is initiated and callus formation begins. In most applications, the latency phase is five to seven days – although there are some maxillofacial situations in which distraction is begun immediately.
- Distraction phase. At this time, the device is activated to create tension across the surgical site. As the segments are distracted, bone formations begin within the callus. The attendant tissues tend to adapt well to change, and there is an increase in size of the soft-tissue envelope. This process is termed distraction histogenesis.
- Consolidation phase. This is the period in which the segments are stabilized in order to allow for complete maturation of the regenerate bone. There is no activation during this phase.
- Remodeling phase. This phase has been recently described in the literature and, as more long-term results have been studied, it is apparent that the soft tissues and bone undergo continuing change over time (AAOMS, 2017).

Craniofacial syndromes encompass a wide range of anomalies of the face and head that can result from abnormal growth patterns, genetics, disease or trauma. Whether congenital or acquired, 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 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 Craniofacial microsomia (CFM), Treacher Collins syndrome (TCS), Pierre Robin sequence or syndrome, Nager syndrome (Nager acrofacial), Binder syndrome (maxillonasal dysplasia), Velocardiofacial syndrome (VCFS) (Shprintzen syndrome), Stickler (hereditary arthroophthalmopathy) and Marshall syndromes, Van der Woude syndrome.

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.

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. 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.

Few absolute contraindications to the use of this technique exist; however, caution is advised in patients who, for one reason or another, will not comply with the distraction regime. DO is contraindicated in post-radiation bone. From a surgical standpoint, an adequate bone stock is necessary to accept the distraction appliances and to provide suitable opposing surfaces capable of generating a healing callus.

U.S. Food and Drug Administration (FDA)

The U.S. Food and Drug Administration (FDA) approved several Class II distraction devices for use as early as the 1990s. 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

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. The procedure can be performed alone or in combination with other standard techniques to address these conditions.

Evidence consists of case reports, both prospective and retrospective case series and published reviews. 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 may be required.

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. Many children are likely to require staged procedures, with secondary distraction and/or conventional orthognathic surgery, to be able to control the symmetry in multiple planes. In many cases, simultaneous maxillary-mandibular distraction, in which mandibular distraction device drives the maxillary distraction, can be beneficial.

There are few small studies addressing maxillary hypoplasia. One small randomized control trial (Chua, et al., 2010; Cheung, et al., 2006) reported on 29 patients in China with maxillary hypoplasia to compare the effects of DO versus conventional orthognathic (CO) surgery (Le Fort I osteotomy) in cleft lip and palate (CLP) who required maxillary advancement ranging from 4 to 10 mm (age > 16 years). Cheung et al. (2006) stated there were no major differences in the clinical morbidities between the osteotomy and distraction groups. Distraction of the cleft maxilla provided better skeletal stability for maintaining its advanced position than conventional cleft orthognathic surgery. Chua et al. (2010) noted results showed no significant differences in speech and velopharyngeal function changes between the two groups at a minimum of two postoperative times: 3–8 months (mean 4 months) and 12–29 months (mean 17 months). In a Cochrane review regarding Maxillary Distraction Osteogenesis versus Orthognathic Surgery for Cleft Lip and Palate patients, Kloukos et al. (2018) noted the quality of the evidence to be very low. The one study was small and there were concerns about aspects of its design and reporting. Horizontal relapse of the maxilla was significantly less in the distraction osteogenesis group five years after surgery. There was no statistically significant difference in speech and velopharyngeal function between the interventions. There was no severe harm to any participant. Kloukos et al. (2018) stated that based on measured outcomes, distraction osteogenesis may produce more satisfactory results; however, further prospective research comprising assessment of a larger sample size with participants with different facial characteristics is required to confirm possible true differences between interventions.

Lin et al. (2018) reported on a retrospective case series of 42 patients in China with maxillary hypoplasia with repaired cleft palate ages 14.2 to 30.5 years who underwent anterior maxillary segmental distraction osteogenesis (AMSDO). Twenty cases were with complete unilateral cleft, and the other 22 with complete bilateral cleft, all of which had undergone cheiloplasty at the age of 6 months and palatoplasty with push-back procedure between the age of 1 and 3 years. Patients were diagnosed as maxillary hypoplasia and skeletal class III malocclusion by cephalometric analysis, had negative overjet >6.0mm, and presented significantly mid-face retrusion deformity. After a latency period of 7 days, distraction is initiated. The distraction devices were activated 0.5mm twice a day (1 mm/day) to lengthen the anterior maxillary on a designed direction. Distraction would be constant until reaching a normal sagittal skeletal profile and normal anterior occlusion as predetermined. When distraction was finished, the distraction devices were kept in situ for the consolidation period of total 3 months. Post-AMSDO orthodontic treatments were needed. Results showed that all cases had successfully accomplished AMSDO with no severe complications. Maxillary advancement has reached 13.80mm on average (ranging from 10.0mm to 20.0mm). Relapse tendency was found in 2 cases, of which maxilla respectively shortened total 1.2mm and 1.4mm after 1 year, but the change showed no statistical significance ($P>0.05$). The authors commented that AMSDO has unique advantages as follows: can effectively correct maxillary hypoplasia in patients with repaired cleft palate; can create a space for postoperative orthodontic treatment to solve the crowding teeth situation; the postoperative velopharyngeal function and speech quality show no significant change.

Professional Societies/Organizations

American Association of Oral and Maxillofacial Surgeons (AAOMS): The AAOMS published a Clinical Condition Statement on Distraction Osteogenesis (2017) and addressed indications for distraction of facial bones stating that the obvious indication for distraction osteogenesis is a situation in which this technique would be more efficient or effective than other available treatment modalities. From that perspective, distraction would be indicated when:

- A degree of improvement unavailable with other techniques would be produced (i.e., a superior result).
- It would produce a similar result in a more cost-effective way. Cost should be considered in a very broad sense, including burden of treatment for the patient and economic factors.

The AAOMS goes on to note that the indications for distraction involving the jaws are limited to conditions in which this technique may be uniquely able to produce significant improvement over more traditional therapy. Examples of these situations are:

- Severe deficiency of either jaw with early correction indicated (e.g., an infant with Pierre Robin with mandibular deficiency so severe that tracheostomy is required and advancement of the mandible is the only way to correct an obstructive situation).
- Severe mandibular deficiency requiring lengthening of the mandible of greater than 10 mm. Growth modification 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 to 10 mm advancement is needed.
- Need for lengthening of 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.
- Widening of the maxilla in an adult. 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.
- Narrow mandible that must be widened. 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.
- Alveolar deficiency. The literature describes grafting techniques for augmenting the alveolar ridge. This is becoming especially popular as an adjunct to implant reconstruction. However, vertical augmentation is often difficult and distraction osteogenesis techniques may offer a means for augmentation of the bony ridge with an increase in soft tissue volume as well.

American Academy of Pediatric Dentistry (AAPD): The AAPD notes it endorses the current statements of the American Cleft Palate-Craniofacial Association (ACPA). The AAPD states that “For patients with craniofacial anomalies, orthodontic treatment may be needed in conjunction with surgical correction (and/or distraction osteogenesis) of the facial deformity” (revised 2019).

Medicare Coverage Determinations

	Contractor	Determination Name/Number	Revision Effective Date
NCD		No National Coverage Determination found	
LCD		No Local Coverage Determination found	

Note: Please review the current Medicare Policy for the most up-to-date information.

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.

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

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 1 plane), unilateral, external fixation system (eg, 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)

CPT®* Codes	Description
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

*Current Procedural Terminology (CPT®) ©2020 American Medical Association: Chicago, IL.

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