Clinical Policy Title: Dental bone grafting

Clinical Policy Number: 14.03.06

Effective Date: April 1, 2017
Initial Review Date: March 15, 2017
Most Recent Review Date: March 15, 2017
Next Review Date: March 2018

Related policies:

CP# 14.03.01 Orthognathic surgery
CP# 14.02.09 Bone graft substitutes

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 reconstructive dental services including dental bone grafting to be clinically proven and, therefore, medically necessary when the following criteria are met:

- The service is rendered to improve a deformity or resolve a deficit that exists from traumatic oro-facial injury or iatrogenic insult (e.g., radical head and neck surgery).
- The service is rendered to improve function where the deficiency is a result of congenital malformation.

Examples of covered indications for reconstructive dental services with dental bone grafting include:

- Procedures in and of the face and oral cavity involving the removal of cysts or tumors of the jaws or facial bones
- Treatment of oro-facial fractures/dislocations
- Treatment of facial and oral wounds or lacerations
• Procedures to stimulate periodontal regeneration when the disease process has led to a deformity of the bone.
• Procedures of simultaneous placement of implants with a concurrent extraction.

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/. All other uses of dental bone grafting are not medically necessary.

Alternative covered services:

• In-network oral surgery and maxillofacial surgery evaluation and management

Background

Bone grafting is inherent to a panoply of dental and maxillofacial surgical procedures intended to increase deficient bony tissue by augmenting and replacing it with a natural or synthetic surrogate. Bone grafting in this setting works collaboratively with the body’s own physiologic regenerative capacity: the implanted material is eventually replaced by natural bone producing a replica of the original bony structure (Kumar 2013).

Dental bone grafting has great utility in instances where a large amount of oral or facial skeleton must be reinforced or reconstructed. In such cases “en bloc” placement of a part of the jaw or the chin may be necessary to cover the entire deficit. Where smaller areas of coverage are desired a small quantity of synthetic bone material may be placed into the defect (e.g., endentulous space left after tooth extraction).

Autogenous bone grafting requires an initial procedure to acquire the material used in reconstruction, while allogenic graft materials carry a risk of viral transmission from donor to host. There is significant morbidity associated with these techniques and those concerns have led to a search for suitable synthetic products that might obviate the need for graft harvesting. A brief guide to the various natural and synthetic adjuncts available in the United States (U.S.) is appended to this document in Appendix A.

The U.S. Food and Drug Administration (FDA 2016) mandates that human allograft materials must be registered with the federal government. They are identified in the FDA’s Human Cell and Tissue Establishment Registration database. The Affordable Care Act (ACA) provides that coverage shall be implemented by qualified health plans for pediatric oral services (up to the age of 19 years) including restorative procedures that may include bone grafting (i.e., treatment of traumatic injury or congenital
defect involving the oro-facial skeleton).

**Searches**

Prestige Health Choice searched PubMed and the databases of:
- UK National Health Services Center 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 December 9, 2016. Searched terms were: "dental bone grafting (MeSH)."

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**

There is substantial medical evidence that dental bone grafting is impactful in positively influencing the effectiveness and clinical outcomes related to preservation and reconstruction of the oral and maxillofacial skeleton (Moura 2016, Sanz 2015, Lutz 2015, Duttenhoefer 2013).

Grafting materials demonstrating clinical efficacy include cancellous and cortical allograft bone, ceramics, demineralized bone matrix, bone marrow, and composite grafts (Motamedian 2016, Papageorgiou 2016). Composite grafts comprised of several materials are often used to maximize bone healing, especially where the grafting site is compromised (Al-Nawas 2014, Jensen 2012, Rickert 2012).

One area of recent clinical interest is in the effect of local angiogenesis on outcomes with disparate techniques demonstrating superiority in this regard (Saghiri 2016). Further advances in tissue engineering (e.g., additional families of growth factors, evolving biological scaffolds and incorporation of mesenchymal stem cells) will likely generate new techniques to repair, regenerate and restore oro-facial tissue to its functional state.

**Summary of clinical evidence:**

<table>
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<tr>
<th>Citation</th>
<th>Content, Methods, Recommendations</th>
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<thead>
<tr>
<th>Source</th>
<th>Title</th>
<th>Key points</th>
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- Iliac crest was site of graft origin in 76.1% of cases.  
- Benign tumors were the major cause of defects (56.8%), and 44.7% of defects were located in the lateral mandibular area.  
- The use of non-vascularized bone grafts for mandibular reconstruction showed an 87.6% overall success rate in this review.  
- The restoration of bone defects due to malignant tumors treated with radiation therapy had lower success rates, and these appear to be a contraindication for the technique. |
- Among bone substitute materials the autogenous bone-grafts, and among the barrier membranes the collagenous membranes, had the highest angiogenic potentials.  
- Other bone-grafting materials or membranes were mostly used with pro-angiogenic factors to enhance their angiogenic properties. |
| Papageorgiou (2016) | Comparative effectiveness of natural and synthetic bone grafts in oral and maxillofacial surgery prior to insertion of dental implants: Systematic review and network meta-analysis of parallel and cluster randomized controlled trials. | - Systematic review of 302 procedures compared evidence of efficacy between natural and synthetic bone grafts in oral and maxillofacial surgery prior to insertion of dental implants and found no statistically significant differences in the %-age of new bone from pairwise comparisons between any two bone grafts.  
- Autografts were associated with the highest percentage of new bone, followed by synthetic grafts, xenografts, and allografts.  
- No differences were noted with regard to patient age, sex, healing time, membrane used or kind of surgical graft used.  
- The authors concluded that synthetic bone substitutes or xenologous bone grafts can be used as an alternative to autologous grafts in order to overcome problems of additional surgeries or limited graft availability. |
- The range of implant survival and success rates varied from 73.8% to 100% and 72.8% to 100%, respectively for autogenous bone blocks.  
- The allogenic bone blocks survival and success rates were 95.3-100% and 93.7-100% respectively.  
- Evidence on implant survival/success rate of both techniques was limited to observational studies with relatively small sample sizes. |
Sanz (2015)

Key points:
- Systematic review aimed at improving dental implant outcomes in three specific clinical situations:
  o The fresh extraction socket with alveolar ridge preservation protocols;
  o The posterior maxilla with limited bone height with either the placement of regular-sized implants after sinus elevation and grafting or short dental implants and;
  o The posterior mandible with limited bone height with either vertical bone augmentation and placement of implants or short dental implants.
- The authors concluded that interventions aimed for alveolar ridge preservation have shown efficacy in terms of allowing the placement of dental implants and for reducing the need of further augmentation procedures at implant placement.
- Placement of implants after sinus elevation and grafting or short dental implants, were valid alternatives in the treatment of the posterior maxilla with deficient bone availability.
- Placement of implants in vertically augmented bone rendered comparable outcomes with those of short implants in the treatment of the posterior mandible, but short implants resulted in fewer complications.

Lutz (2015)
Long-term outcomes of bone augmentation on soft and hard-tissue stability: a systematic review.

Key points:
- Systematic review of the practice of peri-implant hard-tissue augmentation prior to or immediately before implant placement.
- Thirty-seven articles met the inclusion criteria and were included.
- Several different hard-tissue augmentation techniques showed the desired level of stability in peri-implant tissues.

Al-Nawas (2014)
Augmentation procedures using bone substitute materials or autogenous bone – a systematic review and meta-analysis.

Key points:
- Systematic review and meta-analysis compared artificial bone substitutes to autologous bone in augmentation procedures of the edentulous jaw and alveolar ridge augmentation.
- The mean implant survival rate was 98.6% ± 2.6 for bone substitutes, 88.6 ± 4.1% for bone substitutes combined with autologous bone and 97.4 ± 2.2% for autologous bone alone.
- There was no statistically significant difference in implant survival between the two groups ([OR], 0.84; [CI], 0.5-1.42).
- The mean implant survival rate in ridge augmentation was 97.4 ± 2.5% for BSM, 100 ± 0% for bone substitutes combined with autologous bone and 98.6 ± 2.9% for autologous bone alone.
- There was no statistically significant difference in implant survival for ridge augmentation using bone substitutes or using autologous bone ([OR], 1.85; [CI], 0.38 to 8.94).

Duttenhoefer (2013)
Long-term survival of dental implants placed in the grafted maxillary sinus: systematic review and meta-analysis of treatment modalities.

Key points:
- Systematic review and meta-analysis of 16,268 endosseous implants placed in grafted maxillary sinus were carried out to investigate the influence of various treatment modalities on implant survival in the grafted maxillary sinus.
- The treatment parameters surgical approach, grafting material and implant type showed no selective preference; however, application of membranes showed a significantly reduced hazard-ratio, independent of other co-factors.
<table>
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<tr>
<th>Jensen (2012)</th>
<th>Maxillary sinus floor augmentation with Bio-Oss or Bio-Oss mixed with autogenous bone as graft: a systematic review.</th>
<th>Key points:</th>
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<td>Systematic review studied implant treatment outcome when Bio-Oss or Bio-Oss mixed with autogenous bone is used as graft for the maxillary sinus floor augmentation.</td>
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<td>The 1-year implant survival demonstrated no statistically significant difference.</td>
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<td>Implant survival was 96% with Bio-Oss and 94% with a mixture of 80% Bio-Oss and 20% autogenous mandibular bone.</td>
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<td>Addition of a limited amount of autogenous bone to Bio-Oss seemed not to increase the amount of new bone formation and bone-to-implant contact compared with Bio-Oss.</td>
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<th>Rickert (2012)</th>
<th>Maxillary sinus lift with solely autogenous bone compared to a combination of autogenous bone and growth factors or (solely) bone substitutes.</th>
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<td>Systematic review of the literature regarding the outcome of maxillary sinus floor elevation to create sufficient bone fraction to enable implant placement.</td>
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<td>Sinus floor elevations with autogenous bone (controls) were compared with autogenous bone combined with growth factors or bone substitutes, or solely with bone substitutes (test groups).</td>
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<td>Bone fraction after applying autogenous bone, autologous bone with growth factors (platelet rich plasma), or autogenous bone and bone substitutes (bovine hydroxyapatite, bioactive glass, corticocancellous pig bone) revealed no significant differences in bone formation after 5 months.</td>
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<td>The one-year overall implant survival rate showed no significant difference between implants.</td>
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<td>The authors concluded that bone substitutes combined with autogenous bone provide a reliable alternative for autogenous bone as sole grafting material to reconstruct maxillary sinus bony deficiencies.</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 in accordance with those manuals.

<table>
<thead>
<tr>
<th>CPT Code</th>
<th>Description</th>
<th>Comments</th>
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<tbody>
<tr>
<td>21210</td>
<td>Graft, bone; nasal, maxillary, malar areas (includes obtaining graft)</td>
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<tr>
<td>21215</td>
<td>Graft, bone; mandible (includes obtaining graft)</td>
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<tr>
<td>21245</td>
<td>Reconstruction of mandible or maxilla, subperiosteal implant; partial</td>
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<tr>
<td>21246</td>
<td>Reconstruction of mandible or maxilla, subperiosteal implant; complete</td>
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<tr>
<td>21247</td>
<td>Reconstruction of mandibular condyle with bone and cartilage autografts (includes obtaining grafts) (eg, for hemifacial macrosomia)</td>
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<td>21348</td>
<td>Open treatment of nasomaxillary complex fracture fracture (LeFort II type); with bone grafting (includes obtaining graft)</td>
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<td>21365</td>
<td>Open treatment of complicated (eg, comminuted or involving cranial nerve foramina) fracture(s) of malar area including zygomatic arch and malar tripod; with bone grafting (includes obtaining graft)</td>
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<th>ICD-10 Code</th>
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<tr>
<td>M26.9</td>
<td>Deformity jaw</td>
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<tr>
<td>D16.5</td>
<td>Cyst, calcifying odontogenic, lower jaw</td>
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<tr>
<td>Q18.9</td>
<td>Congenital malformation of face and neck, unspecified</td>
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<tr>
<td>S02.609</td>
<td>Fracture mandible</td>
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### Classification of bone grafts based on material groups (Kumar 2013)

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<tr>
<td>Allograft-based bone graft involves allograft bone, used alone or in combination with other materials (e.g., Grafton®, OrthoBlast®).</td>
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<td>Factor-based bone graft are natural and recombinant growth factors, used alone or in combination with other materials such as transforming growth factor-beta (TGF-beta), platelet-derived growth factor (PDGF), fibroblast growth factors (FGF), and bone morphogenetic protein (BMP).</td>
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<td>Cell-based bone grafts use cells to generate new tissue alone or are added onto a support matrix, for example, mesenchymal stem cells.</td>
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<td>Ceramic-based bone graft substitutes include calcium phosphate, calcium sulphate, and bioglass used alone or in combination (e.g., OsteoGraf®, ProOsteon®, OsteoSet®).</td>
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<tr>
<td>Polymer-based bone graft uses degradable and nondegradable polymers alone or in combination with other materials, for example, open porosity polylactic acid polymer.</td>
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