Clinical UM Guideline

Subject: Biological Materials to Aid in Soft and Hard Tissue Grafting
Guideline #: 03-401 **Current Effective Date:** 03/24/2017
Status: New **Last Review Date:** 02/08/2017

Description

This document addresses the materials used for soft and hard tissue grafting whether used alone or in conjunction with other procedures.

Note: Please refer to the following documents for additional information concerning related topics:

- Osseous Surgery: 04-205
- Mucogingival Surgery and Soft Tissue Grafting: 04-204
- Removal (extraction) of teeth: 07-101
- Bone Grafts for Dental Surgical Services: 04-201, 07-901

Clinical Indications

Medically Necessary: According to Healthcare.gov, medically necessary care involves health-care services or supplies needed to prevent, diagnose, or treat an illness, injury, condition, disease, or its symptoms and that meet accepted standards of medicine or dentistry. With any of the circumstances mentioned, if the condition produces debilitating symptoms or side effects, then it is also considered medically necessary for treatment when used according to the U.S. Food and Drug Administration (FDA) labeled indication. The use of bone graft substitutes containing natural demineralized bone matrix (DBM) is considered medically necessary when used as a bone graft extender, or when autograft is not available.

Medically/Dentally Necessary or Medical/Dental Necessity means Medical/Dental Services that are:
(1) Consistent with the Member's diagnosis or condition;
(2) Is rendered:
(A) In response to a life-threatening condition or pain; or
(B) To treat an injury, illness or infection related to the dentition; or
(C) To achieve a level of function to the dentition consistent with prevailing community standards for the diagnosis or condition.

Not Medically Necessary: Off label use for services or supplies are not covered by the plan.

Note:

A group may define covered dental services under either their dental or medical plan, as well as to define those services that may be subject to dollar caps or other limits. The plan documents outline covered benefits, exclusions and limitations. The health plan advises dentists and enrollees to consult the plan documents to determine if there are exclusions or other benefit limitations applicable to the service request. The conclusion that a particular service is medically or dentally necessary does not constitute an indication or warranty that the service requested is a covered benefit payable by the health plan. Some plans exclude coverage for services that the health plan considers either medically or dentally necessary. When there is a discrepancy between the health plan's clinical policy and the group's plan documents, the health plan will defer to the group's plan documents as to whether the dental service is a covered benefit. In addition, if state or federal regulations mandate coverage then the health plan will adhere to the applicable regulatory requirement.

Criteria

The field of tissue engineering or regenerative medicine is a process by which damaged tissues are regenerated rather than using grafts (autografts, allografts) by developing biological substitutes that restore, maintain or improve tissue function. In dentistry, adjunctive regenerative therapy utilizing biological materials can be used for the treatment of periodontal disease defects of natural teeth and recently dental implants. Anthem considers this procedure to be experimental and investigational as research is limited.

rhBMP (recombinant human bone morphogenic protein) is a synthetic product, and should not be confused with naturally occurring BMPs, which may be present in autologous and allogeneic bone graft materials.

The use of recombinant human bone morphogenetic protein-2 is considered **investigational and not medically necessary** for conditions that do not meet the above criteria (according to Anthem medical clinical guidelines), including but not limited to:

- As an adjunct to cervical or thoracic spinal fusion procedures; or
- As an adjunct to posterior lumbar interbody fusion (PLIF) or transforaminal lumbar interbody fusion (TLIF); or
- As management of early stages of osteonecrosis of the vascular head or femoral shaft; or
- As an adjunct to distraction osteogenesis (Iliazarov procedure); or
- Craniofacial applications including, but not limited to, periodontal defect regeneration, cleft palate repair, cranial defect repair, restoration and maintenance of the alveolar dental ridge.

The use of platelet rich plasma (PRP), including autologous conditioned plasma (ACP), is considered **investigational and not medically necessary** for all indications, including the treatment of *any* of the following:

- Cutaneous wounds; or
- Soft tissue injuries (including periodontal disease and sinus surgery); or
- Bone injuries (including surgically created wounds and non-unions).

When covered by specific group contract, indications for the use of biologic materials must be documented by x-rays, a periodontal charting showing the presence of pocket depths at a minimum of 5mm and a letter of medical necessity from the treating provider.

The use of biological materials will not be considered when used in conjunction with soft tissue grafting, bone grafts, guided tissue regeneration, ridge augmentation, periradicular surgery, placed within extraction sites, or when utilized with other regenerative materials regardless of specific group plan coverage.

Coding

The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member

coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

CDT

Including, but not limited to, the following:

D4265	Biologic materials to aid in soft and osseous tissue regeneration
D3431	Biologic materials to aid in soft and osseous tissue regeneration in conjunction with periradicular surgery

CPT

20999	Unlisted procedure, musculoskeletal system, general [when specified as harvesting and injection of bone marrow aspirate concentrate

HCPCS

G0460	Autologous platelet rich plasma for chronic wounds/ulcers, including phlebotomy, centrifugation, and all other preparatory procedures, administration and dressings, per treatment [for example, Aurix]

ICD-10 Diagnosis

K08.20	Atrophy, atrophic – alveolar process or ridge (edentualous)
K08.21	Minimal atrophy of the mandible
K08.22	Moderate atrophy of the mandible
K08.23	Severe atrophy of the mandible
K08.24	Minimal atrophy of the maxilla
K08.25	Moderate atrophy of the maxilla
K08.26	Severe atrophy of the maxilla
Q67.4	Atrophy, hemifacial
K06.9	Disease, alveolar ridge, edentulous
K06.8	Disease, specified NEC
J34.9	Disease, nasal
K08.1	Complete loss of teeth
K00.0	Complete loss of teeth, congenital
K08.0	Complete loss of teeth, exfoliation of teeth due to systemic causes
K08.4	Partial loss of teeth
K08.40	Partial loss of teeth, unspecified
K08.401 – K08.404	Partial loss of teeth, unspecified (class I – class IV)
K08.101 – K08.104	Complete loss of teeth, unspecified causes
K08.11	Complete loss of teeth –due to trauma
K08.111 – K08.119	Complete loss of teeth due to trauma (class I, class II, class III, class IV)
K08.12	Complete loss of teeth due to periodontal disease
K08.121 – K08.129	Complete loss of teeth due to periodontal disease (class I – class IV)
K08.41	Partial loss of teeth due to trauma
K08.411 – K08.419	Partial loss of teeth due to trauma, (class I – class IV; unspecified class)
K08.42	Partial loss of teeth due to periodontal disease
K08.421 – K08.429	Partial loss of teeth due to periodontal disease (class I – class IV, unspecified class)
K08.43	Partial loss of teeth due to caries
K08.431 – K08.439	Partial loss of teeth due to caries (class I – class IV, unspecified class)
K08.49	Partial loss of teeth due to other unspecified causes
K08.491 – K08.499	Partial loss of teeth due to other unspecified causes (class I – class IV, unspecified class)

Discussion/General Information

The use of bone graft substitutes has been widely accepted as the standard of care for many orthopedic conditions, including spinal fusions surgery and degenerative orthopedic conditions when the use of autologous bone graft material is unavailable, or when there is insufficient autograft to meet the needs of the surgical procedure. Such products are usually made from allogeneic bone, but may also be made from non-organic substances such as βTCP, calcium sulfate, hydroxyapatite, or xenographic bone, or any combination of these materials. The purpose of such materials is to provide a scaffold into which new bone forming cells can migrate and proliferate to create new autologous bone.

The use of autologous bone grafts (autografts) is the current "gold standard" bone graft material. The use of bone autografts is believed to provide an optimal combination of matrix or scaffold, growth factors, and osteoprogenitor cells. However, the harvest of autografts is typically associated with donor site pain and morbidity. With some procedures, large amounts of graft material are needed and sufficient quantities of autologous bone may not be available. In such circumstances, conventional allografts, processed allograft products, or synthetic bone graft products have been used. While these types of products have been helpful in allowing surgical procedures to be done in the absence of sufficient autograft, they may be associated with decreased efficacy and safety of autograft.

Definitions

Allograft - a tissue graft from a donor of the same species as the recipient but not genetically identical.

Autograft – a graft of tissue from one point to another of the same individual's body.

Autologous - cells or tissues obtained from the same individual.

Bone Morphogenic Protein – a group of growth factors also known as cytokines and as metabologens.

Osteogenesis - the formation of bone.

Osteoprogenitor – a mesenchymal cell that differentiates into an osteoblast. Also called preosteoblast.

Platelet Rich Plasma - blood plasma that has been enriched with platelets. As a concentrated source of autologous platelets, PRP contains several different growth factors and other cytokines that can stimulate healing of bone and soft tissue.

Xenograft – a tissue graft or organ transplant from a donor of a different species from the recipient.

References

Peer Reviewed Publications:

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2. Giannobile W, Somerman M. Growth and amelogenin-like factors in periodontal wound healing. A systematic review. Ann Periodontol 2003;8:193-204.
3. American Dental Association. CDT 2016. Dental Procedure Codes;34. (©ADA 2015).
4. McGuire MK and Scheyer ET. Xenogenic collagen matrix with coronally advanced flap compared to connective tissue with coronally advanced flap for the treatment of dehiscence-type defects. J Perio 2010; 81:1108-1117.
5. Materials Today, Volume 14, Issue 3, March 2011, pages 88-95: Biomaterials and Scaffolds for Tissue Engineering; Fergal J. O'Brien

6. Yassibag-Berkman Z, Tuncer O, et al. Combined use of platelet-rich plasma and bone grafting with or without guided tissue regeneration in the treatment of anterior interproximal defects. J Perio 2007; 78:801-809.
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9. Meyle J, Hoffman T, et al. A multi-center randomized controlled clinical trial on the treatment of intra-bony defects with enamel matrix derivatives/synthetic bone graft or enamel matrix derivatives alone. J Clin Periodontol 2011;38:652-660.
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13. Markous N, Pepelassi E, et al. The use of platelet--rich plasma combined with demineralized freeze-dried bone allograft in the treatment of periodontal endosseous defects. J Amer Dent Assoc 2010; 141:967-978.