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 (Ilizarov 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 (edentulous)
- **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:**


Federal and State law, as well as contract language, and Dental Policy take precedence over Clinical UM Guidelines. We reserve the right to review and update Clinical UM Guidelines periodically. Clinical guidelines approved by the Clinical Policy Committee are available for general adoption by plans or lines of business for consistent review of the medical or dental necessity of services related to the clinical guideline when the plan performs utilization review for the subject. Due to variances in utilization patterns, each plan may choose whether to implement a particular Clinical UM Guideline. To determine if review is required for this Clinical UM Guideline, please contact the customer service number on the member's card.

Alternatively, commercial or FEP plans or lines of business which determine there is not a need to adopt the guideline to review services generally across all providers delivering services to Plan's or line of business’s members may instead use the clinical guideline for provider education and/or to review the medical or dental necessity of services for any provider who has been notified that his/her/its claims will be reviewed for medical or dental necessity due to billing practices or claims that are not consistent with other providers, in terms of frequency or in some other manner.

No part of this publication may be reproduced, stored in a retrieval system or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from the health plan.

Current Dental Terminology - CDT © 2017 American Dental Association. All rights reserved.
ICD-10-CM 2017: The Complete Official Codebook. All rights reserved.

Anthem Blue Cross is the trade name of Blue Cross of California. Anthem Blue Cross and Anthem Blue Cross Life and Health Insurance Company are independent licensees of the Blue Cross Association. ANTHEM is a registered trademark of Anthem Insurance Companies, Inc. The Blue Cross name and symbol are registered marks of the Blue Cross Association.