Renaissance Clinical Criteria for Utilization Management Decisions

Clinical Criteria for Hydroxyapatite Regeneration

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Introduction

This Renaissance clinical criteria document addresses the hydroxyapatite regeneration procedure. The purpose of this document is to provide written clinical criteria to ensure that Renaissance consistently applies sound and objective clinical evidence when determining the medical necessity and clinical appropriateness of hydroxyapatite regeneration, as well as taking individual patient circumstances and the local delivery system into account.

Modern approaches to treating dental caries are evolving towards lesion management without removing tooth structure. A non-invasive procedure for caries control that has been added to the American Dental Association's dental procedure code set is the application of hydroxyapatite regeneration medicament. Over the last decade, research on biomimetic remineralization of carious lesions has reported that the self-assembling peptide P_{11}-4 was effective in regenerating demineralized tooth tissue in vitro. The P_{11}-4 material was designed to penetrate into early carious lesions, assemble into a biomatrix within the tooth and facilitate the formation of hydroxyapatite on the biomatrix. Further human studies with P_{11}-4 formulations have reported results leading to the conclusion that treatment of initial carious lesions with P_{11}-4 offers a non-invasive therapeutic option for enamel regeneration.

Currently Curodont™ Repair Fluoride Plus, which combines P_{11}-4 with fluoride, is the only known qualifying medicament for hydroxyapatite regeneration. A 2023 systematic review and meta-analysis published in the Journal of the American Dental Association on the effect of the P_{11}-4 formulation on initial caries lesions (Keeper, et al., 2023) stated that "The effects on promoting caries arrest and decreasing lesion size suggest that CR [Curodont] is a viable treatment option for initial caries lesions alongside other evidence-based interventions for initial caries lesions. This finding is a clinically meaningful addition beyond the effect of behavior change and other preventive interventions."

Based on Curodont™ usage instructions, a prophylaxis is performed on the tooth to be treated, after which the tooth is isolated and dried. Two percent sodium hypochlorite is applied to remove any salivary pellicle. A phosphoric acid etch is then applied to the tooth to remove inorganic deposits. The hydroxyapatite regeneration medicament is prepared and applied to the tooth for at least five minutes. After the medicament application, the patient is instructed not to eat, drink or rinse for thirty minutes. Repeat treatment is recommended once or twice a year, or once or twice every six months for patients with more active caries.

Hydroxyapatite regeneration may be performed by general dentists, pediatric dentists and other dental specialists in a variety of healthcare facilities.

Applicable Dental Procedure Codes

The following dental procedure code defined in the current version of the American Dental Association's Code on Dental Procedures and Nomenclature (the CDT® Code) is applicable to this document and is the appropriate code to use when documenting hydroxyapatite regeneration. Inclusion of this code here is for informational purposes only and does not imply benefit coverage or noncoverage of a procedure by a member's dental plan. A determination that a dental procedure is medically necessary and clinically appropriate does not guarantee that the procedure is a covered benefit of a member's dental plan. To determine if hydroxyapatite regeneration is a covered benefit of an individual member's dental plan, please refer to the plan documents in effect on the date of service.

CDT® Procedure Code	Procedure Code Nomenclature
D2991	application of hydroxyapatite regeneration medicament – per tooth

Clinical Criteria[1]

When approval of benefit payment for hydroxyapatite regeneration by a member's dental plan requires a determination by Renaissance that the procedure is medically necessary and clinically appropriate, the patient's dental record must document a generally accepted indication for performing the procedure. The following conditions are generally considered to be indications for application of hydroxyapatite regeneration medicament:

- Incipient non-cavitated carious lesions in patients age 4 or older
- Initial smooth surface caries (white spot lesions following orthodontic fixed multibracket treatment)

For patients who do not meet the published qualifying criteria for the hydroxyapatite regeneration procedure, Renaissance will consider documentation from relevant clinicians that explains the necessity of covering the procedure for conditions not included in the criteria.

Depending on the clinical circumstances, the application of hydroxyapatite regeneration medicament under the following conditions may be considered not medically necessary, inadvisable or deficient in clinical quality and may result in disapproval of benefits based on a professional determination that treatment is not medically necessary or not clinically appropriate:

- The application of hydroxyapatite regeneration medicament to:
  - A tooth with no evidence of a carious lesion
  - A tooth with a cavitated carious lesion
  - A tooth with a restoration present or needed
  - A tooth that has a hopeless periodontal, endodontic or structural prognosis
  - A primary tooth where natural exfoliation is imminent
  - A tooth planned for extraction
- Failure to follow the approved medicament application protocol
- Use of a material not clinically reported to promote hydroxyapatite regeneration
- Allergy to the hydroxyapatite regeneration material and/or other agents used in the treatment
- Hydroxyapatite regeneration medicament applied on the same tooth and on the same date of service as a direct or indirect restoration or on a tooth surface previously treated with silver diamine fluoride

[1] Government regulations or the provisions of a member's dental plan that define when a dental procedure may be considered medically necessary and clinically appropriate with respect to benefit coverage may take precedence over these clinical criteria.

Depending on an individual patient's condition and circumstances, the following additional criteria for application of hydroxyapatite regeneration medicament may be applied for coverage determinations:

- The American Dental Association clinical practice guideline on nonrestorative treatments for carious lesions may be referenced which describes noncavitated carious lesions as surfaces that appear macroscopically intact and without clinical evidence of cavitation versus a cavitated lesion which is described as a carious lesion with a surface that is not macroscopically intact and with a distinct discontinuity or break in the surface integrity, usually determined using visual or tactile means.
  - The diagnosis of primary and secondary cavitated and noncavitated carious lesions on accessible tooth surfaces is generally carried out through visual-tactile examination used in conjunction with an accepted caries classification system. Visual-tactile examination also allows the clinician to assess other variables related to caries activity including surface texture and the nature of overlying biofilm.
  - For inaccessible approximal tooth surfaces, diagnosis of a lesion as cavitated or noncavitated relies on an observation of radiographic depth. In those situations, the ADA guideline indicates that approximal lesions which appear limited to the enamel and outer one-third of the dentin on radiographs are most likely noncavitated where clinicians should prioritize the use of nonrestorative interventions.
  - In certain clinical situations, photography may be a useful adjunct to visual-tactile examination in documenting caries progression over time. The data currently available on the effectiveness of various supplementary non-radiological technologies for caries detection in dental practice is incomplete and the diagnostic information produced must be cautiously applied considering the reported sensitivity in clinical usage, particularly when deciding between restorative and nonrestorative interventions.
- When dental benefit programs have established program-specific criteria that define when hydroxyapatite regeneration is considered medically necessary and eligible for benefit coverage or that limit the number of hydroxyapatite regeneration medicament applications covered per tooth or per time period, Renaissance will apply that criteria when there is a need to evaluate space maintainer treatment for medical necessity.

Other Considerations

When the payment of benefits for a dental procedure by a member's dental plan depends on the application of clinical criteria to determine whether the procedure is medically necessary or clinically appropriate, the following additional information will be taken into consideration, if applicable:

- Individual patient characteristics including age, comorbidities, complications, progress of treatment, psychosocial situation and home environment
- Available services in the local dental delivery system and their ability to meet the member's specific dental care needs when clinical criteria are applied

Required Documentation

The decision to perform hydroxyapatite regeneration medicament application for a patient should be based on a thorough clinical and radiographic examination that facilitates the formulation of an appropriate treatment plan. When the payment of benefits for hydroxyapatite regeneration by a member's dental plan depends on a review of the procedure's medical necessity and clinical appropriateness, the treating practitioner should submit with the claim the following information as applicable from the patient's dental record. If the practitioner is unable to provide this information, benefit payment may be disapproved.

- A description of the use of a self-assembling peptide P_{11}-4 medicament
  - Currently Curodont™ Repair Fluoride Plus is the only known qualifying medicament

- If an agent other than Curodont™ is reported for D2991 hydroxyapatite regeneration, a detailed explanation must be submitted including information on the material used, the specific procedure performed, the tooth surface preparation and the topical application that is likely to produce the outcome of hydroxyapatite regeneration consistent with the D2991 procedure code nomenclature and descriptor

When determining coverage based on medical necessity or clinical appropriateness, Renaissance may request other clinical information relevant to a patient's care if needed to make coverage decisions.

Additional Information

The provision of dental advice and clinical treatment of patients is the sole responsibility of treating dentists, and these clinical criteria are not intended to restrict dentists from carrying out that responsibility or recommend treatment to their patients.

Renaissance's clinical criteria are developed and annually updated by a panel of licensed dental general practitioners and specialists serving on Renaissance's Utilization Management (UM) Committee, including the Dental Director and Utilization Management Director. The criteria are developed in alignment with evidence-based clinical recommendations, guidelines and parameters of care of leading nationally recognized dental public health organizations, health research agencies and professional organizations, credible scientific evidence published in peer-reviewed medical and dental literature, the curriculum of accredited dental schools, the regulatory status of relevant dental technologies, the rules and requirements of the Centers for Medicare and Medicaid Services, Renaissance national processing policies and input from practicing dentists. New and revised clinical criteria must be approved by the Dental Director and adopted by the UM Committee prior to release.

Federal or state statutes or regulations, dental plan contract provisions, local or national claim processing policies or other mandated requirements may take precedence over these clinical criteria.

Renaissance reserves the right to modify or replace this document at any time as appropriate to ensure the soundness, accuracy and objectivity of Renaissance's clinical criteria.

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