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Dental Policy

Subject: **Local Delivery of Antimicrobial Agents**
Guideline #: **04-302** **Publish Date:** **03/27/2018**
Status: **New** **Last Review Date:** **03/27/2018**

Description

This document addresses the use of local delivery of chemotherapeutic agents/local delivery of antimicrobial agents (LDCA or LDAA) as part of periodontal disease management. LDCA/LDAA may be appropriate when used as adjunctive therapy to treat refractory pockets following initial therapy with periodontal scaling and root planing or in conjunction with periodontal maintenance.

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

- 04-301 Scaling and Root Planing
- 04-901 Periodontal Maintenance
- Clinical Policy-01 Teeth with Poor or Guarded Prognosis

Clinical Indications

Appropriateness of Care:

Evaluation for the use of LDCA/LDAA treatment modalities for refractory disease sites is made following completion of definitive non-surgical and/or surgical periodontal treatment. Refractory disease sites include areas of periodontal pocketing equal to or greater than 5 millimeters with persistent signs of inflammation, spontaneous bleeding or bleeding upon probing, suppuration and/or increasing loss of clinical attachment. Local delivery of chemotherapeutic agents may also be indicated when isolated refractory sites are diagnosed at periodontal maintenance appointments.

As it applies to appropriateness of care, dental services must be:

- provided by a Dentist, exercising prudent clinical judgment
- provided to a patient for the purpose of evaluating, diagnosing and/or treating a dental injury or disease or its symptoms
- in accordance with the generally accepted standards of dental practice which means:
    - standards that are based on credible scientific evidence published in peer-reviewed, dental literature generally recognized by the practicing dental community
    - specialty society recommendations/criteria
    - any other relevant factors
- clinically appropriate, in terms of type, frequency and extent
- considered effective for the patient's dental injury or disease
- not primarily performed for the convenience of the patient or Dentist
- not more costly than an alternative service.
- dependent on group contract provisions, cosmetic services may not qualify for benefit coverage even though the services may be clinically appropriate.

Contraindications:

LDCA modalities are not appropriate for periodontal probing depths of less than 5mm, where a pattern of localized non-responsive periodontitis is diagnosed. When a generalized pattern of periodontitis is diagnosed, a more comprehensive intervention may be necessary, surgical therapies should be considered.

Note: Whether a service is covered by the plan, when any service is performed in conjunction with or in preparation for a non-covered or denied service, all related services are also either not covered or denied.

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

1. Scaling and root planing is highly effective in the treatment of chronic periodontitis and is the standard approach to non-surgical periodontal therapy. In most cases the majority of diseased sites will respond to non-surgical and will not require LDCA adjunctive therapy.
2. After allowing adequate time for healing, LDCA may be performed six weeks to six months post scaling and root planing or periodontal surgery.
3. An active/refractory site is usually described as a periodontal pocket, 5 millimeters or greater, that shows signs of inflammation, spontaneous bleeding or bleeding on probing, suppuration, increasing pocket depth and/or increasing attachment loss.
4. If there are multiple sites of recurrent and/or residual inflammation after periodontal scaling and root planing has been completed, more extensive periodontal therapeutic modalities, for example, periodontal surgical procedures, may need to be appropriately employed.
5. The use of subgingivally placed chemotherapeutic agents may also be indicated as an adjunct to periodontal maintenance therapy when localized recurrent and/or residual sites with inflammation are found.
6. The use of the LDCA antimicrobial agents have not been clinically tested for use in the regeneration of alveolar bone. The use of LDCA products in this application is considered by the plan to be experimental and investigational.

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 limited to*

D4381 Localized delivery of antimicrobial agents via a controlled release vehicle into diseased crevicular tissue per tooth
D4341 periodontal scaling and root planing, four or more teeth per quadrant
D4342 periodontal scaling and root planing, one to three teeth per quadrant
D4346 scaling in the presence of generalized moderate or severe gingival inflammation, full mouth, after oral exam
D4910 Periodontal maintenance
D4999 Unspecified periodontal procedure, by report
D6081 Scaling and debridement in the presence of inflammation or mucositis of a single implant, including cleaning Of the implant surfaces, without flap entry and closure.

CPT

Diagnosis

523.0 - .01 Acute Gingivitis

523.10 Chronic gingivitis
523.3 – 523.33 Aggressive and acute periodontitis
523.4 – 523.42 Chronic Periodontitis

ICD-10 *including but limited to*
K03.6 Deposits (accretions) on teeth
K05 Gingivitis and Periodontal diseases
K05.0 Acute gingivitis
K05.1 Chronic Periodontitis
K05.2 Aggressive Periodontitis
K05.3 Chronic Periodontitis
K05.6 Periodontal disease unspecified
Z72.0 Tobacco Use
Z91 Personal Risk Factors, not elsewhere classified

Discussion/General Information

Numerous clinical studies have shown that placement of antimicrobial agents (LDCA or LDAA) into diseased periodontal pockets can result in improvements in the clinical indicators of periodontal disease, suppress the present pathogenic microbiota, and may modulate the host inflammatory process. To be effective, these agents must reach the site of disease, remain at an adequate concentration, and be retained at the site over an adequate period of time for the desired pharmacologic effect to occur. Treatment involves insertion of FDA approved delivery devices containing antimicrobial medications into the diseased periodontal pocket. These devices slowly release pharmacologic agents in therapeutic concentrations over specific periods of time.

Currently there are three commonly used, FDA approved, adjunctive antimicrobial delivery systems for the treatment of progressive refractory periodontal disease sites in adults:
1. Arestin™ – Sulcularly placed 1mg minocycline HCl encapsulated microspheres. Considered locally applied antibiotic.
2. Atridox™ – Injectable 10% doxycycline hyclate in a bio-resorbable polymer gel. . Considered locally applied antibiotic.
3. PerioChip™ – 2.5mg of chlorhexidine gluconate in a bio-resorbable hydrolyzed solid gelatin base. Considered locally applied antiseptic

It should be noted that, when compared to scaling and root planing alone, adjunctive use of local delivery of antimicrobial agents can result in statistically significant improvements in pocket depths and increases of clinical periodontal attachment. However, these improvements are small and may not be considered **clinically** significant. Increases in clinical attachment measurements are generally less than one millimeter.

Systematic reviews of existing data do not reveal that localized delivery of chemotherapeutic agents reduces the need for surgery or improves the long-term prognosis of periodontally involved teeth, or that it is cost effective. Based on existing research, thorough scaling and root planing remains the treatment standard for non-surgical periodontal therapy. Consequently, the decision to treat patients with LCDA remains a matter of individual clinical judgment. If a pattern of generalized non-responsive periodontitis is diagnosed, localized delivery of antimicrobial agents may not be appropriate and a more comprehensive intervention with surgical therapies should be considered.

The 2006 "*American Academy of Periodontology statement on local delivery of sustained or controlled release antimicrobials as adjunctive therapy in the treatment of periodontitis*" stated that the existing data were insufficient to conclude that adjunctive local antimicrobial agents could reduce the need for surgery or improve long-term tooth retention, or was cost effective. The statement held that clinicians might consider the use of local antimicrobial agents in chronic periodontitis patients as an adjunct to scaling and root planing when localized recurrent and/or residual PD greater than or equal to 5mm with inflammation is still present following conventional therapies".

In 2015, the Journal of the American Dental Association published "*Evidence-based clinical practice guideline on the nonsurgical treatment of chronic periodontitis by means of scaling and root planing with or without adjuncts*," which concluded with a weak recommendation for one type of local antimicrobial agent and a low level of certainty for others. Regarding adjuncts, however, the strength of recommendations for chlorhexidine chips was deemed to be "weak" and recommendations for doxycycline hyclate gel and minocycline microspheres were listed as "expert opinion for." (Note that "expert opinion for" does not imply endorsement but instead signifies that evidence is lacking and the

level of certainty in the evidence is low.) These new practice guidelines have prompted the plan to conclude that although benefits may be available in certain plan designs, the use of local antimicrobial agents as adjunctive therapy for the treatment of periodontitis is experimental and investigational at this time".

Definitions

Calculus: Also known as tartar forms on the teeth surfaces which are the ideal site for plaque formation. Tartar is a form of hardened dental plaque caused by the collection of minerals from saliva and surface that is created and provides an ideal surface for further plaque formation. This leads to calculus buildup, which compromises the periodontal health of the gingiva (gums). Calculus can form both along the gumline, where it is referred to as supragingival ("above the gum"), and within the narrow space that exists between the teeth and the gingiva, where it is referred to as subgingival ("below the gum"). Calculus formation is associated with a number of signs and symptoms including bad breath, receding gums and inflamed gingiva. Brushing and flossing can remove plaque from which calculus forms; however, once formed, it is too hard and firmly attached to be removed with a toothbrush requiring removal at the dentist's office.

Dental Plaque: Is a biofilm or mass of bacteria that grows on surfaces within the mouth. It is a sticky colorless deposit at first, but when it forms tartar it is brown or pale yellow and is commonly found between the teeth, on the front of teeth, behind the teeth, on chewing surface, along the gumline, and below the gumline. Dental plaque is also known as microbial plaque, oral biofilm, dental biofilm, dental plaque biofilm or bacterial plaque biofilm. While plaque is commonly associated with oral diseases such as caries (cavities) and periodontal disease (gum diseases), its formation is a normal process that cannot be prevented.

Gingiva: The clinical term for gums. The gums are found in the oral cavity or mouth. They consist of mucosal (soft, pink) tissue that covers the alveolar processes (bone) of the maxilla (upper jaw) and mandible (lower jaw) and finish at the neck of each tooth.

LDCA (local delivery of chemotherapeutic agent) - the local delivery of sustained release technology antimicrobial agents for treating and controlling localized forms of periodontal disease.

LDAA (local delivery of antimicrobial agent) - the local delivery of sustained release technology antimicrobial agents for treating and controlling localized forms of periodontal disease.

Periodontal Disease: Can affect one or more of the tissue/structures associated with teeth {e.g. bone, the ligament that attaches the tooth to bone and gingiva (gums)}. While there are many different periodontal diseases that can affect these tooth-supporting tissues/structures, by far the most common ones are plaque-induced inflammatory conditions, such as gingivitis and periodontitis.

Refractory Periodontal Site: An active site described as a periodontal pocket, 5 millimeters or greater, that shows signs of inflammation, spontaneous bleeding or bleeding on probing, suppuration, increasing pocket depth and/or increasing attachment loss.

References

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2. Hanes PJ and Purvis JP. Local anti-infective therapy: Pharmacological agents. A Systematic review. Annals Periodontol 2003;8:79-98.
3. Bonito AJ, Lux L and Lohr KN. Impact of local adjuncts to scaling and root planing in periodontal disease therapy: A systematic review. J Perio 2005;76:1227-1236.
4. American Academy of Periodontology. The role of controlled drug delivery for periodontitis (Position paper). J Perio 2000;71:125-140.
5. Oringer RJ, Al-Shammari KF, Aldredge WA, et al. Effect of locally delivered minocycline microspheres on markers of bone resorption. J Perio;2002:73:835-842.

6. American Academy of Periodontology. Statement of the AAP on Periochip™ chlorhexidine containing resorbable polymer. May 1998.
7. Greenstein G. Non-surgical periodontal therapy in 2000: A literature Review. J Amer Dent Assoc 2000;131:1580-1592.
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9. Tomasi C, Koutouzis T and Wennstrom JL. Locally delivered doxycycline as an adjunct to mechanical debridement at retreatment of periodontal pockets. J Perio 2008;79:431-439.
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11. American Academy of Periodontology. AAP Statement on Parameters of Care Supplement; Parameter of "Refractoryt" Periodontitis. Volume 71; Number 5
12. American Dental Association JADA. Christopher J. Smiley, DDS et. al., Systematic review and meta-analysis on the nonsurgical treatment of chronic periodontitis by means of scaling and root planing with or without adjuncts. JADA July 2015 Vol 146 Issue 7, pgs 508-524
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Peer Reviewed Publications:

Government Agency, Medical Society, and Other Authoritative Publications:

History

Revision History	Version	Date	Nature of Change	SME
	Initial	3/27/18		Kahn and Clinical Policy Committee

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.