THERAPEUTIC PARENTERAL DRUG ADMINISTRATION AND IN-OFFICE DISPENSING OF MEDICATIONS

Policy Number: DCP033.01  Effective Date: January 1, 2017

INSTRUCTIONS FOR USE

This Dental Coverage Policy provides assistance in interpreting UnitedHealthcare dental benefit plans. When deciding coverage, the member specific benefit plan document must be referenced. The terms of the member specific benefit plan document (e.g., Certificate of Coverage (COC), Schedule of Benefits (SOB), and/or Summary Plan Description (SPD)) may differ greatly from the standard benefit plan upon which this Dental Coverage Policy is based. In the event of a conflict, the member specific benefit plan document supersedes this Dental Coverage Policy. All reviewers must first identify member eligibility, any federal or state regulatory requirements, and the member specific benefit plan coverage prior to use of this Dental Coverage Policy. Other Clinical Policies and Coverage Guidelines may apply. UnitedHealthcare reserves the right, in its sole discretion, to modify its Policies and Guidelines as necessary. This Dental Coverage Policy is provided for informational purposes. It does not constitute medical advice.

BENEFIT CONSIDERATIONS

Before using this policy, please check the member specific benefit plan document and any federal or state mandates, if applicable.

Essential Health Benefits for Individual and Small Group

For plan years beginning on or after January 1, 2014, the Affordable Care Act of 2010 (ACA) requires fully insured non-grandfathered individual and small group health plans (inside and outside of Exchanges) to provide coverage for Pediatric Dental Essential Health Benefits (“EHBs”). Large group plans (both self-funded and fully insured), and small group ASO plans, are not subject to the requirement to offer coverage for Pediatric Dental EHBs. However, if such plans choose to provide coverage for benefits which are deemed Pediatric Dental EHBs, the ACA requires all dollar limits on those benefits to be removed on all Grandfathered and Non-Grandfathered plans. The determination of which benefits constitute Pediatric Dental EHBs is made on a state by state basis. As such, when using this policy, it is important to refer to the member specific benefit plan document to determine benefit coverage.

COVERAGE RATIONALE

Therapeutic Parenteral Drug Administration (Single or Two or More Administrations)

Therapeutic parenteral drug administration may be indicated to enhance healing of surgical procedures, or reduce pain and/or risk of infection. Medications may include antibiotics, steroids or anti-inflammatory medications when administered as a separate IV or intramuscular injection.

Other Drugs and/or Medicaments (By Report)

Includes, but is not limited to oral antibiotics, oral analgesics, and topical fluoride dispensed in the office for home use; does not include writing prescriptions.
Coverage Limitations and Exclusions

- Therapeutic parenteral drug administration is inclusive when administered intravenously (IV) during IV sedation and general anesthesia.
- Drugs/medications, obtainable with or without a prescription, unless they are dispensed and utilized in the dental office during the patient visit.

DEFINITIONS

Parenteral: a technique of administration in which the drug bypasses the gastrointestinal (GI) tract [i.e., intramuscular (IM), intravenous (IV), intranasal (IN), submucosal (SM), subcutaneous (SC), intraosseous (IO)]

APPLICABLE CODES

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this policy does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Clinical Policies and Coverage Guidelines may apply.

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<thead>
<tr>
<th>CDT Code</th>
<th>Description</th>
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<tr>
<td>D9610</td>
<td>therapeutic parenteral drug, single administration</td>
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<tr>
<td>D9612</td>
<td>therapeutic parenteral drugs, two or more administrations, different medications</td>
</tr>
<tr>
<td>D9630</td>
<td>drugs or medicaments dispensed in the office for home use</td>
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DESCRIPTION OF SERVICES

Parenteral administration of drugs is any technique in which the route of administration bypasses the gastrointestinal tract. These routes include, but are not limited to, intravenous administration, intramuscular and subcutaneous injections and the use of medication patches and nasal sprays. There are many therapeutic drugs that may be administered parenterally in dentistry, and the use should be based on careful patient selection. These parenteral drug administration codes are for the administration of antibiotics, steroids, anti-inflammatory drugs, or other therapeutic medications and not to be used to report administration of sedative, anesthetic or reversal agents. Please refer to the General Anesthesia and Conscious Sedation Services Coverage Guideline for these procedures.

CLINICAL EVIDENCE

ArteagaOlta et al (2016) Prophylactic use of amoxicillin and amoxicillin/clavulanic acid, although controversial, is common in routine clinical practice in third molar surgery. The authors conducted a systematic review and meta-analysis including double-blind placebo-controlled randomized clinical trials published up to June 2015 to investigate the efficacy of amoxicillin with or without clavulanic acid on the incidence of the in the prevention of infection and dry socket after third molar extraction. There were 10 papers included in the review. The results of this review showed that the prophylactic use of amoxicillin does not significantly reduce the risk of infection and/or dry socket after third molar extraction, however with amoxicillin/clavulanic acid, the risk decreases significantly. The authors concluded however, that considering the number needed to treat, low prevalence of infection, potential adverse reactions to antibiotics and lack of serious complications in placebo groups, the routine prescription of amoxicillin with or without clavulanic acid is not justified.

Ataoğlu et al (2008) conducted a study to evaluate the efficacy of antibiotic prophylaxis during removal of impacted third molars. 150 patients with impacted mandibular or maxillary third molars were divided randomly into three groups. The first was given amoxicillin 2g combined with clavulanic acid, orally daily for 5 days postoperatively; starting at the end of the operation. The second group was given the same drugs but the regimen started 5 days before the operation. The third was given no antibiotics. Pain, infection, swelling, alveolar osteitis, and interincisal mouth opening (mm) were evaluated. There were no significant differences among the groups in the incidence of these complications. The authors concluded that routine prophylactic use of oral antibiotics in third molar surgery is not recommended.

Dietrich et al (2014). Diclofenac is an effective and well-tolerated nonsteroidal anti-inflammatory drug (NSAID) frequently used in the treatment of acute pain. Marketed formulations for parenteral administration usually contain 75 mg/3 mL of diclofenac sodium, which provide limited dosing flexibility, and are usually given intramuscularly. The authors conducted a randomized double blind trial to investigate the safety and efficacy of low dose subcutaneous (SC) diclofenac containing hydroxypropyl-β-cyclodextrin (HPβCD) as a solubility enhancer for the management of acute
pain. In this study, patients developing moderate-to-severe pain after third molar extraction under local anesthesia were randomized to one of the 4 SC injections: 25, 50, or 75 mg diclofenac, or placebo. The pain intensity differences were measured at 1.5 hours post dose and showed was higher in all diclofenac-treated groups than the placebo group. The authors concluded that this SC delivery of diclofenac containing (HPβCD) is effective at 25 and 50 mg levels for relieving moderate to severe pain following third molar extraction.

Graziani et al (2006) conducted a split-mouth randomized double-masked clinical trial to study the effect of endo-alveolar and sub-mucosal administrations of dexamethasone sodium phosphate to prevent inflammatory sequelae after surgical removal of lower third molars. Forty-three patients underwent bilateral extractions of lower third molars and were randomly assigned to receive either dexamethasone 4 mg (group A) or 10 mg (group B) as endo-alveolar powder or 10 mg as sub-mucosal injection (group C) unilaterally. The contralateral site served as control and did not receive any steroid administration. Facial edema, trismus and pain perception were evaluated at the 2nd and 7th postoperative day. A multivariate analysis revealed that treatment and ostectomy time were both significantly positively associated with the degree of postoperative trismus and edema. Other baseline classification variables (e.g., molar classification) were also predictive of the degree of change in all clinical parameters. Test sites treated (any steroid application) showed greater reductions in all clinical parameters recorded compared to control. No statistically significant differences were observed between the three test groups. The authors concluded that both sub-mucosal and endo-alveolar administration of dexamethasone is effective in reducing postoperative sequelae of surgical removal of lower wisdom teeth.

Grossi et al (2007) conducted a prospective study to evaluate the effect of submucosal administration of dexamethasone sodium phosphate on discomfort after mandibular third molar surgery. Sixty-one patients requiring surgical removal of a single mandibular impacted third molar under local anesthesia were randomly placed into 3 groups. After the onset of local anesthesia, the experimental groups received dexamethasone at 2 different doses (4 or 8 mg) as submucosal injection, and the control group received no drug. Standardized surgical and analgesic protocols were followed. Maximum interincisal distance and facial contours were measured at baseline and at postsurgery days 2 and 7. Pain was objectively measured by counting the number of analgesic tablets required. The patients' perception of the severity of symptoms was assessed with a follow-up questionnaire. On the second postoperative day, facial edema showed a statistically significant reduction in both dexamethasone 4-mg and dexamethasone 8-mg groups compared with the control group, but no statistically significant differences were observed between the 2 dosage regimen of dexamethasone. By contrast, there was no statistically significant difference between all groups when postoperative swelling was evaluated at day 7 (P > .50). The treatment group had a limited and nonsignificant effect on pain and trismus when compared with the control group at the 2 times of evaluation. The conclusion of this prospective study showed that the parenteral use of dexamethasone 4 mg, given as an intraoral injection at the time of surgery, is effective in the prevention of postoperative edema. Increasing the dose to 8 mg provides no further benefit.

Herrera-Briones FJ et al (2013) conducted a systematic literature review on the use of corticosteroids in third molar surgery. A systematic search of the literature was carried out in PubMed, Scopus, MEDLINE, and Cochrane using steroid and third molar as key words. 27 Randomized controlled trials and 1 meta-analysis were selected from among 72 articles identified, and included RCTs that compared perioperative steroids given in any formulation, dose, or route with either placebo or no treatment, and included patients of any age requiring the removal of one or more impacted third molars under local anesthesia, intravenous (IV) sedation, or general anesthesia. Articles were not restricted as a function of the method used to measure pain. The authors of this review concluded the evidence shows that the administration of corticosteroids improves the postoperative experience of patients and has a significant impact on trismus and inflammation. Greater effects appear to be achieved by using the parenteral route and by administering the corticosteroid before the surgery.

Kaczmarzyk et al (2007) conducted a prospective, randomized, double-masked, placebo-controlled trial to evaluate the efficacy of single and multi-dose (5-day) clindamycin therapy for the prevention of inflammatory complications in patients undergoing lower third molar surgical extraction with bone removal. There were 86 Patients who qualified for the study and they were randomly divided into three groups: (1) single dose of oral clindamycin administered preoperatively (single-dose group); (2) clindamycin administered preoperatively with continued therapy for 5 days (5day group); and (3) a placebo group. The following parameters were evaluated on the first, second and seventh days postsurgery: trismus, facial swelling, body temperature, lymphadenopathy, alveolar osteitis and subjective pain sensations. There were 86 patients (31 in the single-dose group, 28 in the 5-day group and 27 in the placebo group) enrolled in the study. There were no statistically significant differences in postoperative inflammatory complications in patients during the first and second days postsurgery. A statistically significant variation in body temperature was reported on the seventh day. Analysis of the postoperative analgesic intake did not show statistically significant differences between examined groups. Clindamycin applied in a single preoperative dose of 600 mg with or without subsequent 5-day therapy does not demonstrate efficacy in prophylaxis for postoperative inflammatory complications after third molar surgery.
Mohan et al (2014) conducted a randomized, controlled clinical study to evaluate the role of antibiotics to prevent postoperative complications after routine periodontal surgery and also to determine whether their administration improved the surgical outcome. Forty-five systemically healthy patients with moderate to severe chronic periodontitis requiring flap surgery were enrolled in the study. They were randomly allocated to Amoxicillin, Doxycycline, and control groups. Surgical procedures were carried out with complete asepsis as per the protocol. Postoperative assessment of patient variables like swelling, pain, temperature, infection, ulceration, necrosis, and trismus was performed at intervals of 24 h, 48 h, 1 week, and 3 months. Changes in clinical parameters such as gingival index, plaque index, probing pocket depth, and clinical attachment level were also recorded. There was no incidence of postoperative infection in any of the patients. Patient variables were comparable in all the three groups. Though there was significant improvement in the periodontal parameters in all the groups, no statistically significant result was observed for any group over the others. The results of this study showed that when periodontal surgical procedures were performed following strict asepsis, the incidence of clinical infection was not significant among all the three groups, and also that antibiotic administration did not influence the outcome of surgery. Therefore, prophylactic antibiotics for patients who are otherwise healthy administered following routine periodontal surgery to prevent postoperative infection are unnecessary and have no demonstrable additional benefits.

U.S. FOOD AND DRUG ADMINISTRATION (FDA)

There are extensive drugs and devices used for parenteral medication delivery. Please refer to the following website and search for product specific name: [http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm](http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm) (Accessed June 29, 2016)

REFERENCES


POLICY HISTORY/REVISION INFORMATION

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