Delta Dental of Michigan Clinical Criteria for Utilization Management Decisions				
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Introduction

This Delta Dental of Michigan (Delta Dental) clinical criteria document addresses treatment involving the placement of direct restorations. The purpose of this document is to provide written clinical criteria to ensure that Delta Dental consistently applies sound and objective clinical evidence when determining the medical necessity and clinical appropriateness of direct restorations, as well as taking individual patient circumstances and the local delivery system into account.

Direct restorations are performed in a single appointment when a tooth requires reconstruction where the degree of damage to the tooth is not extensive enough to require full coverage by an indirectly fabricated crown. Direct restorations may be composed of dental amalgam alloy, resin-based composite, glass ionomer and resin-modified glass ionomer and are commonly referred to as dental "fillings".

The selection of materials for direct restorations depends on the strength, durability, wear and fracture resistance, biocompatibility and appearance required for a particular restoration and patient:

- Dental amalgam is a biocompatible mixture of silver alloy and mercury that is tolerant to the presence of moisture during placement, has good load-bearing characteristics, is wear resistant and has a nonesthetic silver-grey color that contrasts with a tooth's natural color. Amalgam is commonly utilized for posterior direct restorations that must withstand heavy occlusal loading.
- Resin-based composite is a tooth-colored material that combines acrylic resin with a glass filler, has moderate load-bearing characteristics, is not tolerant to the presence of moisture and requires a dry field for placement. Resin-based composite is commonly utilized when tooth esthetics are a concern.
- Glass ionomer is a tooth-colored mixture of organic acid and glass that contains fluoride, has low resistance to occlusal wear and requires a dry field for placement. Glass ionomer is commonly used for small restorations that do not have to withstand occlusal loading. The material's fluoride-releasing characteristic may be useful with patients who have a high caries risk.
- Resin-modified glass ionomer combines acrylic resin, a glass filler and fluoride-containing glass and has characteristics and utility similar to glass ionomer material.

Direct restorations are most commonly performed to restore tooth structure damaged or missing due to dental caries, traumatic injury or other circumstances that slightly or moderately compromise the coronal portion of a tooth. Direct restoration procedures generally require pain control including the administration of a local anesthetic agent. A direct restoration is performed by first preparing a tooth to receive the restoration and then placing the restorative material into the preparation. Direct restorations are shaped during placement to reproduce the contours of a natural tooth in order to establish appropriate function, protect the tooth and provide an acceptable appearance.

Direct restorations 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 codes defined in the current version of the American Dental Association's Code on Dental Procedures and Nomenclature (the CDT® Code) are applicable to this document and are the appropriate codes to use when documenting direct restoration procedures. Inclusion of these codes 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 a direct restoration procedure 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
D2140	amalgam - one surface, primary or permanent
D2150	amalgam - two surfaces, primary or permanent
D2160	amalgam - three surfaces, primary or permanent
D2161	amalgam - four or more surfaces, primary or permanent
D2330	resin-based composite - one surface, anterior
D2331	resin-based composite - two surfaces, anterior
D2332	resin-based composite - three surfaces, anterior
D2335	resin-based composite - four or more surfaces (anterior)
D2390	resin-based composite crown, anterior
D2391	resin-based composite - one surface, posterior
D2392	resin-based composite - two surfaces, posterior
D2393	resin-based composite - three surfaces, posterior
D2394	resin-based composite - four or more surfaces, posterior

Clinical Criteria[1]

When approval of benefit payment for a direct restoration by a member's dental plan requires a determination by Delta Dental 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 placement of a direct restoration:

- A tooth with an active cavitated carious lesion where a nonrestorative intervention is not likely to have a good long-term prognosis for preserving tooth form and function
- A tooth with slight to moderate loss of coronal structure due to tooth fracture, a noncarious cervical lesion or attrition, abrasion or erosion where enough intact tooth structure remains that treatment with a direct restoration is likely to have a good long-term prognosis for restoring and maintaining tooth form and function
- A tooth with slight to moderate loss of coronal structure due to successful endodontic therapy leaving sufficient intact tooth structure remaining where a direct restoration is expected to have a good long-term prognosis in restoring and maintaining tooth form and function
- A tooth with direct or indirect restoration failure where repair with a direct restoration is expected to have a good long-term prognosis for restoring and maintaining tooth form and function

[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.

For patients who do not meet the published qualifying criteria for direct restorations, Delta Dental will consider documentation from relevant clinicians that explains the necessity of covering a direct restoration for conditions not included in the criteria.

Depending on the clinical circumstances, the performance of a direct restoration 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:

- Teeth where there is a lack of pretreatment documentation in the patient record of active cavitated carious lesions, tooth fracture, restoration failure or other accepted indication for placement of a direct restoration
- Placement of a direct restoration solely to improve the esthetic appearance of a tooth, such as diastema closure, cosmetic restoration of a peg lateral tooth or replacement of an intact and functional amalgam restoration with a resin-based composite material
- Appropriate removal of caries is not performed
- Appropriate removal of an existing restoration is not performed
- A direct restoration placed in a tooth that is broken down by dental caries, extensive restoration and/or fracture with insufficient sound tooth structure for successful restoration
- A direct restoration placed in a tooth that has unresolved periapical pathology, failed endodontic treatment, an improperly aligned post and/or failed root integrity due to root fracture or resorptive defect
- A direct restoration placed in a tooth that has insufficient alveolar bone support, advanced furcation involvement and/or advanced mucogingival defects
- A direct restoration placed in a primary tooth undergoing natural exfoliation
- Inadequately prepared/adapted direct restorations, including restorations with marginal defects and/or inadequate interproximal contacts, axial contours or occlusion
- Allergy to a material in a restoration (e.g., nickel)
- A high caries risk and/or poor oral hygiene that presents a relative contraindication to restorative treatment
- Compromised temporomandibular joint likely to cause complications during or after restorative treatment
- An alternative treatment is more appropriate for a patient's condition or circumstance based on accepted standards of care, such as an incipient noncavitated carious lesion that is likely to respond favorably to a nonrestorative intervention

Depending on an individual patient’s condition and circumstances, the following additional criteria for direct restoration treatment may be applied for coverage determinations:

- A comprehensive evaluation of the condition of the teeth and surrounding tissues including the identification of noncavitated and cavitated carious lesions must be carried out and fully documented prior to planning and performing direct restoration treatment. Any untreated dental caries or fractures, failed restorations, periodontal disease, endodontic pathology or structural weakness in the dentition must be addressed as part of overall treatment. Direct restorations must meet the applicable standards of dental practice for restorative material selection, preparation, marginal integrity, interproximal contacts and occlusion.
- Direct restorations placed on a single tooth surface without extension onto another contiguous tooth surface must be reported using the appropriate single surface procedure code. Direct restorations placed without interruption on two or more contiguous tooth surfaces must be reported using the appropriate multiple surface procedure code. A restoration is generally considered to extend onto a contiguous tooth surface when it extends across the line angle

between two surfaces. Dental benefit programs may establish program-specific criteria that define when a restoration is covered as a multiple surface procedure.

- 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.
- Resin-based composite restorations placed in noncarious pits and fissures that are contained within a tooth's enamel should be reported as a sealant. Restoration of active carious lesions in pits and fissures that do not extend into dentin should be reported with the D1352 preventive resin restoration procedure code. Composite restorations extending into dentin should be reported with the appropriate resin-based composite restoration procedure code.
- The American Academy of Pediatric Dentistry guidance regarding restorative dental care for children may be referenced which states that the use of prefabricated crowns is indicated over amalgam or resin-based restorations for high-risk children with large or multi-surface cavitated or noncavitated lesions on primary molars, particularly when treatment must be performed under sedation or general anesthesia.
- Direct restorations performed solely for one of the following conditions or reasons may not be covered by a member's dental plan: tooth structure loss resulting from attrition, abrasion, abfraction or erosion, periodontal splinting, diagnosis or treatment of temporomandibular joint dysfunction, correction of congenital or developmental malformations, vertical dimension adjustment, stabilization of occlusion or improvement of appearance. To determine if these services are a covered benefit of an individual member’s dental plan, the plan documents in effect on the date of service should be referenced.

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 place a direct restoration 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 a direct restoration 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.

- Preoperative diagnostic quality radiographs should be submitted that provide evidence of cavitated carious lesions or other conditions requiring restorative intervention. Submitted radiographs should allow evaluation of involved teeth from crown to root tip.
- If the submitted radiographs do not clearly support the decision that placement of a direct restoration was medically necessary, documentation such as photographs and narratives that are consistent with the patient record should be submitted which explain the preoperative rationale for treatment planning the procedure.

When determining coverage based on medical necessity or clinical appropriateness, Delta Dental 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.

Delta Dental's clinical criteria are developed and annually updated by a panel of licensed dental general practitioners and specialists serving on Delta Dental'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, Delta Dental 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.

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

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