CORALDNA® LABS

Insurance Coding Guide

*The codes provided are for the ordering healthcare provider's consideration when filing for dental or medical insurance. Please contact the insurance provider directly for any questions.



OralDNA Insurance Coding Guide Contents

Saliva-based diagnostic testing is an evolving area of clinical practice, offering non-invasive alternatives for detecting oral and systemic health biomarkers. Understanding the distinction between tests for diagnostic purposes and wellness-focused saliva tests is important for proper coding. As saliva-based testing continues to evolve, dental professionals should stay informed about appropriate procedural coding to ensure accurate documentation and reporting.

CDT codes enable every dentist to accurately document services delivered in a patient's dental record and reported on a claim. As stated in the CDT manual's preface, the presence of a CDT code does not guarantee that the procedure is covered or reimbursed by a dental benefit plan. Reimbursement for any procedure is determined by the dental benefit plans. Any questions about reimbursement are best addressed by contacting the specific insurance company involved.

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Dental Billing Insurance Codes (CDT®)

The CDT® code examples are based on ADA guidelines and are for informational purposes only. CDT® coding is the sole responsibility of the billing party.

Consider For Use With: MYPERIOPATH®

- **DO414** Laboratory processing of microbial specimen to include culture and sensitivity studies, preparation and transmission of written report
- DO417 Collection and preparation of saliva sample for laboratory diagnostic testing
- DO418 Analysis of saliva sample Chemical or biological analysis of saliva sample for diagnostic purposes
- **D9999** Unspecified adjunctive procedure, by report (for other risk determinations; this can be used as an alternative for non-diagnostic purposes as opposed to DO418)

Consider For Use With: MYPERIOID[®] IL-6

- DO417 Collection and preparation of saliva sample for laboratory diagnostic testing
- DO418 Analysis of saliva sample Chemical or biological analysis of saliva sample for diagnostic purposes
- DO422 Collection and preparation of genetic sample material for laboratory analysis and report
- **DO423** Genetic test for susceptibility to diseases, specimen analysis certified laboratory analysis to detect specific genetic variations associated with increased susceptibility for diseases
- **D9999** Unspecified adjunctive procedure, by report (for other risk determinations; this can be used as an alternative for non-diagnostic purposes as opposed to DO418)

Consider For Use With:

CELSUS ONE[™]

- **DO414** Laboratory processing of microbial specimen to include culture and sensitivity studies, preparation and transmission of written report
- DO417 Collection and preparation of saliva sample for laboratory diagnostic testing
- DO418 Analysis of saliva sample Chemical or biological analysis of saliva sample for diagnostic purposes
- DO422 Collection and preparation of genetic sample material for laboratory analysis and report
- **DO423** Genetic test for susceptibility to diseases, specimen analysis certified laboratory analysis to detect specific genetic variations associated with increased susceptibility for diseases.
- **D9999** Unspecified adjunctive procedure, by report (for other risk determinations; this can be used as an alternative for non-diagnostic purposes as opposed to DO418)



Consider For Use With: ORARISK® HPV

- **DO414** Laboratory processing of microbial specimen to include culture and sensitivity studies, preparation and transmission of written report
- DO417 Collection and preparation of saliva sample for laboratory diagnostic testing
- DO418 Analysis of saliva sample Chemical or biological analysis of saliva sample for diagnostic purposes
- **DO431** Adjunctive pre-diagnostic test that aids in detection of mucosal abnormalities including premalignant and malignant lesions
- **D9999** Unspecified adjunctive procedure, by report (for other risk determinations; this can be used as an alternative for non-diagnostic purposes as opposed to DO418)

Consider For Use With:

ORARISK®CARIES

- **DO414** Laboratory processing of microbial specimen to include culture and sensitivity studies, preparation and transmission of written report
- DO417 Collection and preparation of saliva sample for laboratory diagnostic testing
- DO418 Analysis of saliva sample Chemical or biological analysis of saliva sample for diagnostic purposes
- DO425 Caries Susceptibility tests, diagnostic test for determining a patient's propensity for caries
- DO6O1 Caries risk assessment and documentation, with a finding of low risk
- DO6O2 Caries risk assessment and documentation, with a finding of moderate risk
- **D0603** Caries risk assessment and documentation, with a finding of high risk
- **D9999** Unspecified adjunctive procedure, by report (for other risk determinations; this can be used as an alternative for non-diagnostic purposes as opposed to DO418)

Consider For Use With: ORARISK[®] CANDIDA

- **DO414** Laboratory processing of microbial specimen to include culture and sensitivity studies, preparation and transmission of written report
- DO417 Collection and preparation of saliva sample for laboratory diagnostic testing
- DO418 Analysis of saliva sample Chemical or biological analysis of saliva sample for diagnostic purposes
- **DO431** Adjunctive pre-diagnostic test that aids in detection of mucosal abnormalities including premalignant and malignant lesions
- **D9999** Unspecified adjunctive procedure, by report (for other risk determinations; this can be used as an alternative for non-diagnostic purposes as opposed to DO418)



Consider For Use With: ORARISK[®] HSV

- **DO414** Laboratory processing of microbial specimen to include culture and sensitivity studies, preparation and transmission of written report
- DO417 Collection and preparation of saliva sample for laboratory diagnostic testing
- DO418 Analysis of saliva sample Chemical or biological analysis of saliva sample for diagnostic purposes
- **DO431** Adjunctive pre-diagnostic test that aids in detection of mucosal abnormalities including premalignant and malignant lesions
- **D9999** Unspecified adjunctive procedure, by report (for other risk determinations; this can be used as an alternative for non-diagnostic purposes as opposed to DO418)

Consider For Use With:

ORARISK[®] CT/NG

- **DO414** Laboratory processing of microbial specimen to include culture and sensitivity studies, preparation and transmission of written report
- DO417 Collection and preparation of saliva sample for laboratory diagnostic testing
- DO418 Analysis of saliva sample Chemical or biological analysis of saliva sample for diagnostic purposes
- **DO431** Adjunctive pre-diagnostic test that aids in detection of mucosal abnormalities including premalignant and malignant lesions
- **D9999** Unspecified adjunctive procedure, by report (for other risk determinations; this can be used as an alternative for non-diagnostic purposes as opposed to DO418)



Medical Billing Insurance Codes (CPT®)

The CPT® code examples are based on AMA guidelines and are for informational purposes only. CPT® coding is the sole responsibility of the billing party.

Consider For Use With: MYPERIOPATH[®]

• 87801 Infectious agent detection by nucleic acid; multiple organisms; amplified probe technique

Consider For Use With: MYPERIOID® IL-6

• **81479** Unlisted molecular pathology procedure – Narrative description required to describe performed procedure: e.g.: IL6 gene analysis

Consider For Use With:

CELSUS ONE[™]

• **81479** Unlisted molecular pathology procedure– Narrative description required to describe performed procedure: e.g.: DEFB1 / CD14 / TLR4 / TNF / IL1 / IL6 / IL17A / MMP3 gene analysis

Consider For Use With: ORARISK® HPV

• 87624 Human Papillomavirus (HPV), high-risk types

Consider For Use With: ORARISK®CARIES

• **41899** Unlisted procedure, dentoalveolar structures, must include a detailed description of the actual service provided on the claim form

Consider For Use With:

ORARISK[®] CANDIDA

• 87481 Candida species, amplified probe technique

Consider For Use With: ORARISK® HSV

• 87529 Herpes simplex virus, amplified probe technique (CPT® applied for each germline variant HSV1 or HSV2 and may require the use of a modifier, consult your payors accordingly.)

Consider For Use With:

ORARISK[®] CT/NG

- 87491 Chlamydia trachomatis, amplified probe technique
- 87591 Neisseria gonorrhoeae, amplified probe technique



International Classification of Diseases, Tenth Edition (Medical Diagnosis Codes)

Example ICD1O diagnosis codes that may apply to your patient's condition:

- **A48.8** Other specified bacterial disease
- B10.89 Other human herpes virus infection
- **BOO.2** Herpetic gingivostomatitis
- BO7.9 Viral wart, unspecified
- **B2O** Human immunodeficiency virus [HIV] disease
- B37.0 Candidal stomatitis
- B37.83 Candidal cheilitis
- B37.9 Candidiasis, unspecified
- B99.8 Other infectious disease
- **B99.9** Unspecified infectious disease
- **DO4.9** Carcinoma in situ of skin, unspecified
- **D23.9** Other benign neoplasm of skin, unspecified
- D37.01 Neoplasm of uncertain behavior of lip
- **D37.02** Neoplasm of uncertain behavior of tongue
- **D37.030** Neoplasm of uncertain behavior of the parotid salivary glands
- D37.O31 Neoplasm of uncertain behavior of the sublingual salivary glands
- **D37.032** Neoplasm of uncertain behavior of the submandibular salivary glands
- **D37.039** Neoplasm of uncertain behavior of the major salivary glands, unspecified
- **D37.04** Neoplasm of uncertain behavior of the minor salivary glands
- D37.05 Neoplasm of uncertain behavior of pharynx
- **D37.09** Neoplasm of uncertain behavior of other specified sites of the oral cavity
- D48.5 Neoplasm of uncertain behavior of skin
- **D49.2** Neoplasm of unspecified behavior of bone, soft tissue, and skin
- **D49.89** Neoplasm of unspecified behavior of other specified sites
- KO1.11 Chronic gingivitis, non---plaque induced
- KO2.3 Arrested dental caries
- KO2.9 Dental caries, unspecified
- **KO2.51** Dental caries on pit and fissure surface limited to enamel
- **KO2.52** Dental caries on pit and fissure surface penetrating into dentin
- KO2.53 Dental caries on pit and fissure surface penetrating into pulp

- **KO2.61** Dental caries on smooth surface limited to enamel
- **KO2.62** Dental caries on smooth surface penetrating into dentin
- KO2.63 Dental caries on smooth surface penetrating into pulp
- KO2.7 Dental root caries
- KO5.00 Acute gingivitis, plaque induced
- KO5.01 Acute gingivitis, non---plaque induced
- KO5.10 Chronic gingivitis, plaque induced
- KO5.20 Aggressive periodontitis, unspecified
- KO5.21 Aggressive periodontitis, localized
- KO5.22 Aggressive periodontitis, generalized
- KO5.30 Chronic periodontitis, unspecified
- KO5.31 Chronic periodontitis, localized
- **KO5.32** Chronic periodontitis, generalized
- KO5.5 Other specified periodontal diseases
- KO6.O Gingival recession
- M35.01 Sicca syndrome with Keratoconjunctivits
- R21 Rash and other nonspecific skin eruption
- Z11.2 Encounter for screening for other bacterial diseases
- **Z11.3** Encounter for screening for infections with a predominantly sexual mode of transmission
- **Z11.51** Encounter for screening for human papillomavirus (HPV)
- **Z11.59** Encounter for screening for other specified viral diseases
- **Z11.8** Encounter for screening for other infectious and parasitic diseases
- **Z13.84** Encounter for screening for dental disorders
- **Z2O.2** Contact with and (suspected) exposure to infections with a predominantly sexual mode of transmission
- **Z34.80** Encounter for supervision of other normal pregnancy, unspecified trimester
- **Z34.90** Encounter for supervision of normal pregnancy, unspecified, unspecified trimester
- Z33.1 Pregnant state, incidental
- Z72.51 High risk heterosexual behavior
- Z72.52 High risk homosexual behavior
- Z72.53 High risk bisexual behavior
- Z91.841 Risk for dental caries, low



Coding Tips

INDICATING LAB COSTS (See Medical Claim form) when an outside lab is used for pathology service, the lab fee is inserted in box 20 on the CMS1500 form to indicate this information.

What are modifiers used for? To inform the insurance company of a more in depth look at the meaning of the code. The following are the most commonly used:

59 Distinct Procedural Service

90 Reference (Outside) Laboratory

- Commonly used with the following modifier(s):
 - 91 Repeat Clinical Diagnostic Laboratory Test
 - GW Service unrelated to the hospice patient's terminal condition
 - GZ Not reasonable and necessary

91 Repeat Clinical Diagnostic Laboratory Test

- Commonly used with the following modifier(s):
 - 90 Reference (Outside) Laboratory
 - GZ Not reasonable and necessary
 - Commonly used with the following modifier(s):

90 Reference (Outside) Laboratory

Important notes: CPT® Codes that are unspecified need to have an additional information to describe the service performed, condition or circumstances of patient health or status that allow the code to be payable. The following tips below are helpful in making the proper determinations for claim filing.

- Make sure there is no listed code for the service, or it will be denied
- Be sure to verify...Is the service separately reportable and not a component of a more comprehensive procedure?
- Check the CPT® Category III codes, as well as HCPCS codes, to see if there is a code that could be used.

Also important to note, if you perform an unlisted procedure in an ASC, Medicare will not pay a facility fee for the procedure. Unlisted codes are strictly off the ASC list of payable codes.



Reimbursement Tips

Always check your payer's policy for any special documentation or billing instructions. The Payer should tell you what is required for reimbursement.

- Private payers often require pre-authorization for any unlisted procedure.
- Some payers have specific documentation criteria, depending on the type of unlisted procedure provided (e.g., an op note to support an unlisted surgery, an imaging report for a procedure or the NDC number for an unlisted drug code).
- Many payers will ask you to submit a code with comparable work relative value units (RVUs) they can use to price the code.
- Many payers tell you DO NOT attach a modifier to the code or to report only one unit of an unlisted code regardless of the number of services it involves
- Other information that may be required (Be sure your documentation supports any/all information you submit to the payer.
- A clear description, Nature, extent and need for the service being performed.
- Time, Effort, Equipment used to provide the treatment.
- Time spent, Number of times the service was provided

"When reporting an unlisted code to describe a procedure or service, it may be necessary to submit supporting documentation (e.g., procedure report) along with the claim to provide an adequate description of the nature, extent, need for the procedure, and the time, effort, and equipment necessary to provide the service." (Nov. 2008 CPT® Assistant)

ADA American Dental Association[®] Dental Claim Form

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ADA American Dental Association®

America's leading advocate for oral health

The following information highlights certain form completion instructions. Comprehensive ADA Dental Claim Form completion instructions are posted on the ADA's web site (https://www.ADA.org/en/publications/cdt/ada-dental-claim-form).

GENERAL INSTRUCTIONS

- A. The form is designed so that the name and address (Item 3) of the third-party payer receiving the claim (insurance company/dental benefit plan) is visible in a standard #9 window envelope (window to the left). Please fold the form using the 'tick-marks' printed in the margin.
- B. Complete all items unless noted otherwise on the form or in the instructions posted on the ADA's web site (ADA.org).
- C. Enter the full name of an individual or a full business name, address and zip code when a name and address field is required.
- D. All dates must include the four-digit year.
- E. If the number of procedures reported exceeds the number of lines available on one claim form, list the remaining procedures on a separate, fully completed claim form.
- F. GENDER Codes (Items 7, 14 and 22) M = Male; F = Female; U = Unknown

COORDINATION OF BENEFITS (COB)

When a claim is being submitted to the secondary payer, complete the entire form and attach the primary payer's Explanation of Benefits (EOB) showing the amount paid by the primary payer. You may also note the primary carrier paid amount in the "Remarks" field (Item 35).

DIAGNOSIS CODING

The form supports reporting up to four diagnosis codes per dental procedure. This information is required when the diagnosis may affect claim adjudication when specific dental procedures may minimize the risks associated with the connection between the patient's oral and systemic health conditions. Diagnosis codes are linked to procedures using the following fields:

Item 29a – Diagnosis Code Pointer ("A" through "D" as applicable from Item 34a)

Item 34 – Diagnosis Code List Qualifier (AB for ICD-10-CM)

Item 34a - Diagnosis Code(s) / A, B, C, D (up to four, with the primary adjacent to the letter "A")

PLACE OF TREATMENT

Enter the 2-digit Place of Service Code for Professional Claims, a HIPAA standard maintained by the Centers for Medicare and Medicaid Services. Frequently used codes are:

11 = Office; 12 = Home; 21 = Inpatient Hospital; 22 = Outpatient Hospital; 31 = Skilled Nursing Facility; 32 = Nursing Facility

The full list is available online at:

https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/Downloads/Website-POS-database.pdf

PROVIDER SPECIALTY

This code is entered in Item 56a and indicates the type of dental professional who delivered the treatment. The general code listed as "Dentist" may be used instead of any of the other codes.

Category / Description Code	Code
Dentist A dentist is a person qualified by a doctorate in dental surgery (D.D.S.) or dental medicine (D.M.D.) licensed by the state to practice dentistry, and practicing within the scope of that license.	122300000X
General Practice	1223G0001X
Dental Specialty (see following list)	Various
Dental Public Health	1223D0001X
Endodontics	1223E0200X
Orthodontics	1223X0400X
Pediatric Dentistry	1223P0221X
Periodontics	1223P0300X
Prosthodontics	1223P0700X
Oral & Maxillofacial Pathology	1223P0106X
Oral & Maxillofacial Radiology	1223X0008X
Oral & Maxillofacial Surgery	1223S0112X

Provider taxonomy codes listed above are a subset of the full code set that is posted at:

https://www.nucc.org/index.php/code-sets-mainmenu-41/provider-taxonomy-mainmenu-40



HEALTH INSURANCE CLAIM FORM

APPROVED BY NATIONAL UNIFORM CLAIM COMMITTEE (NUCC) 02/12

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NUCC Instruction Manual available at: www.nucc.org

APPROVED OMB-0938-1197 FORM 1500 (02-12

-CARRIER

PLEASE PRINT OR TYPE

BECAUSE THIS FORM IS USED BY VARIOUS GOVERNMENT AND PRIVATE HEALTH PROGRAMS, SEE SEPARATE INSTRUCTIONS ISSUED BY APPLICABLE PROGRAMS.

NOTICE: Any person who knowingly files a statement of claim containing any misrepresentation or any false, incomplete or misleading information may be guilty of a criminal act punishable under law and may be subject to civil penalties.

REFERS TO GOVERNMENT PROGRAMS ONLY

MEDICARE AND CHAMPUS PAYMENTS: A patient's signature requests that payment be made and authorizes release of any information necessary to process the claim and certifies that the information provided in Blocks 1 through 12 is true, accurate and complete. In the case of a Medicare claim, the patient's signature authorizes any entity to release to Medicare medical and nonmedical information, including employment status, and whether the person has employer group health insurance, liability, no-fault, worker's compensation or other insurance which is responsible to pay for the services for which the Medicare claim is made. See 42 CFR 411.24(a). If item 9 is completed, the patient's signature authorizes release of the information to the health plan or agency shown. In Medicare assigned or CHAMPUS participation cases, the physician agrees to accept the charge determination of the Medicare carrier or CHAMPUS fiscal intermediary as the full charge, and the patient is responsible only for the deductible, coinsurance and noncovered services. Coinsurance and the deductible are based upon the charge determination of the Medicare carrier or CHAMPUS fiscal intermediary if this is less than the charge submitted. CHAMPUS is not a health insurance program but makes payment for health benefits provided through certain affiliations with the Uniformed Services. Information on the patient's sponsor should be provided in those items captioned in "Insured"; i.e., items 1a, 4, 6, 7, 9, and 11.

BLACK LUNG AND FECA CLAIMS

The provider agrees to accept the amount paid by the Government as payment in full. See Black Lung and FECA instructions regarding required procedure and diagnosis coding systems.

SIGNATURE OF PHYSICIAN OR SUPPLIER (MEDICARE, CHAMPUS, FECA AND BLACK LUNG)

I certify that the services shown on this form were medically indicated and necessary for the health of the patient and were personally furnished by me or were furnished incident to my professional service by my employee under my immediate personal supervision, except as otherwise expressly permitted by Medicare or CHAMPUS regulations.

For services to be considered as "incident" to a physician's professional service, 1) they must be rendered under the physician's immediate personal supervision by his/her employee, 2) they must be an integral, although incidental part of a covered physician's service, 3) they must be of kinds commonly furnished in physician's offices, and 4) the services of nonphysicians must be included on the physician's bills.

For CHAMPUS claims, I further certify that I (or any employee) who rendered services am not an active duty member of the Uniformed Services or a civilian employee of the United States Government, either civilian or military (refer to 5 USC 5536). For Black-Lung claims, I further certify that the services performed were for a Black Lung-related disorder.

No Part B Medicare benefits may be paid unless this form is received as required by existing law and regulations (42 CFR 424.32).

NOTICE: Any one who misrepresents or falsifies essential information to receive payment from Federal funds requested by this form may upon conviction be subject to fine and imprisonment under applicable Federal laws.

NOTICE TO PATIENT ABOUT THE COLLECTION AND USE OF MEDICARE, CHAMPUS, FECA, AND BLACK LUNG INFORMATION (PRIVACY ACT STATEMENT)

We are authorized by CMS, CHAMPUS and OWCP to ask you for information needed in the administration of the Medicare, CHAMPUS, FECA, and Black Lung programs. Authority to collect information is in section 205(a), 1862, 1872 and 1874 of the Social Security Act as amended, 42 CFR 411.24(a) and 424.5(a) (6), and 44 USC 3101;41 CFR 101 et seq and 10 USC 1079 and 1086; 5 USC 8101 et seq; and 30 USC 901 et seq; 38 USC 613; E.O. 9397.

The information we obtain to complete claims under these programs is used to identify you and to determine your eligibility. It is also used to decide if the services and supplies you received are covered by these programs and to insure that proper payment is made.

The information may also be given to other providers of services, carriers, intermediaries, medical review boards, health plans, and other organizations or Federal agencies, for the effective administration of Federal provisions that require other third parties payers to pay primary to Federal program, and as otherwise necessary to administer these programs. For example, it may be necessary to disclose information about the benefits you have used to a hospital or doctor. Additional disclosures are made through routine uses for information contained in systems of records.

FOR MEDICARE CLAIMS: See the notice modifying system No. 09-70-0501, titled, 'Carrier Medicare Claims Record,' published in the Federal Register, Vol. 55 No. 177, page 37549, Wed. Sept. 12, 1990, or as updated and republished.

FOR OWCP CLAIMS: Department of Labor, Privacy Act of 1974, "Republication of Notice of Systems of Records," Federal Register Vol. 55 No. 40, Wed Feb. 28, 1990, See ESA-5, ESA-6, ESA-12, ESA-13, ESA-30, or as updated and republished.

FOR CHAMPUS CLAIMS: <u>PRINCIPLE PURPOSE(S)</u>: To evaluate eligibility for medical care provided by civilian sources and to issue payment upon establishment of eligibility and determination that the services/supplies received are authorized by law.

<u>ROUTINE USE(S)</u>: Information from claims and related documents may be given to the Dept. of Veterans Affairs, the Dept. of Health and Human Services and/or the Dept. of Transportation consistent with their statutory administrative responsibilities under CHAMPUS/CHAMPVA; to the Dept. of Justice for representation of the Secretary of Defense in civil actions; to the Internal Revenue Service, private collection agencies, and consumer reporting agencies in connection with recoupment claims; and to Congressional Offices in response to inquiries made at the request of the person to whom a record pertains. Appropriate disclosures may be made to other federal, state, local, foreign government agencies, private business entities, and individual providers of care, on matters relating to entitlement, claims adjudication, fraud, program abuse, utilization review, quality assurance, peer review, program integrity, third-party liability, coordination of benefits, and civil and criminal litigation related to the operation of CHAMPUS.

<u>DISCLOSURES:</u> Voluntary; however, failure to provide information will result in delay in payment or may result in denial of claim. With the one exception discussed below, there are no penalties under these programs for refusing to supply information. However, failure to furnish information regarding the medical services rendered or the amount charged would prevent payment of claims under these programs. Failure to furnish any other information, such as name or claim number, would delay payment of the claim. Failure to provide medical information under FECA could be deemed an obstruction.

It is mandatory that you tell us if you know that another party is responsible for paying for your treatment. Section 1128B of the Social Security Act and 31 USC 3801-3812 provide penalties for withholding this information.

You should be aware that P.L. 100-503, the "Computer Matching and Privacy Protection Act of 1988", permits the government to verify information by way of computer matches. **MEDICAID PAYMENTS (PROVIDER CERTIFICATION)**

I hereby agree to keep such records as are necessary to disclose fully the extent of services provided to individuals under the State's Title XIX plan and to furnish information regarding any payments claimed for providing such services as the State Agency or Dept. of Health and Human Services may request.

I further agree to accept, as payment in full, the amount paid by the Medicaid program for those claims submitted for payment under that program, with the exception of authorized deductible, coinsurance, co-payment or similar cost-sharing charge.

SIGNATURE OF PHYSICIAN (OR SUPPLIER): I certify that the services listed above were medically indicated and necessary to the health of this patient and were personally furnished by me or my employee under my personal direction.

NOTICE: This is to certify that the foregoing information is true, accurate and complete. I understand that payment and satisfaction of this claim will be from Federal and State funds, and that any false claims, statements, or documents, or concealment of a material fact, may be prosecuted under applicable Federal or State laws.

According to the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0938-0999. The time required to complete this information collection is estimated to average 10 minutes per response, including the time to review instructions, search existing data resources, gather the data needed, and complete and review the information collection. If you have any comments concerning the accuracy of the time estimate(s) or suggestions for improving this form, please write to: CMS, Attn: PRA Reports Clearance Officer, 7500 Security Boulevard, Baltimore, Maryland 21244-1850. T his address is for comments and/or suggestions only. DO NOT MAIL COMPLETED CLAIM FORMS TO THIS ADDRESS.



Sample Letter of Medical Necessity

<Dentist> DMD,DDS <Institution> <Address 1> <City>, <State> <ZIP>

<Date>

<Medical Director/Physician Name>, M D <Insurance Company Name> <Address 1> <City>, <ST> <ZIP>

Re: <Patient Full Name> DOB: <MM/DD/YYYY> Member ID: <Enter Member ID> Group ID: <Enter Group ID>

Dear Medical Director:

I am writing this letter on behalf of my patient <Patient Name> to request coverage for the <Test Name>. This letter documents the medical necessity for this test to confirm the diagnosis of <Disease Name> (NOTE: Use one of the oral diagnosis codes and description -- see pg.4) and provides information about the patient's medical history and treatment.

e.g.: Gingivitis: (NOTE: use 523.3, 523.8, 528.9, 210.1, 352.1, 522.8, 523.3, 528.6 -- see pgs.6/7)--Approximately 50 percent of the population has the gum disease gingivitis. The oral systemic connection is an important tool in inflammation affecting many body systems, as the bacteria from the mouth have also been found systemically. The inflammation may be reduced significantly by treatment of the infection.

<Insert narrative supporting remarks here> See choices at the end of letter template I am requesting that <Patient Name> be approved for <Test Name> testing through OralDNA Labs, Federal Tax ID #:41-2007276 and NPI #: 1265458921 with the following CPT® code(s): <CPT® Codes>.

I am specifying OralDNA Labs to perform <Test Name> analysis because (Reason for using OralDNA Labs) for this testing.

I hope you will support this letter of medical necessity for <Patient Name>. Please feel free to contact me at <Physician Phone> if you have additional questions.

Sincerely,

<Physician Name>, DDS or MD NPI #: <Physician NPI#>



Narrative Support for Consideration

Periodontal Bacteria

Certain periodontal bacteria may be locally invasive, cause tissue destruction, invade host cells and enter the blood stream. Possible introduction into the bloodstream may complicate certain systemic situations such as cardiovascular disease, diabetes, preterm and low birth weight babies and other systems.

Inflammatory Disease

Research has connected C-reactive protein and other cytokines and chemokines to periodontal disease. The literature shows that gum disease is a significant cause of elevations in CRP levels.

Diabetes Mellitus (DM)

Current evidence suggests that diabetes mellitus DM is associated with an increased prevalence and severity of gingivitis and periodontitis. Periodontitis may increase the risk for worsening glycemic control in diabetic patients, as well as increasing the risk for diabetic complications. The resulting increase levels of inflammation can result in impairments in the body's ability to manage blood sugar levels. Reference: Diabetes Mellitus and Periodontal Diseases: Mealey, Oates; J. Peridontology 2006.

Preterm Births

Hormonal changes and pregnancy gingivitis requires aggressive treatment as research has shown that periodontal disease may be significantly related to preterm low birth weight. Reference: Periodontal Therapy May Reduce the Incidence of Preterm Birth and Low Birth Weight Infants: Journal of Periodontology, 2007, Vol. 78 No. 5.

Cardiovascular Disease

Studies find a direct association between cardiovascular disease and periodontal bacteria. Even small amounts of an inflammatory stimulus can provoke a substantial amount of C-reactive protein (CRP) production which then circulates throughout the body in the bloodstream. Periodontal disease is a primary cause of inflammation in the body and may be predictive of heart disease. References: Moise Devarieus, MD, PhD, Columbia University; NIH News; April 6, 2006; Conclusion: "...older adults who have higher proportions of four periodontal disease---causing bacteria (A.a., P.g., T.f., T.d.) inhabiting their mouths also tend to have thicker carotid arteries, a strong predictor of stroke and heart attack"

Patient History and Diagnosis:

<Patient Name> is a <Age> year old <Gender> with a suspected diagnosis of <Disease Name> due to the following symptoms and clinical findings:

- <Symptom #1 with ICD-9 code>
- <Symptom #2 with ICD-9 code>

NOTE: Use one of the periodontal codes and back up with a medical code that describes patient's health history: e.g.: Heart, Diabetic, Organ Issues or any other issues.

Family History

<Family History> these symptoms, as well as the examination are indicative of <Disease Name>. The only way to confirm a diagnosis of <Disease Name> is to perform this test.

Test Methodology Benefits

Molecular testing plays an important role in making a definitive diagnosis in cases of suspected <Disease Name> to treat the patient appropriately. An accurate diagnosis provides the following benefits to the patient:

- <Benefit 1> e.g.: List what the outcome of treatment would be with OralDNA <Test> as a tool that helps with diagnostics and treatment choices.
- <Benefit 2> e.g.: Patient has a medical issue (for example-diabetes, heart disease, auto immune disease) may
 pose additional risk from the infection thru the oral cavity. The lab test allows for knowing type of infection
 present and customizing the treatment to better suit the patient's condition.



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***Coding and billing decisions are personal choices to be made by individual health practitioners exercising their own professional medical judgment in each situation.