

LCD L32567 - Molecular Diagnostics: Genitourinary Infectious Disease Testing and Other Applications for Amplified Probe

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Contractor Information

Contractor Name:	Contractor Number(s):	Contractor Type:
Novitas Solutions, Inc.	12101, 12102, 12201, 12202, 12301, 12302, 12401, 12402, 12901, 12502	MAC Part A & B

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LCD Information

Document Information

LCD ID Number	Primary Geographic Jurisdiction
L32567	Pennsylvania, Maryland, District of Columbia, New Jersey, Delaware
LCD Title	Oversight Region
Molecular Diagnostics: Genitourinary Infectious Disease Testing and Other Applications for Amplified Probe Testing	Central Office
Contractor's Determination Number	Original Determination Effective Date
L32567	For services performed on or after 11/15/2012
AMA CPT/ADA CDT Copyright Statement	Original Determination Ending Date
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	Revision Effective Date
	For services performed on or after N/A
	Revision Ending Date
	N/A

CMS National Coverage Policy

Title XVIII of the Social Security Act, Section 1862(a)(1)(A) states that no Medicare payment shall be made for items or services which are not reasonable and necessary for the diagnosis or treatment of illness or injury.

Title XVIII of the Social Security Act, Section 1862(a)(7). This section excludes routine physical examinations.

Title XVIII of the Social Security Act, Section 1833(e) states that no payment shall be made to any provider for any claim that lacks the necessary information to process the claim.

Title XVIII of the Social Security Act, Section 1862(a)(1)(D) states that no Medicare payment may be made for any expenses incurred for items or services that are investigational or experimental.

42 Code of Federal Regulations (CFR) section 410.32 indicates diagnostic tests are payable only when ordered by the physician who is treating the beneficiary for a specific medical problem and who uses the results in such treatment.

CMS Internet-Only Manual (IOM), Publication 100-02, Medicare Benefit Policy Manual, Chapter 15, Section 80.1, 80.1.1, 80.1.2, 80.1.3, laboratory services must meet applicable requirements of CLIA.

CMS IOM, Publication 100-08, Medicare Program Integrity Manual, Chapter 3, Section 3.4.1.3, Diagnosis Code Requirement.

CMS IOM, Publication 100-08, Medicare Program Integrity Manual, Chapter 3, Section 3.6.2.3, Limitation of Liability Determinations.

Indications and Limitations of Coverage and/or Medical Necessity

Compliance with the provisions in this policy may be monitored and addressed through post payment data analysis and subsequent medical review audits.

Molecular diagnostic testing, which includes DNA- or RNA-based analysis, with or without amplification/quantification, provides sensitive, specific and timely (i.e., relative to that of traditional culture-based methods) identification of diverse biological entities, including microorganisms and tumors. The current LCD will focus upon such techniques for the former category, in which three basic nucleic acid assay platforms are utilized.

Assay Format #1: A standardized nucleic acid probe reacts directly with nucleic acids in the test sample. This format is termed a Nucleic Acid Test (NAT). If the test sample contains the organism of interest, then the reaction (e.g., hybridization) of these elements will create a detectable endpoint.

Assay Format #2: Test sample nucleic acid is detected following amplification. This format is termed a Nucleic Acid Amplification Test (NAAT). The NAAT format increases diagnostic sensitivity by decreasing the lower limit of detection. Several techniques are available to perform such amplification, but one example is the polymerase chain reaction in which logarithmic copies of baseline nucleic acid material can be replicated via cyclical reactions involving "primer" nucleic acid,

enzymes and requisite heating/cooling parameters.

Assay Format #3: Finally, there may be a need for the above process to quantify, rather than simply detect the presence of, certain microorganisms. Examples include Human Immunodeficiency Virus (HIV), hepatitis C and Cytomegalovirus (CMV) treatment, which can require such quantitative monitoring to determine if therapy is producing the intended reductions in circulating levels of virus.

Furthermore, other techniques (i.e., nucleic acid sequencing) are utilized to assay anti-viral resistance signatures for HIV-1 and hepatitis C. Either genotypic or phenotypic analysis can allow therapy to be directed in response to such observed resistance markers.

There are many different organisms whose clinical presentations can be grouped into several categories or clusters. The limited coverage table below denotes infectious disease manifestations in the area of genitourinary ("GU") testing for those organisms where specific CPT codes exist versus organisms which would require non-specific coding. **However, this current LCD will focus upon more atypical, less frequent pathogens, whose application in the area of GU, using Assay Format #2 above (that is, the amplified probe technique), has NOT been well-established.**

These organisms, which generally pertain to the non-GU setting are as follows: Ehrlichia species, Herpes virus-7, West Nile virus, Leishmania species, Parvovirus B19, Babesia species, Bordetella pertussis, parainfluenza virus 1/2/3, SARS-related coronavirus, H1N1 virus, Toxoplasma gondii, Epstein-Barr virus, Varicella-zoster virus, Polyomavirus [JC/BK], and HTLV-1. Furthermore, the practice of large multiplex panels do not serve beneficiaries nearly as well as targeting amplification methods for no more than two organisms at a time, which reflect the most pertinent clinical presentations of such beneficiaries. Finally, amplification testing for Candida infections should be reserved for either serious, recurrent infections or those infections which have been refractory to therapy.

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Coding Information

Bill Type Codes

Contractors may specify Bill Types to help providers identify those Bill Types typically used to report this service. Absence of a Bill Type does not guarantee that the policy does not apply to that Bill Type. Complete absence of all Bill Types indicates that coverage is not influenced by Bill Type and the policy should be assumed to apply equally to all claims.

012x	Hospital Inpatient (Medicare Part B only)
013x	Hospital Outpatient
014x	Hospital - Laboratory Services Provided to Non-patients

018x	Hospital - Swing Beds
021x	Skilled Nursing - Inpatient (Including Medicare Part A)
022x	Skilled Nursing - Inpatient (Medicare Part B only)
023x	Skilled Nursing - Outpatient
071x	Clinic - Rural Health
072x	Clinic - Hospital Based or Independent Renal Dialysis Center
073x	Clinic - Freestanding
075x	Clinic - Comprehensive Outpatient Rehabilitation Facility (CORF)
077x	Clinic - Federally Qualified Health Center (FQHC)
083x	Ambulatory Surgery Center
085x	Critical Access Hospital

Revenue Codes

Contractors may specify Revenue Codes to help providers identify those Revenue Codes typically used to report this service. In most instances Revenue Codes are purely advisory; unless specified in the policy services reported under other Revenue Codes are equally subject to this coverage determination. Complete absence of all Revenue Codes indicates that coverage is not influenced by Revenue Code and the policy should be assumed to apply equally to all Revenue Codes.

030X	Laboratory - General Classification
031X	Laboratory Pathology - General Classification

CPT/HCPCS Codes

Italicized and/or quoted material is excerpted from the American Medical Association, *Current Procedural Terminology (CPT)* codes.

87480	INFECTIOUS AGENT DETECTION BY NUCLEIC ACID (DNA OR RNA); CANDIDA SPECIES, DIRECT PROBE TECHNIQUE
87490	INFECTIOUS AGENT DETECTION BY NUCLEIC ACID (DNA OR RNA); CHLAMYDIA TRACHOMATIS, DIRECT PROBE TECHNIQUE
87491	INFECTIOUS AGENT DETECTION BY NUCLEIC ACID (DNA OR RNA); CHLAMYDIA TRACHOMATIS, AMPLIFIED PROBE

	TECHNIQUE
87510	INFECTIOUS AGENT DETECTION BY NUCLEIC ACID (DNA OR RNA); GARDNERELLA VAGINALIS, DIRECT PROBE TECHNIQUE
87590	INFECTIOUS AGENT DETECTION BY NUCLEIC ACID (DNA OR RNA); NEISSERIA GONORRHOEAE, DIRECT PROBE TECHNIQUE
87591	INFECTIOUS AGENT DETECTION BY NUCLEIC ACID (DNA OR RNA); NEISSERIA GONORRHOEAE, AMPLIFIED PROBE TECHNIQUE
87660	INFECTIOUS AGENT DETECTION BY NUCLEIC ACID (DNA OR RNA); TRICHOMONAS VAGINALIS, DIRECT PROBE TECHNIQUE
87798	INFECTIOUS AGENT DETECTION BY NUCLEIC ACID (DNA OR RNA), NOT OTHERWISE SPECIFIED; AMPLIFIED PROBE TECHNIQUE, EACH ORGANISM

ICD-9 Codes that Support Medical Necessity

It is the provider's responsibility to select codes carried out to the highest level of specificity and selected from the ICD-9-CM code book appropriate to the year in which the service is rendered for the claim(s) submitted.

Medicare is establishing the following limited coverage for Chlamydia trachomatis (87490,87491), Neisseria gonorrhoeae (87590,87591), Candida species (87480), Gardnerella vaginalis (87510) and Trichomonas vaginalis (87660):

076.0 - 076.1	TRACHOMA INITIAL STAGE - TRACHOMA ACTIVE STAGE
076.9	TRACHOMA UNSPECIFIED
077.0	INCLUSION CONJUNCTIVITIS
077.98 - 077.99	UNSPECIFIED DISEASES OF CONJUNCTIVA DUE TO CHLAMYDIAE - UNSPECIFIED DISEASES OF CONJUNCTIVA DUE TO VIRUSES
098.0	GONOCOCCAL INFECTION (ACUTE) OF LOWER GENITOURINARY TRACT
098.10 - 098.17	GONOCOCCAL INFECTION (ACUTE) OF UPPER GENITOURINARY TRACT SITE UNSPECIFIED - GONOCOCCAL SALPINGITIS SPECIFIED AS ACUTE
098.19	OTHER GONOCOCCAL INFECTION (ACUTE) OF UPPER GENITOURINARY TRACT
098.2	GONOCOCCAL INFECTION CHRONIC OF LOWER

	GENITOURINARY TRACT
098.30 - 098.37	CHRONIC GONOCOCCAL INFECTION OF UPPER GENITOURINARY TRACT SITE UNSPECIFIED - GONOCOCCAL SALPINGITIS (CHRONIC)
098.39	OTHER CHRONIC GONOCOCCAL INFECTION OF UPPER GENITOURINARY TRACT
098.40 - 098.43	GONOCOCCAL CONJUNCTIVITIS (NEONATORUM) - GONOCOCCAL KERATITIS
098.49	OTHER GONOCOCCAL INFECTION OF EYE
098.50 - 098.53	GONOCOCCAL ARTHRITIS - GONOCOCCAL SPONDYLITIS
098.59	OTHER GONOCOCCAL INFECTION OF JOINT
098.6 - 098.7	GONOCOCCAL INFECTION OF PHARYNX - GONOCOCCAL INFECTION OF ANUS AND RECTUM
098.81 - 098.86	GONOCOCCAL KERATOSIS (BLENNORRHAGICA) - GONOCOCCAL PERITONITIS
098.89	GONOCOCCAL INFECTION OF OTHER SPECIFIED SITES
099.1	LYMPHOGRANULOMA VENEREUM
099.3	REITER'S DISEASE
099.41	OTHER NONGONOCOCCAL URETHRITIS CHLAMYDIA TRACHOMATIS
099.50 - 099.56	OTHER VENEREAL DISEASES DUE TO CHLAMYDIA TRACHOMATIS UNSPECIFIED SITE - OTHER VENEREAL DISEASES DUE TO CHLAMYDIA TRACHOMATIS PERITONEUM
099.59	OTHER VENEREAL DISEASES DUE TO CHLAMYDIA TRACHOMATIS OTHER SPECIFIED SITE
112.1 - 112.2	CANDIDIASIS OF VULVA AND VAGINA - CANDIDIASIS OF OTHER UROGENITAL SITES
131.00 - 131.03	UROGENITAL TRICHOMONIASIS UNSPECIFIED - TRICHOMONAL PROSTATITIS
131.09	OTHER UROGENITAL TRICHOMONIASIS
131.8 - 131.9	TRICHOMONIASIS OF OTHER SPECIFIED SITES - TRICHOMONIASIS UNSPECIFIED
288.00 - 288.04	NEUTROPENIA, UNSPECIFIED - NEUTROPENIA DUE TO

	INFECTION
288.09	OTHER NEUTROPENIA
288.66	BANDEMIA
288.8	OTHER SPECIFIED DISEASE OF WHITE BLOOD CELLS
289.1	CHRONIC LYMPHADENITIS
289.53	NEUTROPENIC SPLENOMEGALY
289.83	MYELOFIBROSIS
372.00	ACUTE CONJUNCTIVITIS UNSPECIFIED
372.02 - 372.03	ACUTE FOLLICULAR CONJUNCTIVITIS - OTHER MUCOPURULENT CONJUNCTIVITIS
372.10 - 372.12	CHRONIC CONJUNCTIVITIS UNSPECIFIED - CHRONIC FOLLICULAR CONJUNCTIVITIS
595.4	CYSTITIS IN DISEASES CLASSIFIED ELSEWHERE
597.80 - 597.81	URETHRITIS UNSPECIFIED - URETHRAL SYNDROME NOS
601.0	ACUTE PROSTATITIS
601.8 - 601.9	OTHER SPECIFIED INFLAMMATORY DISEASES OF PROSTATE - PROSTATITIS UNSPECIFIED
604.0	ORCHITIS EPIDIDYMITIS AND EPIDIDYMO-ORCHITIS WITH ABSCESS
604.90 - 604.91	ORCHITIS AND EPIDIDYMITIS UNSPECIFIED - ORCHITIS AND EPIDIDYMITIS IN DISEASES CLASSIFIED ELSEWHERE
608.89	OTHER SPECIFIED DISORDERS OF MALE GENITAL ORGANS
614.0	ACUTE SALPINGITIS AND OOPHORITIS
614.2 - 614.4	SALPINGITIS AND OOPHORITIS NOT SPECIFIED AS ACUTE SUBACUTE OR CHRONIC - CHRONIC OR UNSPECIFIED PARAMETRITIS AND PELVIC CELLULITIS
614.6	PELVIC PERITONEAL ADHESIONS FEMALE (POSTOPERATIVE) (POSTINFECTION)
614.8 - 614.9	OTHER SPECIFIED INFLAMMATORY DISEASE OF FEMALE PELVIC ORGANS AND TISSUES - UNSPECIFIED INFLAMMATORY DISEASE OF FEMALE PELVIC ORGANS AND TISSUES

616.0	CERVICITIS AND ENDOCERVICITIS
616.81	MUCOSITIS (ULCERATIVE) OF CERVIX, VAGINA, AND VULVA
616.89	OTHER INFLAMMATORY DISEASE OF CERVIX, VAGINA AND VULVA
616.9	UNSPECIFIED INFLAMMATORY DISEASE OF CERVIX VAGINA AND VULVA
628.2	INFERTILITY FEMALE OF TUBAL ORIGIN
629.89	OTHER SPECIFIED DISORDERS OF FEMALE GENITAL ORGANS
683	ACUTE LYMPHADENITIS
711.90 - 711.99	UNSPECIFIED INFECTIVE ARTHRITIS SITE UNSPECIFIED - UNSPECIFIED INFECTIVE ARTHRITIS INVOLVING MULTIPLE SITES
716.50 - 716.59	UNSPECIFIED POLYARTHROPATHY OR POLYARTHROSITIS SITE UNSPECIFIED - UNSPECIFIED POLYARTHROPATHY OR POLYARTHROSITIS INVOLVING MULTIPLE SITES
716.60 - 716.68	UNSPECIFIED MONOARTHROSITIS SITE UNSPECIFIED - UNSPECIFIED MONOARTHROSITIS INVOLVING OTHER SPECIFIED SITES
716.90 - 716.99	UNSPECIFIED ARTHROPATHY SITE UNSPECIFIED - UNSPECIFIED ARTHROPATHY INVOLVING MULTIPLE SITES
719.40 - 719.49	PAIN IN JOINT SITE UNSPECIFIED - PAIN IN JOINT INVOLVING MULTIPLE SITES
727.00	SYNOVITIS AND TENOSYNOVITIS UNSPECIFIED
727.05 - 727.06	OTHER TENOSYNOVITIS OF HAND AND WRIST - TENOSYNOVITIS OF FOOT AND ANKLE
727.09	OTHER SYNOVITIS AND TENOSYNOVITIS
771.6	NEONATAL CONJUNCTIVITIS AND DACRYOCYSTITIS
780.60 - 780.61	FEVER, UNSPECIFIED - FEVER PRESENTING WITH CONDITIONS CLASSIFIED ELSEWHERE
782.1	RASH AND OTHER NONSPECIFIC SKIN ERUPTION
785.6	ENLARGEMENT OF LYMPH NODES
788.1	DYSURIA

788.64 - 788.65	URINARY HESITANCY - STRAINING ON URINATION
788.7	URETHRAL DISCHARGE
789.00 - 789.07	ABDOMINAL PAIN UNSPECIFIED SITE - ABDOMINAL PAIN GENERALIZED
789.09	ABDOMINAL PAIN OTHER SPECIFIED SITE
789.1 - 789.2	HEPATOMEGALY - SPLENOMEGALY
789.30 - 789.37	ABDOMINAL OR PELVIC SWELLING MASS OR LUMP UNSPECIFIED SITE - ABDOMINAL OR PELVIC SWELLING MASS OR LUMP GENERALIZED
789.39	ABDOMINAL OR PELVIC SWELLING MASS OR LUMP OTHER SPECIFIED SITE
789.40 - 789.47	ABDOMINAL RIGIDITY UNSPECIFIED SITE - ABDOMINAL RIGIDITY GENERALIZED
789.49	ABDOMINAL RIGIDITY OTHER SPECIFIED SITE
789.51	MALIGNANT ASCITES
789.59	OTHER ASCITES
789.60 - 789.67	ABDOMINAL TENDERNESS UNSPECIFIED SITE - ABDOMINAL TENDERNESS GENERALIZED
789.69	ABDOMINAL TENDERNESS OTHER SPECIFIED SITE
789.9	OTHER SYMPTOMS INVOLVING ABDOMEN AND PELVIS
790.4 - 790.5	NONSPECIFIC ELEVATION OF LEVELS OF TRANSAMINASE OR LACTIC ACID DEHYDROGENASE (LDH) - OTHER NONSPECIFIC ABNORMAL SERUM ENZYME LEVELS
790.7	BACTEREMIA
791.0 - 791.7	PROTEINURIA - OTHER CELLS AND CASTS IN URINE
791.9	OTHER NONSPECIFIC FINDINGS ON EXAMINATION OF URINE

Medicare is establishing the following limited coverage for human papillomavirus (87621):

622.10 - 622.12	DYSPLASIA OF CERVIX, UNSPECIFIED - MODERATE DYSPLASIA OF CERVIX
795.00 - 795.01	ABNORMAL GLANDULAR PAPANICOLAOU SMEAR OF CERVIX - PAPANICOLAOU SMEAR OF CERVIX WITH ATYPICAL

	SQUAMOUS CELLS OF UNDETERMINED SIGNIFICANCE (ASC-US)
795.03	PAPANICOLAOU SMEAR OF CERVIX WITH LOW GRADE SQUAMOUS INTRAEPITHELIAL LESION (LGSIL)

Medicare is establishing the following limited coverage for 87798 (Detect agent nos dna amp):
NOTE: Both H1N1 and Polyomavirus [JC/BK] viruses are still pending the most precise ICD-9 coding, and for any such organisms not amenable to final specific ICD-9 coding, please report the presumed organism in block 19 (or the electronic claim).

033.0	WHOOPING COUGH DUE TO BORDETELLA PERTUSSIS (B. PERTUSSIS)
053.0 - 053.9	HERPES ZOSTER WITH MENINGITIS - HERPES ZOSTER WITHOUT COMPLICATION
058.82	HUMAN HERPESVIRUS 7 INFECTION
066.40	WEST NILE FEVER, UNSPECIFIED
075	INFECTIOUS MONONUCLEOSIS
079.51	HUMAN T-CELL LYMPHOTROPIC VIRUS TYPE I [HTLV-I]
079.83	PARVOVIRUSB19
079.89	OTHER SPECIFIED VIRAL INFECTION
082.40 - 082.49	UNSPECIFIED EHRLICHIOSIS - OTHER EHRLICHIOSIS
085.1 - 085.9	CUTANEOUS LEISHMANIASIS URBAN - LEISHMANIASIS UNSPECIFIED
088.82	BABESIOSIS
130.9	TOXOPLASMOSIS UNSPECIFIED

Diagnoses that Support Medical Necessity

Conditions that are listed in the "ICD-9 Codes that Support Medical Necessity" section of this policy.

ICD-9 Codes that DO NOT Support Medical Necessity

All those not listed under the "ICD-9 Codes that Support Medical Necessity" section of this policy.

ICD-9 Codes that DO NOT Support Medical Necessity Asterisk Explanation

Diagnoses that DO NOT Support Medical Necessity

Conditions that are not listed in the "ICD-9 Codes that Support Medical Necessity" section of this policy.

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Other Information

Documentation Requirements

1. All documentation must be maintained in the patient's medical record and available to the contractor upon request.
2. Every page of the record must be legible and include appropriate patient identification information (e.g., complete name, dates of service(s)). The documentation must include the legible signature of the physician or non-physician practitioner responsible for and providing the care to the patient.
3. The submitted medical record must support the use of the selected ICD-9-CM code(s). The submitted CPT/HCPCS code must describe the service performed.
4. The medical record documentation must support the medical necessity of the services as directed in this policy.

Appendices

N/A

Utilization Guidelines

In accordance with CMS Ruling 95-1 (V), utilization of these services should be consistent with locally acceptable standards of practice.

No more than two individual microorganisms may be concurrently billed for CPT 87798.

Sources of Information and Basis for Decision

Contractor is not responsible for the continued viability of websites listed.

Full disclosure of the sources of information is found with original contractor LCD.

Novitas adopted, with deletions, minor text revisions and ICD-9/CPT coding updates, the TrailBlazer LCD "Infectious Disease Molecular Diagnostic Testing"

There were extensive in-person consultations with both nationally-recognized infectious disease and clinical microbiology specialists (via logistical support from the American Society for Microbiology) in order to assist with the above medical necessity language and procedure-to-diagnosis code pairings.

Other Contractor(s)' Policies

Contractor Medical Directors

Advisory Committee Meeting Notes

This policy does not reflect the sole opinion of the contractor or Contractor Medical Directors. Although the final decision rests with the contractor, this policy was developed in cooperation with advisory groups, which includes representatives from the appropriate specialty (ies).

CAC Distribution: 05/15/2012

Start Date of Comment Period

05/15/2012

End Date of Comment Period:

07/05/2012

Start Date of Notice Period

09/27/2012

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L32567

Revision History Explanation

Date	Policy #	Description
09/27/2012	L32568	Final LCD posted for notice and will become effective for dates of service on and after 11/15/2012.
05/15/2012	DL32568	Draft LCD posted for comment

Reason for Change

Coverage Change (actual change in medical parameters)

Related Documents

This LCD has no related documents.

LCD Attachments

There are no attachments for this LCD.