

LCD for Molecular Diagnostics: Genitourinary Infectious Disease Testing (L35015)

Contractor Information

Contractor Name: Novitas Solutions, Inc.

Contractor Number: 12501

Contractor Type: MAC A

LCD Information

LCD ID Number: L35015 **Status:** A-Approved

LCD Title: Molecular Diagnostics: Genitourinary Infectious Disease Testing

Geographic Jurisdiction: Pennsylvania [Other Jurisdictions](#)

Original Determination Effective Date: 10/01/2015

Original Determination Ending Date:

Revision Effective Date: 10/01/2018

Revision End Date:

CMS National Coverage Policy:

This LCD supplements but does not replace, modify or supersede existing Medicare applicable National Coverage Determinations (NCDs) or payment policy rules and regulations for molecular diagnostic testing. Federal statute and subsequent Medicare regulations regarding provision and payment for medical services are lengthy. They are not repeated in this LCD. Neither Medicare payment policy rules nor this LCD replace, modify or supersede applicable state statutes regarding medical practice or other health practice professions acts, definitions and/or scopes of practice. All providers who report services for Medicare payment must fully understand and follow all existing laws, regulations and rules for Medicare payment for molecular diagnostic testing and must properly submit only valid claims for them. Please review and understand them and apply the medical necessity provisions in the policy within the context of the manual rules. Relevant CMS manual instructions and policies may be found in the following Internet-Only Manuals (IOMs) published on the CMS Web site:

IOM Citations:

- CMS IOM Publication 100-02, *Medicare Benefit Policy Manual*, Chapter 15, Section 80.1, 80.1.1, 80.1.2, and 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, Section 3.6.2.3 Limitation of Liability Determinations

Social Security Act (Title XVIII) Standard References:

- 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.

Federal Register References:

42 CFR, Section 410.32 Diagnostic x-ray tests, diagnostic laboratory tests, and other diagnostic tests: Conditions.

Indications and Limitations of Coverage and/or Medical Necessity:

Notice: It is not appropriate to bill Medicare for services that are not covered (as described by this entire LCD) as if they are covered. When billing for non-covered services, use the appropriate modifier.

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 coverage of the more prevalent (typical) bacterial and fungal organisms (per the eight organism-specific CPT codes, ranging from 87480 to 87660) which are encountered for the majority of gynecological infectious presentations. Conversely, there are less typically encountered (rare) pathogens for which genitourinary (GU) microbiological evaluations (i.e., sometimes including panel testing) are less well-established and even investigational. In this context, medical review, educational outreach, etc. will be conducted on an as-needed basis.

For frequency limitations please refer to the Utilization Guidelines section below.

Notice: This LCD imposes frequency limitations as well as diagnosis limitations that support diagnosis to procedure code automated denials. However, services performed for any given diagnosis must meet all of the indications and limitations stated in this policy, the general requirements for medical necessity as stated in CMS payment policy manuals, any and all existing CMS national coverage determinations, and all Medicare payment rules.

As published in CMS IOM 100-08, Chapter 13, Section 13.5.1, in order to be covered under Medicare, a service shall be reasonable and necessary. When appropriate, contractors shall describe the circumstances under which the proposed LCD for the service is considered reasonable and necessary under Section 1862 (a)(1)(A). Contractors shall consider a service to be reasonable and necessary if the contractor determines that the service is:

- Safe and effective.
- Not experimental or investigational (exception: routine costs of qualifying clinical trial services with dates of service on or after September 19, 2000, that meet the requirements of the Clinical Trials NCD are considered reasonable and necessary).
- Appropriate, including the duration and frequency that is considered appropriate for the service, in terms of whether it is:
 - Furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient's condition or to improve the function of a malformed body member.
 - Furnished in a setting appropriate to the patient's medical needs and condition.
 - Ordered and furnished by qualified personnel.
 - One that meets, but does not exceed, the patient's medical needs.
 - At least as beneficial as an existing and available medically appropriate alternative

The redetermination process may be utilized for consideration of services performed outside of the reasonable and necessary requirements in the LCD.

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.

12	Hospital Inpatient (Medicare Part B only)
13	Hospital Outpatient
14	Hospital - Laboratory Services Provided to Non-patients
18	Hospital - Swing Beds
21	Skilled Nursing - Inpatient (Including Medicare Part A)
22	Skilled Nursing - Inpatient (Medicare Part B only)
23	Skilled Nursing - Outpatient
71	Clinic - Rural Health
72	Clinic - Hospital Based or Independent Renal Dialysis Center
73	Clinic - Freestanding
75	Clinic - Comprehensive Outpatient Rehabilitation Facility (CORF)
77	Clinic - Federally Qualified Health Center (FQHC)
83	Ambulatory Surgery Center
85	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.

0314	Laboratory Pathology - Biopsy
0319	Laboratory Pathology - Other Laboratory Pathology
0312	Laboratory Pathology - Histology

0311	Laboratory Pathology - Cytology
0309	Laboratory - Other Laboratory
0310	Laboratory Pathology - General Classification
0300	Laboratory - General Classification
0307	Laboratory - Urology
0306	Laboratory - Bacteriology & Microbiology
0304	Laboratory - Non-Routine Dialysis
0305	Laboratory - Hematology
0303	Laboratory - Renal Patient (Home)
0302	Laboratory - Immunology
0301	Laboratory - Chemistry

CPT/HCPCS Codes:

Providers are reminded to refer to the long descriptors of the CPT codes in their CPT book.

- 87480 INFECTIOUS AGENT DETECTION BY NUCLEIC ACID (DNA OR RNA); CANDIDA SPECIES, DIRECT PROBE TECHNIQUE
- 87481 INFECTIOUS AGENT DETECTION BY NUCLEIC ACID (DNA OR RNA); CANDIDA SPECIES, AMPLIFIED 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-10 Codes that Support Medical Necessity:

It is the providers responsibility to select codes carried out to the highest level of specificity and selected from the ICD-10-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):

A54.00	Gonococcal infection of lower genitourinary tract, unspecified
A54.01	Gonococcal cystitis and urethritis, unspecified
A54.02	Gonococcal vulvovaginitis, unspecified
A54.03	Gonococcal cervicitis, unspecified
A54.09	Other gonococcal infection of lower genitourinary tract
A54.1	Gonococcal infection of lower genitourinary tract with periurethral and accessory gland abscess
A54.21	Gonococcal infection of kidney and ureter
A54.22	Gonococcal prostatitis
A54.23	Gonococcal infection of other male genital organs
A54.24	Gonococcal female pelvic inflammatory disease
A54.29	Other gonococcal genitourinary infections
A54.30	Gonococcal infection of eye, unspecified
A54.31	Gonococcal conjunctivitis
A54.32	Gonococcal iridocyclitis
A54.33	Gonococcal keratitis
A54.39	Other gonococcal eye infection
A54.40	Gonococcal infection of musculoskeletal system, unspecified

A54.41	Gonococcal spondylopathy
A54.42	Gonococcal arthritis
A54.43	Gonococcal osteomyelitis
A54.49	Gonococcal infection of other musculoskeletal tissue
A54.5	Gonococcal pharyngitis
A54.6	Gonococcal infection of anus and rectum
A54.81	Gonococcal meningitis
A54.82	Gonococcal brain abscess
A54.83	Gonococcal heart infection
A54.84	Gonococcal pneumonia
A54.85	Gonococcal peritonitis
A54.86	Gonococcal sepsis
A54.89	Other gonococcal infections
A54.9	Gonococcal infection, unspecified
A55	Chlamydial lymphogranuloma (venereum)
A56.00	Chlamydial infection of lower genitourinary tract, unspecified
A56.01	Chlamydial cystitis and urethritis
A56.02	Chlamydial vulvovaginitis
A56.09	Other chlamydial infection of lower genitourinary tract
A56.11	Chlamydial female pelvic inflammatory disease
A56.19	Other chlamydial genitourinary infection
A56.2	Chlamydial infection of genitourinary tract, unspecified
A56.3	Chlamydial infection of anus and rectum
A56.4	Chlamydial infection of pharynx
A56.8	Sexually transmitted chlamydial infection of other sites
A59.00	Urogenital trichomoniasis, unspecified
A59.01	Trichomonal vulvovaginitis
A59.02	Trichomonal prostatitis
A59.03	Trichomonal cystitis and urethritis
A59.09	Other urogenital trichomoniasis
A59.8	Trichomoniasis of other sites
A59.9	Trichomoniasis, unspecified
A71.0	Initial stage of trachoma
A71.1	Active stage of trachoma
A71.9	Trachoma, unspecified
A74.0	Chlamydial conjunctivitis
B30.9	Viral conjunctivitis, unspecified
B37.3	Candidiasis of vulva and vagina
B37.41	Candidal cystitis and urethritis
B37.42	Candidal balanitis
B37.49	Other urogenital candidiasis
D70.0	Congenital agranulocytosis
D70.1	Agranulocytosis secondary to cancer chemotherapy
D70.2	Other drug-induced agranulocytosis
D70.3	Neutropenia due to infection
D70.4	Cyclic neutropenia
D70.8	Other neutropenia
D70.9	Neutropenia, unspecified
D72.825	Bandemia
D72.89	Other specified disorders of white blood cells
D73.81	Neutropenic splenomegaly

D75.81	Myelofibrosis
H10.011	Acute follicular conjunctivitis, right eye
H10.012	Acute follicular conjunctivitis, left eye
H10.013	Acute follicular conjunctivitis, bilateral
H10.019	Acute follicular conjunctivitis, unspecified eye
H10.021	Other mucopurulent conjunctivitis, right eye
H10.022	Other mucopurulent conjunctivitis, left eye
H10.023	Other mucopurulent conjunctivitis, bilateral
H10.029	Other mucopurulent conjunctivitis, unspecified eye
H10.30	Unspecified acute conjunctivitis, unspecified eye
H10.31	Unspecified acute conjunctivitis, right eye
H10.32	Unspecified acute conjunctivitis, left eye
H10.33	Unspecified acute conjunctivitis, bilateral
H10.401	Unspecified chronic conjunctivitis, right eye
H10.402	Unspecified chronic conjunctivitis, left eye
H10.403	Unspecified chronic conjunctivitis, bilateral
H10.409	Unspecified chronic conjunctivitis, unspecified eye
H10.421	Simple chronic conjunctivitis, right eye
H10.422	Simple chronic conjunctivitis, left eye
H10.423	Simple chronic conjunctivitis, bilateral
H10.429	Simple chronic conjunctivitis, unspecified eye
H10.431	Chronic follicular conjunctivitis, right eye
H10.432	Chronic follicular conjunctivitis, left eye
H10.433	Chronic follicular conjunctivitis, bilateral
H10.439	Chronic follicular conjunctivitis, unspecified eye
I88.1	Chronic lymphadenitis, except mesenteric
L04.0	Acute lymphadenitis of face, head and neck
L04.1	Acute lymphadenitis of trunk
L04.2	Acute lymphadenitis of upper limb
L04.3	Acute lymphadenitis of lower limb
L04.8	Acute lymphadenitis of other sites
L04.9	Acute lymphadenitis, unspecified
M01.X0	Direct infection of unspecified joint in infectious and parasitic diseases classified elsewhere
M01.X19	Direct infection of unspecified shoulder in infectious and parasitic diseases classified elsewhere
M01.X29	Direct infection of unspecified elbow in infectious and parasitic diseases classified elsewhere
M01.X39	Direct infection of unspecified wrist in infectious and parasitic diseases classified elsewhere
M01.X49	Direct infection of unspecified hand in infectious and parasitic diseases classified elsewhere
M01.X59	Direct infection of unspecified hip in infectious and parasitic diseases classified elsewhere
M01.X69	Direct infection of unspecified knee in infectious and parasitic diseases classified elsewhere
M01.X79	Direct infection of unspecified ankle and foot in infectious and parasitic diseases classified elsewhere
M01.X8	Direct infection of vertebrae in infectious and parasitic diseases classified elsewhere
M01.X9	Direct infection of multiple joints in infectious and parasitic diseases classified elsewhere
M02.30	Reiter's disease, unspecified site
M02.311	Reiter's disease, right shoulder
M02.312	Reiter's disease, left shoulder
M02.319	Reiter's disease, unspecified shoulder
M02.321	Reiter's disease, right elbow
M02.322	Reiter's disease, left elbow
M02.329	Reiter's disease, unspecified elbow
M02.331	Reiter's disease, right wrist
M02.332	Reiter's disease, left wrist

M02.339	Reiter's disease, unspecified wrist
M02.341	Reiter's disease, right hand
M02.342	Reiter's disease, left hand
M02.349	Reiter's disease, unspecified hand
M02.351	Reiter's disease, right hip
M02.352	Reiter's disease, left hip
M02.359	Reiter's disease, unspecified hip
M02.361	Reiter's disease, right knee
M02.362	Reiter's disease, left knee
M02.369	Reiter's disease, unspecified knee
M02.371	Reiter's disease, right ankle and foot
M02.372	Reiter's disease, left ankle and foot
M02.379	Reiter's disease, unspecified ankle and foot
M02.38	Reiter's disease, vertebrae
M02.39	Reiter's disease, multiple sites
M12.9	Arthropathy, unspecified
M13.0	Polyarthritis, unspecified
M13.10	Monoarthritis, not elsewhere classified, unspecified site
M13.111	Monoarthritis, not elsewhere classified, right shoulder
M13.112	Monoarthritis, not elsewhere classified, left shoulder
M13.119	Monoarthritis, not elsewhere classified, unspecified shoulder
M13.121	Monoarthritis, not elsewhere classified, right elbow
M13.122	Monoarthritis, not elsewhere classified, left elbow
M13.129	Monoarthritis, not elsewhere classified, unspecified elbow
M13.131	Monoarthritis, not elsewhere classified, right wrist
M13.132	Monoarthritis, not elsewhere classified, left wrist
M13.139	Monoarthritis, not elsewhere classified, unspecified wrist
M13.141	Monoarthritis, not elsewhere classified, right hand
M13.142	Monoarthritis, not elsewhere classified, left hand
M13.149	Monoarthritis, not elsewhere classified, unspecified hand
M13.151	Monoarthritis, not elsewhere classified, right hip
M13.152	Monoarthritis, not elsewhere classified, left hip
M13.159	Monoarthritis, not elsewhere classified, unspecified hip
M13.161	Monoarthritis, not elsewhere classified, right knee
M13.162	Monoarthritis, not elsewhere classified, left knee
M13.169	Monoarthritis, not elsewhere classified, unspecified knee
M13.171	Monoarthritis, not elsewhere classified, right ankle and foot
M13.172	Monoarthritis, not elsewhere classified, left ankle and foot
M13.179	Monoarthritis, not elsewhere classified, unspecified ankle and foot
M25.50	Pain in unspecified joint
M25.511	Pain in right shoulder
M25.512	Pain in left shoulder
M25.519	Pain in unspecified shoulder
M25.521	Pain in right elbow
M25.522	Pain in left elbow
M25.529	Pain in unspecified elbow
M25.531	Pain in right wrist
M25.532	Pain in left wrist
M25.539	Pain in unspecified wrist
M25.541	Pain in joints of right hand
M25.542	Pain in joints of left hand

M25.549	Pain in joints of unspecified hand
M25.551	Pain in right hip
M25.552	Pain in left hip
M25.559	Pain in unspecified hip
M25.561	Pain in right knee
M25.562	Pain in left knee
M25.569	Pain in unspecified knee
M25.571	Pain in right ankle and joints of right foot
M25.572	Pain in left ankle and joints of left foot
M25.579	Pain in unspecified ankle and joints of unspecified foot
M65.10	Other infective (teno)synovitis, unspecified site
M65.111	Other infective (teno)synovitis, right shoulder
M65.112	Other infective (teno)synovitis, left shoulder
M65.119	Other infective (teno)synovitis, unspecified shoulder
M65.121	Other infective (teno)synovitis, right elbow
M65.122	Other infective (teno)synovitis, left elbow
M65.129	Other infective (teno)synovitis, unspecified elbow
M65.131	Other infective (teno)synovitis, right wrist
M65.132	Other infective (teno)synovitis, left wrist
M65.139	Other infective (teno)synovitis, unspecified wrist
M65.141	Other infective (teno)synovitis, right hand
M65.142	Other infective (teno)synovitis, left hand
M65.149	Other infective (teno)synovitis, unspecified hand
M65.151	Other infective (teno)synovitis, right hip
M65.152	Other infective (teno)synovitis, left hip
M65.159	Other infective (teno)synovitis, unspecified hip
M65.161	Other infective (teno)synovitis, right knee
M65.162	Other infective (teno)synovitis, left knee
M65.169	Other infective (teno)synovitis, unspecified knee
M65.171	Other infective (teno)synovitis, right ankle and foot
M65.172	Other infective (teno)synovitis, left ankle and foot
M65.179	Other infective (teno)synovitis, unspecified ankle and foot
M65.18	Other infective (teno)synovitis, other site
M65.19	Other infective (teno)synovitis, multiple sites
M65.80	Other synovitis and tenosynovitis, unspecified site
M65.811	Other synovitis and tenosynovitis, right shoulder
M65.812	Other synovitis and tenosynovitis, left shoulder
M65.819	Other synovitis and tenosynovitis, unspecified shoulder
M65.821	Other synovitis and tenosynovitis, right upper arm
M65.822	Other synovitis and tenosynovitis, left upper arm
M65.829	Other synovitis and tenosynovitis, unspecified upper arm
M65.831	Other synovitis and tenosynovitis, right forearm
M65.832	Other synovitis and tenosynovitis, left forearm
M65.839	Other synovitis and tenosynovitis, unspecified forearm
M65.841	Other synovitis and tenosynovitis, right hand
M65.842	Other synovitis and tenosynovitis, left hand
M65.849	Other synovitis and tenosynovitis, unspecified hand
M65.851	Other synovitis and tenosynovitis, right thigh
M65.852	Other synovitis and tenosynovitis, left thigh
M65.859	Other synovitis and tenosynovitis, unspecified thigh
M65.861	Other synovitis and tenosynovitis, right lower leg

M65.862	Other synovitis and tenosynovitis, left lower leg
M65.869	Other synovitis and tenosynovitis, unspecified lower leg
M65.871	Other synovitis and tenosynovitis, right ankle and foot
M65.872	Other synovitis and tenosynovitis, left ankle and foot
M65.879	Other synovitis and tenosynovitis, unspecified ankle and foot
M65.88	Other synovitis and tenosynovitis, other site
M65.89	Other synovitis and tenosynovitis, multiple sites
M65.9	Synovitis and tenosynovitis, unspecified
M67.30	Transient synovitis, unspecified site
M67.311	Transient synovitis, right shoulder
M67.312	Transient synovitis, left shoulder
M67.319	Transient synovitis, unspecified shoulder
M67.321	Transient synovitis, right elbow
M67.322	Transient synovitis, left elbow
M67.329	Transient synovitis, unspecified elbow
M67.331	Transient synovitis, right wrist
M67.332	Transient synovitis, left wrist
M67.339	Transient synovitis, unspecified wrist
M67.341	Transient synovitis, right hand
M67.342	Transient synovitis, left hand
M67.349	Transient synovitis, unspecified hand
M67.351	Transient synovitis, right hip
M67.352	Transient synovitis, left hip
M67.359	Transient synovitis, unspecified hip
M67.361	Transient synovitis, right knee
M67.362	Transient synovitis, left knee
M67.369	Transient synovitis, unspecified knee
M67.371	Transient synovitis, right ankle and foot
M67.372	Transient synovitis, left ankle and foot
M67.379	Transient synovitis, unspecified ankle and foot
M67.38	Transient synovitis, other site
M67.39	Transient synovitis, multiple sites
M79.646	Pain in unspecified finger(s)
N30.80	Other cystitis without hematuria
N30.81	Other cystitis with hematuria
N34.1	Nonspecific urethritis
N34.3	Urethral syndrome, unspecified
N41.0	Acute prostatitis
N41.4	Granulomatous prostatitis
N41.8	Other inflammatory diseases of prostate
N41.9	Inflammatory disease of prostate, unspecified
N44.1	Cyst of tunica albuginea testis
N44.2	Benign cyst of testis
N44.8	Other noninflammatory disorders of the testis
N45.1	Epididymitis
N45.2	Orchitis
N45.3	Epididymo-orchitis
N45.4	Abscess of epididymis or testis
N50.3	Cyst of epididymis
N50.811	Right testicular pain
N50.812	Left testicular pain

N50.819	Testicular pain, unspecified
N50.89	Other specified disorders of the male genital organs
N51	Disorders of male genital organs in diseases classified elsewhere
N53.12	Painful ejaculation
N53.8	Other male sexual dysfunction
N53.9	Unspecified male sexual dysfunction
N70.01	Acute salpingitis
N70.02	Acute oophoritis
N70.03	Acute salpingitis and oophoritis
N70.91	Salpingitis, unspecified
N70.92	Oophoritis, unspecified
N70.93	Salpingitis and oophoritis, unspecified
N72	Inflammatory disease of cervix uteri
N73.0	Acute parametritis and pelvic cellulitis
N73.1	Chronic parametritis and pelvic cellulitis
N73.2	Unspecified parametritis and pelvic cellulitis
N73.5	Female pelvic peritonitis, unspecified
N73.6	Female pelvic peritoneal adhesions (postinfective)
N73.8	Other specified female pelvic inflammatory diseases
N73.9	Female pelvic inflammatory disease, unspecified
N74	Female pelvic inflammatory disorders in diseases classified elsewhere
N75.0	Cyst of Bartholin's gland
N75.1	Abscess of Bartholin's gland
N75.8	Other diseases of Bartholin's gland
N75.9	Disease of Bartholin's gland, unspecified
N76.0	Acute vaginitis
N76.1	Subacute and chronic vaginitis
N76.2	Acute vulvitis
N76.3	Subacute and chronic vulvitis
N76.4	Abscess of vulva
N76.5	Ulceration of vagina
N76.6	Ulceration of vulva
N76.81	Mucositis (ulcerative) of vagina and vulva
N76.89	Other specified inflammation of vagina and vulva
N77.0	Ulceration of vulva in diseases classified elsewhere
N77.1	Vaginitis, vulvitis and vulvovaginitis in diseases classified elsewhere
N94.89	Other specified conditions associated with female genital organs and menstrual cycle
N97.1	Female infertility of tubal origin
P39.1	Neonatal conjunctivitis and dacryocystitis
R10.0	Acute abdomen
R10.10	Upper abdominal pain, unspecified
R10.11	Right upper quadrant pain
R10.12	Left upper quadrant pain
R10.13	Epigastric pain
R10.2	Pelvic and perineal pain
R10.30	Lower abdominal pain, unspecified
R10.31	Right lower quadrant pain
R10.32	Left lower quadrant pain
R10.33	Periumbilical pain
R10.811	Right upper quadrant abdominal tenderness
R10.812	Left upper quadrant abdominal tenderness

R10.813	Right lower quadrant abdominal tenderness
R10.814	Left lower quadrant abdominal tenderness
R10.815	Periumbilic abdominal tenderness
R10.816	Epigastric abdominal tenderness
R10.817	Generalized abdominal tenderness
R10.819	Abdominal tenderness, unspecified site
R10.821	Right upper quadrant rebound abdominal tenderness
R10.822	Left upper quadrant rebound abdominal tenderness
R10.823	Right lower quadrant rebound abdominal tenderness
R10.824	Left lower quadrant rebound abdominal tenderness
R10.825	Periumbilic rebound abdominal tenderness
R10.826	Epigastric rebound abdominal tenderness
R10.827	Generalized rebound abdominal tenderness
R10.829	Rebound abdominal tenderness, unspecified site
R10.84	Generalized abdominal pain
R10.9	Unspecified abdominal pain
R16.0	Hepatomegaly, not elsewhere classified
R16.1	Splenomegaly, not elsewhere classified
R16.2	Hepatomegaly with splenomegaly, not elsewhere classified
R18.0	Malignant ascites
R18.8	Other ascites
R19.00	Intra-abdominal and pelvic swelling, mass and lump, unspecified site
R19.01	Right upper quadrant abdominal swelling, mass and lump
R19.02	Left upper quadrant abdominal swelling, mass and lump
R19.03	Right lower quadrant abdominal swelling, mass and lump
R19.04	Left lower quadrant abdominal swelling, mass and lump
R19.05	Periumbilic swelling, mass or lump
R19.06	Epigastric swelling, mass or lump
R19.07	Generalized intra-abdominal and pelvic swelling, mass and lump
R19.09	Other intra-abdominal and pelvic swelling, mass and lump
R19.30	Abdominal rigidity, unspecified site
R19.31	Right upper quadrant abdominal rigidity
R19.32	Left upper quadrant abdominal rigidity
R19.33	Right lower quadrant abdominal rigidity
R19.34	Left lower quadrant abdominal rigidity
R19.35	Periumbilic abdominal rigidity
R19.36	Epigastric abdominal rigidity
R19.37	Generalized abdominal rigidity
R19.8	Other specified symptoms and signs involving the digestive system and abdomen
R21	Rash and other nonspecific skin eruption
R30.0	Dysuria
R30.9	Painful micturition, unspecified
R36.0	Urethral discharge without blood
R36.9	Urethral discharge, unspecified
R39.11	Hesitancy of micturition
R39.16	Straining to void
R50.2	Drug induced fever
R50.81	Fever presenting with conditions classified elsewhere
R50.9	Fever, unspecified
R59.0	Localized enlarged lymph nodes
R59.1	Generalized enlarged lymph nodes

R59.9	Enlarged lymph nodes, unspecified
R74.0	Nonspecific elevation of levels of transaminase and lactic acid dehydrogenase [LDH]
R74.8	Abnormal levels of other serum enzymes
R74.9	Abnormal serum enzyme level, unspecified
R78.81	Bacteremia
R80.0	Isolated proteinuria
R80.1	Persistent proteinuria, unspecified
R80.8	Other proteinuria
R80.9	Proteinuria, unspecified
R81	Glycosuria
R82.0	Chyluria
R82.1	Myoglobinuria
R82.2	Biliuria
R82.3	Hemoglobinuria
R82.4	Acetonuria
R82.5	Elevated urine levels of drugs, medicaments and biological substances
R82.6	Abnormal urine levels of substances chiefly nonmedicinal as to source
R82.71	Bacteriuria
R82.79	Other abnormal findings on microbiological examination of urine
R82.8	Abnormal findings on cytological and histological examination of urine
R82.90	Unspecified abnormal findings in urine
R82.91	Other chromoabnormalities of urine
R82.991	Hypocitraturia
R82.992	Hyperoxaluria
R82.993	Hyperuricosuria
R82.994	Hypercalciuria
R82.998	Other abnormal findings in urine

General Information

Associated 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-10-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 stated in this policy.
5. In specific, there must be documentation that miscellaneous, less prevalent microorganisms (i.e., outside the designated range CPT 87480-87660) are medically necessary to support the use of CPT 87798.

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 87481 and 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

Original JH ICD-9 Source LCD L33644, Molecular Diagnostics: Genitourinary Infectious Disease Testing

Revision History Information

Revision History Date	Revision History Number	Revision History Explanation
10/01/2018	R3	LCD revised and published on 10/25/2018 effective for dates of service on and after 10/01/2018 to reflect the ICD-10-CM Annual Code Updates and Annual Review. The following ICD-10-CM code(s) have been deleted and therefore removed from Group 1 Codes of the LCD: R82.99. The following ICD-10-CM code(s) have been added to Group 1 Codes: R82.991, R82.992, R82.993, R82.994, R82.998. Per annual review, the IOM citations have been updated and standard LCD verbiage applied to the policy. At this time 21st Century Cures Act will apply to new and revised LCDs that restrict coverage which requires comment and notice. This revision is not a restriction to the coverage determination; therefore, not all the fields included on the LCD are applicable as noted in this policy.
10/01/2016	R2	LCD revised and published on 09/29/2016 effective for dates of service on and after 10/01/2016 to reflect the ICD-10 Annual Code Updates. The following ICD-10 codes have been deleted from Group 1: N50.8 and R82.7, and therefore removed from the LCD. ICD-10 codes have been added to Group 1: M25.541, M25.542, M25.549, N50.811, N50.812, N50.819, N50.89, R82.71, and R82.79.
12/11/2015	R1	LCD reviewed for administrative purposes. No changes were made to the LCD itself.

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