OHCA Guideline

Medical Procedure Class:	**Molecular Diagnostic Testing for Infectious Diseases**
Initial Implementation Date:	November 1, 2022
Last Review Date:	September 2024
Effective Date:	October 1, 2024
Next Review/Revision Date:	September 2027
* This document is not a contract, and these guidelines do not reflect or represent every conceived situation. Although all items contained in these guidelines may be met, this does not reflect, or imply any responsibility of this agency or department to change the plan provision to include the stated service as an eligible benefit.	
☐ New Criteria	☒ Revision of Existing Criteria

Summary	
Purpose:	To provide guidelines to assure medical necessity and consistency in the coverage of molecular diagnostic infectious disease testing.
CPT Codes (see CPT manual for code descriptions) **87468 - 87801**	

Definitions

Polymerase Chain Reaction (PCR) – a biochemical laboratory technique used to make thousands or even millions of copies of a segment of DNA. It is commonly used to amplify a small amount of specific targeted DNA from among a mixture of DNA samples. PCR is a type of Nucleic Acid Amplification Test (NAAT)

Direct Probe Technique – detection methods where nucleic acids are detected without initial amplification processing.

Amplified Probe Technique – technique without quantification, detection method in which the sensitivity of the assay is improved over direct probe techniques.

Probe with Quantification Technique – methods used to report absolute or relative amounts of nucleic acid sequences in the original sample.

***High risk behaviors for acquiring a sexually transmitted disease include the following:**

1. Early sexual activity, for example before age 18
2. Multiple sex partners
3. Sex with a high-risk partner (one who has multiple sex partners or other risk factors)
4. Unprotected intercourse without consistent or correct condom use, except in a long-term, single-partner (monogamous) relationship
5. Unprotected mouth-to-genital contact, except in a long-term monogamous relationship.
6. Having anal sex or a partner who does, except in a long-term, single-partner monogamous relationship
7. Having sex with a partner who injects or has ever injected drugs
8. Exchange of sex (sex work) for drugs or money
9. Having had Chlamydia trachomatis or other sexually transmitted diseases in the past.

Description of Service:

The purpose of molecular pathogen testing using nucleic acid laboratory methods is to identify the deoxyribonucleic acid (DNA) and ribonucleic acid (RNA) of disease-causing microorganisms, including viruses, bacteria, and fungi, including yeast. Nucleic acid pathogen testing provides sensitive, specific, and timely identification of microorganisms. A nucleic acid test analyzes tiny amounts of DNA or RNA in a sample of blood, tissue, or body fluid. Because the amount of genetic material is very small the test may include a step where the DNA or RNA of the microorganism is amplified or increased. This type of nucleic acid pathogen test is known as a nucleic acid amplification test or NAAT. The NAAT format increases diagnostic sensitivity by decreasing the lower limit of detection. There may also be a need to quantify rather than simply detect the presence of certain microorganisms (i.e., quantification).

General Considerations:

1) Healthcare practitioners are expected to use clinical knowledge, judgement, and skills in determining most likely etiologies and most appropriate medical decisions and not to rely on molecular diagnostic testing for common ailments and treatment decisions.
2) Molecular diagnostic testing for pathogens that can reasonably be diagnosed with history, physical exam, and usual clinical testing like flu screening, rapid strep, urine analysis, culture and sensitivity, simple smears or wet preps and microscopic detection are not considered medically necessary. Molecular diagnostic testing should only be considered when these tests are inconclusive, or the medical condition persists or worsens.
3) Molecular diagnostic testing is most appropriate for use in inpatient facilities in situations where less common conditions and increased illness severity require this type of testing. There is limited use in the outpatient setting and should be reserved for diagnostic dilemmas and uncommon occurrences.
4) Because viruses cause most upper respiratory tract infections, the diagnostic role of laboratory investigations and radiologic studies is limited. Only after common conditions are ruled out, should testing be considered for uncommon viral conditions.
5) Molecular testing just to determine antibiotic necessity or selection of antibiotic when empiric prescription is the usual course is not considered medically necessary.
6) **The Oklahoma Health Care Authority (OHCA) does not consider routine molecular diagnostic screening or testing for urinary tract infections to be medically necessary.**
7) It is not appropriate to simultaneously bill for both direct and amplification probes or to simultaneously bill for quantification with direct or amplification probes.
8) Laboratories must have the appropriate CLIA specialty/subspecialty certifications for the lab tests they perform.
9) OHCA, in general, follows the guidelines established by the Infectious Disease Society of America for infectious disease testing.

Documentation

1) The medical record must contain documentation that the testing is expected to influence treatment of the condition towards which the testing is directed.
2) The laboratory or billing provider must have on file the physician requisition which sets forth the diagnosis or condition that warrants the test(s).
3) Examples of documentation requirements for the ordering provider include, but are not limited to, history and physical exam findings that support the decision making, problems/diagnoses, relevant data (e.g., lab testing results).

4) The performing laboratory should have the following documentation available upon request: CLIA certificate that contains specialty/subspecialty certifications for the lab tests performed, test requisitions, test reports (preliminary and final), quality control records, and information to support use of any lab developed tests.
5) Billing providers are required to code specificity; however, if a 'not otherwise specified' CPT code is used the documentation must clearly identify the unique procedure performed. When multiple procedure codes are submitted (unique and/or unlisted) the documentation supporting each code should be easily identifiable. If on review the billed code cannot be linked to the documentation, this service may be denied.
6) When the documentation does not meet the criteria for the service rendered/requested or the documentation does not establish the medical necessity for the service, the service may be denied as not reasonable and necessary.

Coverage considerations for individual test codes in the outpatient setting (outpatient hospitals, clinics, and/or independent laboratories)

Please note: payment for laboratory testing in the inpatient setting is included in the hospital DRG payment and therefore coverage is not addressed in these guidelines.

87471– Bartonella henselae and Bartonella quintana, amplified probe technique

- Covered for testing in **OUTPATIENT hospital only** for the following indications:
  - Testing may be recommended to confirm diagnosis in immunocompromised or severely ill members with signs and symptoms of Bartonella infection; or
  - May be used to distinguish B. henselae from B. quintana infection in HIV-infected members and other immunocompromised members with s/s of bacillary angiomatosis or peliosis hepatitis

87472 – Bartonella henselae and Bartonella quintana, quantitative

- **Not covered** – not considered medically necessary in the outpatient setting

87475 – Borrelia burgdorferi, direct probe technique

- **Not covered** – not considered medically necessary in the outpatient setting

87476 – Borrelia burgdorferi, amplified probe technique

- **Not covered** – not considered medically necessary in the outpatient setting

87480 – Candida species, direct probe technique

- Testing covered when performed by a **hospital lab, independent lab, or clinic lab** for the following indications:
  - **Routine screening**
    - Evidence does not support routine screening for Candida species, even in asymptomatic pregnant members.
  - **Diagnostic testing**
    - Candida testing is generally diagnosed by non-molecular methods (clinical criteria, microscopy, and culture).
    - When necessary to evaluate vaginitis with molecular testing, only direct probe DNA tests are considered medically necessary. Amplified DNA-probe tests are not considered medically necessary as it has not been shown to improve clinical outcomes over direct probe DNA testing.
    - Subtyping for Candida glabrata and other nonalbicans Candida species is not routinely medically necessary. Exceptions may be considered if complicated vulvovaginal candidiasis (VVC) is diagnosed. Complicated VVC may include the following:
      - Recurrent VVC – defined as four or more episodes of symptomatic VVC within one year; or
      - Severe VVC such as extensive vulvar erythema, edema, excoriation, and fissure formation.

87481 – Candida species, amplified probe technique

- Testing covered when performed by a **hospital lab, independent lab, or clinic lab** for the following indications:
    - **Routine screening**
        - Evidence does not support routine screening for Candida species, even in asymptomatic pregnant members.
    - **Diagnostic testing**
        - Candida testing is generally diagnosed by non-molecular methods (clinical criteria, microscopy, and culture).
        - When necessary to evaluate vaginitis with molecular testing, only direct probe DNA tests are considered medically necessary. Amplified DNA-probe tests are not considered medically necessary as it has not been shown to improve clinical outcomes over direct probe DNA testing.
        - Subtyping for Candida glabrata and other nonalbicans Candida species is not routinely medically necessary. Exceptions may be considered if complicated vulvovaginal candidiasis (VVC) is diagnosed. Complicated VVC may include the following:
            - Recurrent VVC – defined as four or more episodes of symptomatic VVC within one year; or
            - Severe VVC such as extensive vulvar erythema, edema, excoriation, and fissure formation.

87482 – Candida species, quantification
- **Not covered** – not considered medically necessary in the outpatient setting

87483 – Central nervous system pathogen panel, 12-25 targets
- **Not covered** – not considered medically necessary in the outpatient setting

87485 – Chlamydia pneumoniae, direct probe technique
- **Not covered** – not considered medically necessary in the outpatient setting. Chlamydia Pneumoniae can cause an atypical pneumonia/community acquired pneumonia. Specific diagnosis is not indicated in most cases. Specific diagnosis might be indicated in severely ill individuals who are hospitalized.

87486– Chlamydia pneumoniae, amplified probe technique
- **Not covered** – not considered medically necessary in the outpatient setting. Chlamydia Pneumoniae can cause an atypical pneumonia/community acquired pneumonia. Specific diagnosis is not indicated in most cases. Specific diagnosis might be indicated in severely ill individuals who are hospitalized.

87487 – Chlamydia pneumoniae, quantification
- **Not covered** – not considered medically necessary in the outpatient setting

87490 – Chlamydia Trachomatis, direct probe technique
- **Not covered** – not considered medically necessary in the outpatient setting as direct sampling has less sensitivity than NAAT (nucleic acid amplified testing)

87491 – Chlamydia Trachomatis, amplified probe technique

- Testing covered when performed by a **hospital lab, independent lab, or clinic lab** for the following indications:
    - **Screening**
        - Routine annual screening of all sexually active individuals assigned female at birth ages 24 years or younger; or
        - Screening of sexually active individuals assigned female at birth ages 25 years or older with risk factors*; or
        - Routine screening of all pregnant individuals during one of first prenatal visits; or
        - Re-testing of all pregnant individuals ages 24 years or younger performed during the third trimester; or
        - Re-testing of all pregnant individuals ages 25 or older during the third trimester when at increased risk* for Chlamydia; or
        - Screening of sexually active individuals assigned male at birth with risk factors*
    - **Diagnostic testing**
        - Cervicitis; or
        - Urethritis
    - Routine test of cure is not recommended and therefore, is not considered medically necessary.
    - Repeat testing to document eradication of infection after completing an appropriate treatment regimen is recommended only in the following settings:
        - Patient is pregnant; or
        - Symptoms persist; or
        - Re-infection is suspected; or
        - Compliance with therapy is in question

87492 – Chlamydia Trachomatis, quantification

- **Not covered** – not considered medically necessary in the outpatient setting

87493 – Clostridium difficile, toxin gene(s), amplified probe technique

Covered for **OUTPATIENT hospital testing only**

- Testing does not distinguish between carrier and active infection
- May be recommended in connection with additional testing in members with signs and symptoms of C. Difficile including, but not limited to watery diarrhea (10-15 times per day), strong foul odor of diarrhea, abdominal pain and cramping, fever, nausea and/or vomiting, dehydration, or blood or pus in stools

87495 – Cytomegalovirus, direct probe technique

- **Not covered** – not considered medically necessary in the outpatient setting

87496 – Cytomegalovirus, amplified probe technique

- **Not covered** – not considered medically necessary in the outpatient setting

87497 – Cytomegalovirus, quantification

- Testing covered when performed by a **hospital lab, independent lab, or clinic lab** for the following indications:
    - Covered for immunocompromised individuals only; and

- Used to monitor response to therapy

87498 – Enterovirus, amplified probe technique, includes reverse transcription when performed

- **Not covered** – not considered medically necessary in the outpatient setting

87500 – Vancomycin resistance, amplified probe technique

- Covered for **OUTPATIENT hospital testing only**
  - Testing may be recommended for individuals at risk for Vancomycin resistant enterococci with signs/symptoms consistent with disease, such as fever, chills, redness, swelling, pain, and drainage or pus from a wound or surgical site.

87501 – Influenza virus, includes reverse transcription, when performed, and amplified probe technique

- **Not covered** - not considered medically necessary in the outpatient setting as testing for only one type of influenza is not recommended

87502 – Influenza virus, for multiple types or sub-types, includes multiplex reverse transcription, when performed, and multiplex amplified probe technique

- Testing covered when performed by a **hospital lab, independent lab, or clinic lab** for the following indications:
  - At this time, the evidence supporting testing in the outpatient setting is limited to individuals who are at high risk for complications of respiratory viral infection, including immunocompromised individuals, those with chronic respiratory illness, influenza complicated by pneumonia, or pregnant, when the result of testing is used to guide or alter management.
  - Evidence does not demonstrate clinical utility in average risk individuals in the outpatient setting; use of these tests has not been shown to change treatment decisions and/or improve subsequent clinical outcomes.

87503 – Influenza virus, for multiple types or sub-types, includes multiplex reverse transcription, when performed, and multiplex amplified probe technique, each additional influenza virus type or sub-type beyond 2

- Testing covered when performed by a **hospital lab, independent lab, or clinic lab** for the following indications:
  - At this time, the evidence supporting testing in the outpatient setting is limited to individuals who are at high risk for complications of respiratory viral infection, including immunocompromised individuals, those with chronic respiratory illness, influenza complicated by pneumonia, or pregnant, when the result of testing is used to guide or alter management.
  - Evidence does not demonstrate clinical utility in average risk individuals in the outpatient setting; use of these tests has not been shown to change treatment decisions and improve subsequent clinical outcomes.

87505 – Gastrointestinal pathogen (e.g., Clostridium difficile, E. coli, Salmonella, Shigella, norovirus, Giardia) includes multiplex reverse transcription, when performed, and multiplex amplified probe technique, multiple types, or subtypes, 3-5 targets

- **Not covered** – not considered medical necessary in the outpatient setting as standard of care for confirmation of infection is culture not PCR testing.

87506 – Gastrointestinal pathogen (e.g., Clostridium difficile, E. coli, Salmonella, Shigella, norovirus, Giardia) includes multiplex reverse transcription, when performed, and multiplex amplified probe technique, multiple types, or subtypes, 6-11 targets

- **Not covered** – not considered medical necessary in the outpatient setting as standard of care for confirmation of infection is culture not PCR testing.

87507 – Gastrointestinal pathogen (e.g., Clostridium difficile, E. coli, Salmonella, Shigella, norovirus, Giardia) includes multiplex reverse transcription, when performed, and multiplex amplified probe technique, multiple types, or subtypes, 12-25 targets

- **Not covered** – not considered medical necessary in the outpatient setting as standard of care for confirmation of infection is culture not PCR testing.

87510 – Gardnerella vaginalis, direct probe technique

- Testing covered when performed by a **hospital lab, independent lab, or clinic lab** for the following indications:
  - **Screening**
    - Evidence does not support routine screening for Gardnerella vaginalis for any indications.
  - **Diagnostic testing**
    - No indications for testing in individuals assigned male at birth.
    - Gardnerella vaginalis testing is generally diagnosed with non-molecular methods such as clinical criteria and microscopy. Molecular testing for G. vaginalis should rarely be necessary.
    - Guidelines do support molecular testing for G. vaginalis in symptomatic individuals assigned female at birth only when microscopy is not available. Symptoms may include but are not limited to foul smelling vaginal discharge, burning while urinating, or vaginal itching.

87511 – Gardnerella vaginalis, amplified probe technique

- Testing covered when performed by a **hospital lab, independent lab, or clinic lab** for the following indications:
  - **Screening**
    - Evidence does not support routine screening for Gardnerella vaginalis for any indications.
  - **Diagnostic testing**
    - No indications for testing in individuals assigned male at birth.

- ✞ Gardnerella vaginalis testing is generally diagnosed with non-molecular methods such as clinical criteria and microscopy. Molecular testing for G. vaginalis should rarely be necessary.
- ✞ Guidelines do support molecular testing for G. vaginalis in symptomatic individuals assigned female at birth only when microscopy is not available. Symptoms may include but are not limited to foul smelling vaginal discharge, burning while urinating, or vaginal itching.

87512 – Gardnerella vaginalis, quantification

- **Not covered** – not considered medical necessary in the outpatient setting

87516 – Hepatitis B, amplified probe technique

- Covered for testing in **OUTPATIENT hospital only**
  - The standard of care is to use antibody/antigen testing for diagnosis, not PCR

87517 – Hepatitis B, quantification

- Testing covered when performed by a **hospital lab, independent lab, or clinic lab** for the following indication:
  - Testing is used to monitor treatment for Hepatitis B, not for diagnosis.

87520 – Hepatitis C, direct probe technique

- **Not covered** - not considered medically necessary in the outpatient setting

87521 – Hepatitis C, amplified probe technique

- **Not covered** – not considered medically necessary in the outpatient setting as standard diagnostic testing is not usually done with PCR but with antibody testing

87522 – Hepatitis C, quantification

- Testing covered when performed by a **hospital lab, independent lab, or clinic lab** for the following indication:
  - Testing used to monitor treatment for hepatitis C, not for diagnosis

87525 – Hepatitis G, direct probe technique

- **Not covered** – not considered medically necessary in the outpatient setting

87526 - Hepatitis G, amplified probe technique

- **Not covered** – not considered medically necessary in the outpatient setting

87527 – Hepatitis G, quantification

- **Not covered** – not considered medically necessary in the outpatient setting

87528 – Herpes Simplex Virus, direct probe technique

- **Not covered** – not considered medically necessary in the outpatient setting

87529 – Herpes Simplex Virus, amplified probe technique

- Testing covered when performed in a **hospital lab, independent lab, or clinic lab** for the following indications:
  - **Screening**
    - Current guidelines explicitly recommend against testing asymptomatic individuals for HSV and therefore is not covered.
  - **Diagnostic testing**
    - Indications for testing symptomatic individuals ○ New or recurrent vesicular and/or ulcerative lesions, vesicles, or ulcers on or around the genitals, rectum, buttocks, or thighs.
      - ○ Recurrent genital symptoms and atypical symptoms with negative HSV cultures

87530 – Herpes Simplex Virus, quantification

- Covered for **OUTPATIENT hospital testing only** when used to monitor treatment for disseminated herpes. Not covered for diagnostic testing for HSV.

87531 – Herpes Virus 6, direct probe technique

- **Not covered** – not considered medically necessary in the outpatient setting

87532 – Herpes Virus 6, amplified probe technique

- Covered for **OUTPATIENT hospital testing only**
  - Herpes virus 6 is not common and severe disease is usually limited to immunocompromised individuals.

87533 – Herpes Virus 6, quantification

- Covered for **OUTPATIENT hospital testing only**
  - Herpes virus 6 is not common and severe disease is usually limited to immunocompromised individuals
  - Quantification testing should only be used for treatment monitoring

87534 – HIV 1, direct probe technique

- **Not covered** - not considered medically necessary in the outpatient setting

87535 – HIV 1, amplified probe technique

- Testing is covered when performed by a **hospital lab, independent lab, or clinic lab for** the following indications:
  - Screening for a diagnosis of HIV in any adolescent or adult 15-65 years of age; or
  - Screening for a diagnosis of HIV in any individual with a potential HIV exposure or engaging in behavior associated with an increased risk of HIV infection who is within the window period when standard combined antibody/antigen screening may not be effective; or
  - Screening for a diagnosis of HIV in pregnancy

87536 – HIV 1, quantification

- Testing is covered when performed by a **hospital lab, independent lab, or clinic lab** for the following indication:
    - Monitoring treatment of HIV

87537 – HIV 2, direct probe technique

- **Not covered** - not considered medically necessary in the outpatient setting

87538 – HIV 2, amplified probe technique

- Testing is covered when performed by a **hospital lab, independent lab, or clinic lab for** the following indications:
    - Screening for a diagnosis of HIV in any adolescent or adult 15-65 years of age; or
    - Screening for a diagnosis of HIV in any individual with a potential HIV exposure or engaging in behavior associated with an increased risk of HIV infection who is within the window period when standard combined antibody/antigen screening may not be effective; or
    - Screening for a diagnosis of HIV in pregnancy

87539 – HIV 2, quantification

- Testing is covered when performed by a **hospital lab, independent lab, or clinic lab for** the following indication:
    - Monitoring treatment of HIV

87540 – Legionella pneumoniae, direct probe technique

- **Not covered** – not considered medically necessary in the outpatient setting

87541 – Legionella pneumoniae, amplified probe technique

- Covered for **OUTPATIENT hospital testing only**
    - Legionella pneumoniae can cause an atypical pneumonia/community acquired pneumonia. Covered by most treatment for community acquired pneumonia without a need for testing.
    - Testing may be recommended for those who are immunocompromised and/or hospitalized with pneumonia.
    - Should be suspected when there is an outbreak of legionella in the community.

87542 – Legionella pneumoniae, quantification

- **Not covered** – not considered medically necessary in the outpatient setting

87550 – Mycobacteria species, direct probe technique

- **Not covered** – not considered medically necessary in the outpatient setting

87551 – Mycobacteria species, amplified probe technique

- Covered for **OUTPATIENT hospital testing only**

- Appropriate to test only those individuals with a positive culture for non-tuberculosis mycobacterium.

87552 – Mycobacteria species, quantification

- **Not covered** – not considered medically necessary in the outpatient setting

87555 – Mycobacteria tuberculosis, direct probe technique

- **Not covered** – not considered medically necessary in the outpatient setting

87556 – Mycobacteria tuberculosis, amplified probe technique

- Testing covered when performed by **a hospital lab, independent lab, or clinic lab** for the following indication:
  - Testing recommended for members with signs/symptoms of TB with risk factors and for rapid diagnostic testing of acid-fast stain positive respiratory tract specimens.

87557 – Mycobacteria tuberculosis, quantification

- **Not covered** – not considered medically necessary in the outpatient setting

87560 – Mycobacteria avium-intracellulare, direct probe technique

- **Not covered** – not considered medically necessary in the outpatient setting

87561 – Mycobacteria avium-intracellulare, amplified probe technique

- Testing covered when performed by a **hospital lab, independent lab, or clinic lab** for the following indication:
  - Test only those with positive culture for non-tuberculosis mycobacterium who are at risk for mycobacterium avium-intracellulare

87562 – Mycobacteria avium intracellulare, quantification

- **Not covered** – not considered medically necessary in the outpatient setting

87563 – Mycobacteria genitalium, amplified probe technique

- Testing covered when performed by a **hospital lab, independent lab, or clinic lab** for the following indication:
  - Testing is only indicated for treatment resistant/recurrent urethritis or cervicitis

87580 – Mycoplasma pneumoniae, direct probe technique

- **Not covered** – not considered medically necessary in the outpatient setting

87581 – Mycoplasma pneumoniae, amplified probe technique

- **Not covered** – not considered medically necessary in the outpatient setting. Mycoplasma pneumoniae can cause an atypical pneumonia/community acquired pneumonia. Specific

diagnosis is not indicated in most cases. Specific diagnosis might be indicated in severely ill individuals who are hospitalized.

87582 – Mycoplasma pneumoniae, quantification

- **Not covered** – not considered medically necessary in the outpatient setting

87590 – Neisseria gonorrhea, direct probe technique

- **Not covered** – not considered medically necessary in the outpatient setting

87591 – Neisseria gonorrhea, amplified probe technique

- Testing is covered when performed by a **hospital lab, independent lab, or clinic lab** for the following indications:
  - **Screening**
    - Routine annual screening of all sexually active individuals assigned female at birth ages 24 years and younger; or
    - Screening of sexually active individuals assigned female at birth ages 25 years and older who are at increased risk* of infection; or
    - All pregnant individuals at increased risk for gonorrhea should be screened at the first prenatal visit for N. gonorrhea; or
    - Uninfected pregnant individuals who remain at high risk of gonococcal infection also should be retested during the third trimester; or
    - Screening of sexually active individuals who have an infected partner; or
    - Screening of all sexually active adults prescribed preexposure prophylaxis (PrEP) for prevention of HIV infection.
  - **Diagnostic testing**
    - Cervicitis; or
    - Urethritis
  - **Test Frequency**
    - When indicated, repeat testing to document eradication should not be performed until 3-4 weeks after the positive result. Pregnant individuals diagnosed with gonococcal infection during the first trimester should be retested within approximately 3-6 months, preferably in the third trimester. Recently infected individuals should be retested 3 to 12 months after treatment.

87592 – Neisseria gonorrhea, quantification

- **Not covered** – not considered medically necessary in the outpatient setting

87593 – Orthopoxvirus (e.g., monkeypox virus, cowpox virus, vaccinia virus) amplified probe technique

- Covered for **outpatient hospital and health department testing** for the following indications:
  - Testing is only recommended for a rash consistent with monkeypox; and
  - Requires a swab sample taken directly from a lesion (not appropriate for throat, saliva, or blood samples)

87623 – HPV, low risk types (e.g., 6, 11, 42, 43, 44)

- **Not covered** – not considered medically necessary in the outpatient setting

87624 – HPV, high risk types (e.g., 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 68)

- Testing is covered when performed by a **hospital lab, independent lab, or clinic lab** for the following indications:
  - HPV testing should only be performed to detect high-risk (oncogenic) types of HPV; testing for low-risk types is considered not medically necessary.
  - Covered as a **screening** tool for the following indications:
    - Individuals assigned female at birth ages 25-65 years of age – high risk HPV testing alone or combined with Pap smear (co-testing) may be allowed every 5 years.
    - Individuals assigned female at birth ages 25 years and older who are HPV positive, but cytology negative may:
      - Test again by co-testing in one year; or
      - Be tested by HPV high-risk oncogenic subtype genotyping
    - Individuals assigned female at birth ages 25 and older with cytology reported as negative and with absent or insufficient endocervical/transformation zone (EC/TZ) component and no or unknown HPV test results
  - **Diagnostic** testing
    - Reflex to HPV testing for management of individuals assigned female at birth with atypical squamous cells of undetermined significance (ASC-US) cervical cytology results starting at age 21 years; or
    - Co-testing at 1 yar post cervical intraepithelial neoplasia grade 1 (CIN 1) or no lesion preceded by HPV-16 or HPV-18 positivity, persistent untyped oncogenic HPV, ASC-US, and low grade squamous intraepithelial lesion (LSIL) starting at age 25 years.
    - For individuals assigned female at birth testing for cervical intraepithelial neoplasia (CIN 2, CIN 3, or CIN 2,3), co-testing at 12 months and 24 months is recommended.
    - Post-menopausal individuals with LSIL.

87625 – HPV, high risk types 16 and 18 only, includes type 45 if performed

- Testing covered when performed by a **hospital lab, independent lab, or clinic lab** for the following indications:
  - May be allowed in addition to 87624 only when results for 87624 are positive and knowing if type 16, 18, or 45 are positive will influence treatment.
  - HPV testing should only be performed to detect high-risk (oncogenic) types of HPV; testing for low-risk types is considered not medically necessary.
  - Covered as a **screening** tool for the following indications:
    - Individuals assigned female at birth ages 25-65 years of age – high risk HPV testing alone or combined with Pap smear (co-testing) may be allowed every 5 years.
    - Individuals assigned female at birth ages 25 years and older who are HPV positive, but cytology negative may:

- Test again by co-testing in one year; or
- Be tested by HPV high-risk oncogenic subtype genotyping

- Individuals assigned female at birth ages 25 and older with cytology reported as negative and with absent or insufficient endocervical/transformation zone (EC/TZ) component and no or unknown HPV test results

- **Diagnostic** testing
  - Reflex to HPV testing for management of individuals with atypical squamous cells of undetermined significance (ASC-US) cervical cytology results starting at age 21 years; or
  - Co-testing at 1 year post cervical intraepithelial neoplasia grade 1 (CIN 1) or no lesion preceded by HPV-16 or HPV-18 positivity, persistent untyped oncogenic HPV, ASC-US, and low grade squamous intraepithelial lesion (LSIL) starting at age 25 years.
  - For individuals tested for cervical intraepithelial neoplasia (CIN 2, CIN3, or CIN2,3), co-testing at 12 months and 24 months is recommended.
  - Post-menopausal individuals with LSIL

87631 – Respiratory virus (e.g., adenovirus, influenza, coronavirus, metapneumovirus, parainfluenza virus, RSV, rhinovirus), includes multiplex reverse transcription when performed, and multiplex amplified probe technique, multiple types, or subtypes, 3-5 targets

- Testing covered when performed by a **hospital lab, independent lab, or clinic lab** for the following indications:
  - At this time, the evidence supporting testing in the outpatient setting is limited to individuals who are at high risk for complications of respiratory viral infection, including immunocompromised individuals, those with chronic respiratory illness, influenza complicated by pneumonia, or pregnant, when the result of testing is used to guide or alter management.
  - Evidence does not demonstrate clinical utility in average risk individuals in the outpatient setting; use of these tests has not been shown to change treatment decisions and improve subsequent clinical outcomes.

87632 - Respiratory virus (e.g., adenovirus, influenza, coronavirus, metapneumovirus, parainfluenza virus, RSV, rhinovirus), includes multiplex reverse transcription when performed, and multiplex amplified probe technique, multiple types, or subtypes, 6-11 targets

- **Not covered** – not considered medically necessary in the outpatient setting

87633 - Respiratory virus (e.g., adenovirus, influenza, coronavirus, metapneumovirus, parainfluenza virus, RSV, rhinovirus), includes multiplex reverse transcription when performed, and multiplex amplified probe technique, multiple types, or subtypes, 12-25 targets

- **Not covered** – not considered medically necessary in the outpatient setting

87634 – Respiratory syncytial virus, amplified probe technique

- Testing covered when performed by a **hospital lab, independent lab, or clinic lab** for the following indications:
  - At this time, the evidence supporting testing in the outpatient setting is limited to individuals who are at high risk for complications of respiratory viral infection, including

immunocompromised individuals, those with chronic respiratory illness, influenza complicated by pneumonia, or pregnant, when the result of testing is used to guide or alter management.
    - Evidence does not demonstrate clinical utility in average risk individuals in the outpatient setting; use of these tests has not been shown to change treatment decisions and improve subsequent clinical outcomes.

87635 – Severe acute respiratory syndrome, coronavirus 2 [COVID-19], amplified probe technique
- Testing covered when performed by a **hospital lab, independent lab, or clinic lab** for indications consistent with CDC guidance related to COVID-19.

87636 – Severe acute respiratory syndrome, coronavirus 2 [COVID-19] and influenza type A and B, multiplex amplified probe technique
- Testing covered when performed by a **hospital lab, independent lab, or clinic lab** for the following indications:
    - At this time, the evidence supporting testing in the outpatient setting is limited to individuals who are at high risk for complications of respiratory viral infection, including immunocompromised individuals, those with chronic respiratory illness, influenza complicated by pneumonia, or pregnant, when the result of testing is used to guide or alter management.
    - Evidence does not demonstrate clinical utility in average risk individuals in the outpatient setting; use of these tests has not been shown to change treatment decisions and improve subsequent clinical outcomes.

87637 – Severe acute respiratory syndrome, coronavirus 2 [COVID-19] and influenza type A and B, and RSV, multiplex amplified probe technique
- Testing covered when performed by a **hospital lab, independent lab, or clinic lab** for the following indications:
    - At this time, the evidence supporting testing in the outpatient setting is limited to individuals who are at high risk for complications of respiratory viral infection, including immunocompromised individuals, those with chronic respiratory illness, influenza complicated by pneumonia, or pregnant, when the result of testing is used to guide or alter management.
    - Evidence does not demonstrate clinical utility in average risk individuals in the outpatient setting; use of these tests has not been shown to change treatment decisions and improve subsequent clinical outcomes.

87640 – Staphylococcus aureus, amplified probe technique
- **Not covered** – not considered medically necessary in the outpatient setting

87641 – Staphylococcus aureus, methicillin resistant (MRSA), amplified probe technique
- Covered for **OUTPATIENT hospital testing only**
    - Used to distinguish MRSA from non-resistant forms of S. aureus, not for the mere presence of S. aureus

87650 – Streptococcus, group A, direct probe technique

- **Not covered** – not considered medically necessary in the outpatient setting as there are other reliable tests for Strep A in the outpatient setting

87651 – Streptococcus, group A, amplified probe technique

- **Not covered** – not considered medically necessary in the outpatient setting as there are other reliable tests for Strep A in the outpatient setting

87652 – Streptococcus, group A, quantification

- **Not covered** – not considered medically necessary in the outpatient setting as there are other reliable tests for Strep A in the outpatient setting

87653 – Streptococcus, group B, amplified probe technique

- **Not covered** – not considered medically necessary in the outpatient setting

87660 – Trichomonas vaginalis, direct probe technique

- Testing is covered when performed in a **hospital lab, independent lab, or clinic lab** for the following indications:
  - **Screening**
    - Screening for those at increased risk* for Trichomonas vaginalis infection; or
    - Screening for sexually active individuals assigned female at birth who are HIV positive at entry into care and then at least annually; or
    - Screening of sexually active individuals who have an infected partner.
    - Routine screenings are not indicated for Trichomonas vaginalis in asymptomatic individuals who are not at high risk* for infection.
  - **Diagnostic testing**
    - Symptomatic individuals with vaginitis, abnormal vaginal discharge, cervicitis, urethritis, vulvar pruritis, or pelvic inflammatory disease

87661 – Trichomonas vaginalis, amplified probe technique

- Testing is covered when performed in a **hospital lab, independent lab, or clinic lab** for the following indications:
  - **Screening**
    - Screening for those at increased risk* for Trichomonas vaginalis infection; or
    - Screening for sexually active individuals assigned female at birth who are HIV positive at entry into care and then at least annually; or
    - Screening of sexually active individuals who have an infected partner.
    - Routine screenings are not indicated for Trichomonas vaginalis in asymptomatic individuals who are not at high risk* for infection.
  - **Diagnostic testing**
    - Symptomatic individuals with vaginitis, abnormal vaginal discharge, cervicitis, urethritis, vulvar pruritis, or pelvic inflammatory disease

87662 – Zika virus, amplified probe technique

- Covered for **OUTPATIENT hospital testing only**

- Covered to establish diagnosis for the following:
    - Symptomatic or asymptomatic pregnant individuals who have traveled to endemic areas; or
    - Testing of infants with microcephaly or intracranial calcifications born to individuals who traveled to or resided in an area with Zika virus transmissions while pregnant; or
    - Infants born to mothers with positive or inconclusive test results for Zika virus infection; or
    - Persons with symptoms consistent with Zika virus infection who have traveled to or resided in an area with Zika virus transmissions; or

87797 – Not otherwise specified, direct probe technique, each organism

Not covered – not considered medically necessary in the outpatient setting as DNA direct probes have less sensitivity (ability to identify infected individuals) than amplified prove testing.

87798 – Not otherwise specified, amplified probe technique, each organism

- Coverage limited to **OUTPATIENT hospital testing only**
    - Documentation must clearly identify organism(s) for which testing is being performed, the medical necessity for each test, and the type of testing being performed.
    - The genitourinary organisms for which molecular testing is supported by guidelines are represented by organism specific CPT codes. Currently there is no clinical indications for any infectious agents billed under not otherwise specified (NOS) procedure codes that are supported by currently evidence for the evaluation and management of genitourinary conditions, including bacterial vaginosis. Therefore, testing for organisms NOS is considered investigational in the setting of testing genitourinary conditions and will not be allowed.

87799 – Not otherwise specified, quantification, each organism

- Coverage limited to **OUTPATIENT hospital testing only**
    - Documentation must clearly identify organism(s) for which testing is being performed, the medical necessity for each test, and the type of testing being performed.
    - The genitourinary organisms for which molecular testing is supported by guidelines are represented by organism specific CPT codes. Currently there is no clinical indications for any infectious agents billed under not otherwise specified (NOS) procedure codes that are supported by currently evidence for the evaluation and management of genitourinary conditions, including bacterial vaginosis. Therefore, testing for organisms NOS is considered investigational in the setting of testing genitourinary conditions and will not be allowed.

87800 – Multiple organisms, direct probe technique

- Testing covered when performed by a **hospital lab, independent lab, or clinic lab** for the following indications:
    - This procedure code is used when direct probe technique testing for multiple organisms with a single test or test kit

- When a provider performs a single direct probe test for multiple organisms, it is appropriate to bill one unit of 87800, it would not be appropriate to bill for each organism separately.
- Documentation must clearly identify the organisms for which testing is being performed, the medical necessity for each organism being tested, and the type of testing being performed.

87801 – Multiple organisms, amplified probe technique

- Testing covered when performed by a **hospital lab, independent lab, or clinic lab** for the following indications:
  - This procedure code is used when amplified probe technique testing for multiple organisms with a single test or test kit.
  - When a provider performs a single amplified probe test for multiple organisms, it is appropriate to bill one of unit 87801, it would not be appropriate to bill for each organism separately.
  - Documentation must clearly identify the organisms for which testing is being performed, the medical necessity for each organism being tested, and the type of testing being performed.

OHCA does not consider PCR testing for the following indications as medically necessary:

Acinetobacter baumannii
Anaplasma phagocytophilum
Aspergillosis
Astrovirus
Autoimmune lymphoproliferative syndrome
Babesia Borrelia miyamotoi
Babesia microtim
Bacterial vaginosis (Atopobium vaginae, Mobiluncus muliens, M. curtisii, and megasphaera type 1 and 2)
Bacterial vaginosis associated bacteria 2 (BVAB2)
Bacteroides spp. (B. fragilis, B. Urolyticus)
Blastomycosis
Caliciviruses (noroviruses and sapoviruses)
Campylobacteriosis (*Campylobacter* infection)
Castleman's disease
Cervical intraepithelial neoplasia (CIN) metastasis
Coagulase-negative staphylococcus (including *Staphylococcus saprophyticus*, and *Staphylococcus lugdunensis*)
Coccidiodomycosis (*Coccidioides* species)
Cochliobolus lunatus
Cochliobolus spicifer
Colorectal cancer screening (PreGen Plus)

Coronavirus (other than SARS-coronavirus and COVID-19)
Creutzfeldt-Jakob disease
Cryptococcus (*Cryptococcus neoformans*)
Cryptosporidiosis (cryptosporidium infection)
Cyclosporiasis (Cyclospora infection)
Cytochrome P450 genotyping
Donovanosis, or granuloma inguinale (*Klebsiella granulomatis*)
Eastern equine encephalitis
Eggerthella (screening)
Ehrlichia chaffeensis
Enterobacter aerogenes
Enterobacter cloacae
Enterococcus faecalis
Enterococcus faecium
Escherichia coli (except for detection of Shiga toxin)
Giardia lamblia
Hepatitis A virus
Hepatitis G virus (HGV)/GB virus type C
Histoplasma capsulatum histoplasmosis
Human bocavirus
Human herpesvirus type 7 (HHV-7)
Human herpesvirus type 8 (HHV-8)
Joint effusion
Kawasaki disease
Klebsiella pneumoniae carbapenemase (KPC)-producing bacteria
LaCrosse encephalitis
Lactobacillus vaginitis
Leptospirosis (*Leptospira* organisms)
Listeria
Lyme disease (*Borrelia burgdorferi*)
Malaise and fatigue (including chronic fatigue syndrome)
Melanoma (p16, Melaris) and melanoma micrometastases
MTHFR mutation in persons with hyper-homocysteinemia
Molluscum contagiosum
Moraxella catarrhalis
Mycoplasma fermentans
Mycoplasma hominis screening in asymptomatic pregnant individuals
Mycoplasma penetrans

Nanobacteria
Non-albicans Candida
Onychomycosis (tinea unguium)
Parainfluenza virus
Parechovirus for recurrent fever
Peptic ulcer disease (*Helicobacter pylori*) (other than in persons with MALT lymphomas and marginal zone lymphomas)
Peripheral neuropathy
Plesiomonas shigelloides
Pneumococcal infections (*S. pneumoniae*)
Pneumocystis pneumonia (*Pneumocystis jiroveci* (formerly *P. carinii*))
Prevotella bivia for diagnosis of vaginitis
Prevotella spp.
Prostate cancer micrometastasis
Prostatitis (e.g., Pathnostics Comprehensive Guidance)
Proteus mirabilis
Pseudomonas (*P. aeruginosa*)
Pleuropulmonary coccidioidomycosis
Rhinovirus
Rotavirus
Routine screening of trichomonas in asymptomatic individuals
Saccharomyces cerevisiae
Salmonella
Serratia spp. (including *S. marcescens*)
Sporotrichosis (*Sporothrix schenckii*)
St. Louis encephalitis
Staphylococcus epidermidis
Stenotrophomonas maltophilia
Streptococcus group C
Streptococcus group G
Trichosporonosis (Trichosporon spp.)
Urinary tract infections
Vibrio cholerae
Vibrio parahaemolyticus
Vibrio vulnificus
Western equine encephalitis
Wound infection
Xenotropic murine leukemia
Yersinia enterocolitica

Sources:

1. Oklahoma Health Care Authority Policy OAC 317:30-3-1;30-5-20; 30-5-20.2
2. Infectious Disease Society of America: A Guide to Utilization of the Microbiology Laboratory for Diagnosis of Infectious Diseases; 2018 Update by the Infectious Disease Society of America and the American Society for Microbiology
3. CMS LCD L38988, MolDX: Molecular Syndromic Panels for Infectious Disease Pathogen Identification Testing, effective 6/9/22
4. CMS Local Coverage Article, Billing and Coding: MolDX: Molecular Syndromic Panels for Infectious Disease Pathogen Identification Testing, effective 5/17/22.
5. Aetna Clinical Policy Bulletin; Polymerase Chain Reaction Testing; Selected indications; Number 0650
6. U.S. Preventive Services Task Force; A&B recommendations; accessed Sept. 2022.