PAYMENT POLICY STATEMENT:
OH MEDICAID

Original Effective Date	Next Annual Review Date	Last Review / Revision Date
08/10/2016	08/10/2017	08/10/2016

Policy Name	Policy Number
Sexually Transmitted Infections	PY-0037

Policy Type		
☐ Medical	☐ Administrative	☒ Payment

Payment Policies prepared by CSMG Co. and its affiliates (including CareSource) are intended to provide a general reference regarding billing, coding and documentation guidelines. Coding methodology, regulatory requirements, industry-standard claims editing logic, benefits design and other factors are considered in developing Payment Policies.

In addition to this Policy, payment of services is subject to member benefits and eligibility on the date of service, medical necessity, adherence to plan policies and procedures, claims editing logic, provider contractual agreement, and applicable referral, authorization, notification and utilization management guidelines. Medically necessary services include, but are not limited to, those health care services or supplies that are proper and necessary for the diagnosis or treatment of disease, illness, or injury and without which the patient can be expected to suffer prolonged, increased or new morbidity, impairment of function, dysfunction of a body organ or part, or significant pain and discomfort. These services meet the standards of good medical practice in the local area, are the lowest cost alternative, and are not provided mainly for the convenience of the member or provider. Medically necessary services also include those services defined in any federal or state coverage mandate, Evidence of Coverage documents, Medical Policy Statements, Provider Manuals, Member Handbooks, and/or other policies and procedures.

This Policy does not ensure an authorization or payment of services. Please refer to the plan contract (often referred to as the Evidence of Coverage) for the service(s) referenced herein. If there is a conflict between this Policy and the plan contract (i.e., Evidence of Coverage), then the plan contract (i.e., Evidence of Coverage) will be the controlling document used to make the determination.

CSMG Co. and its affiliates may use reasonable discretion in interpreting and applying this Policy to services provided in a particular case and may modify this Policy at any time.

A. SUBJECT

Sexually Transmitted Infections (STI) Screening

B. BACKGROUND

Reimbursement policies are designed to assist you when submitting claims to CareSource. They are routinely updated to promote accurate coding and policy clarification. These proprietary policies are not a guarantee of payment. Reimbursement for claims may be subject to limitations and/or qualifications. Reimbursement will be established based upon a review of the actual services provided to a member and will be determined when the claim is received for processing. Health care providers and their office staff are encouraged to use self-service channels to verify member's eligibility.

It is the responsibility of the submitting provider to submit the most accurate and appropriate CPT/HCPCS code(s) for the product or service that is being provided. The inclusion of a code does not imply any right to reimbursement or guarantee claims payment.

Sexually transmitted infections (STIs) cause significant morbidity and mortality in the United States each year. The United States Preventive Services Task Force (USPSTF) recommends that women at increased risk of infection be screened for chlamydia, gonorrhea, human immunodeficiency virus, and syphilis. Men at increased risk should be screened for human immunodeficiency virus and syphilis. All pregnant women should be screened for hepatitis B, human immunodeficiency virus, and syphilis; pregnant women at increased risk also should be screened for chlamydia and gonorrhea. Non-pregnant women and men not at increased risk do not require routine screening for sexually transmitted infections. Engaging in high-risk sexual behavior places persons at increased risk of sexually transmitted infections. The USPSTF recommends that all sexually active women younger than 25 years be considered at increased risk of chlamydia and gonorrhea.[1] Because not all communities present equal risk of sexually transmitted infections, the USPSTF, the US Centers for Disease Control (CDC), the American College of Obstetricians and Gynecologists (ACOG) and other authorities encourage physicians to consider expanding or limiting the routine sexually transmitted infection screening they provide based on the community and populations they serve. [2-8]

Historically, intervention efforts have focused on individual-level factors associated with STD risk. For example, It is important to educate members to practice safer sex, and for providers to screen high-risk individuals for common STI's. Investigators are now also evaluating higher-level factors (e.g., peer norms. media influences, and other social and cultural factors) which may also influence behaviors.[9]

Until effective strategies involving higher-level factors emerge, matching individual factors to screening test indications is the mainstay of STI screening. Generally, a recommendation for screening is based upon the strength of evidence that acting upon results of a screening test will lead to a significantly decreased infection rate for the target population evaluated.

CareSource encourages screening for Sexually Transmitted Infections consistent with the grade A and B recommendations of the USPSTF and the Centers for Medicare & Medicaid ("CMS") National Coverage Determination ("NCD") Policy 210.10 for Screening for Sexually Transmitted Infections. CareSource has eliminated the annual screen limitations set forth in the NDC as well as the order of billing STI diagnosis codes. The specific rules that apply for diagnosis codes (for Medicaid members *only*) are outlined in this policy.

C. DEFINITIONS

- **Sexually transmitted infections** (**STI)** - are infections that are passed from one person to another through sexual contact.
- **Nucleic acid amplification tests** (NAAT's) are gene amplification laboratory tests such as polymerase chain reaction (PCR) that are cleared by the United States Food and Drug Administration (FDA) and are recommended for detection of genital tract infections caused by Chlamydia trachomatis and Neisseria gonorrhoeae with or without symptoms. For detecting these infections of the genital tract, optimal specimen types for NAATs are vaginal swabs from women and first catch urine from men. Older nonculture tests and non-NAATs have inferior sensitivity and specificity characteristics and no longer are recommended. Since 2002, improvements in chlamydia and gonorrhea NAAT technologies have enabled significant implementation and expansion of screening programs using less invasive specimen collection.[5]
- **High risk behaviors for acquiring a sexually transmitted disease** are considered in the medical history of a clinical evaluation. Many STI's are asymptomatic, but without detection

by appropriate screening evaluation may lead to morbidity or preterm labor in pregnant women [7]

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 male or female 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

D. POLICY

I. Prior authorization is not required for any medically necessary STI screenings.

II. Screening tests for the STIs referred to in this policy are selected laboratory tests. Material related to diagnostic testing in this policy is included to clarify coverage for diagnostic versus screening indications.

III. Sexually Transmitted Infections ("STI") *Screening*: Chlamydia and Gonorrhea

A. CareSource considers screening for Chlamydia trachomatis ("Chlamydia") and Neisseria gonorrhea ("Gonorrhea") infections as medically necessary preventive care for these member groups according to the USPSTF, CDC, and NCQA:

1. All pregnant women younger than 25 years of age
2. All sexually active women younger than 25 years of age
3. Women with high-risk factors of any age for Chlamydia trachomatis and/or Gonorrhea infection.

B. In agreement with the USPSTF, CareSource considers Chlamydia and Gonorrhea screening experimental and investigational for asymptomatic men, and for women who do not meet the above criteria, because of insufficient evidence in the peer-reviewed literature for low-risk populations.

C. Routine repeat testing of NAAT-positive genital tract specimens is not recommended because the practice does not improve the positive predictive value of the test.

IV. Sexually Transmitted Infections ("STI") *Diagnosis*: Chlamydia and Gonorrhea

A. CareSource considers Chlamydia and/or Gonorrhea diagnostic testing medically necessary for members with signs or symptoms of Chlamydia and/or Gonorrhea infection.

B. CareSource considers home testing for Chlamydia and/or Gonorrhea experimental and investigational because of insufficient evidence in the peer-reviewed literature.

V. Sexually Transmitted Infections ("STI") *Screening*: Trichomonas vaginalis

A. CareSource provides coverage for screening test for trichomonas vaginalis in high risk women, pregnant women, and women under 25.[7]

B. The screening of asymptomatic pregnant women for bacterial vaginosis to reduce the likelihood of pre-term birth is considered experimental and investigational and is not covered by the American College of Obstetricians and Gynecologists.[3]

C. CareSource considers screening for Trichomonas vaginalis medically necessary for women with high risk factors.
D. Culture is a sensitive and highly specific commercially available method of diagnosis. Among women in whom trichomoniasis is suspected but not confirmed by microscopy, vaginal secretions should be cultured for T. vaginalis.
E. An FDA-cleared PCR assay for detection of gonorrhea and chlamydial infection (Amplicor, Roche Diagnostic Corp.) has been modified for T. vaginalis detection in vaginal or endocervical swabs and in urine from women and men; sensitivity ranges from 88%–97% and specificity from 98%–99%.[10] APTIMA T. vaginalis Analyte Specific Reagents (ASR, Gen-Probe, Inc.) also can detect T. vaginalis RNA by transcription-mediated amplification using the same instrumentation platforms available for the FDA-cleared APTIMA Combo2 assay for diagnosis of gonorrhea and chlamydial infection; published validation studies of T. vaginalis ASR found sensitivity ranging from 74%–98% and specificity of 87%–98%.[11]

VI. Coverage
A. CareSource will cover screening for these USPSTF-indicated STIs with the appropriate Food and Drug Administration ("FDA")-approved/cleared laboratory tests when ordered and performed by an eligible provider for these services, and when used consistent with FDA-approved labeling and in compliance with the Clinical Laboratory Improvement Act ("CLIA") regulations.
B. High-Intensity Behavioral Counseling ("HIBC") to prevent STIs may be provided on the same date of services as an annual wellness visit, evaluation and management (E&M) service, or during the global billing period for obstetrical care, but only one HIBC may be provided on any one date of service.

VII. Billing
A. If policy criteria are met, CareSource will reimburse for the following CPT codes once per calendar year for screening when medically necessary to test for sexually transmitted infections (STIs) in asymptomatic women if accompanied by one or more of the following ICD-10 codes:
1. Z00 Encounter for general examination without complaint, suspected or reported diagnosis
2. Z01.419 Encounter for gynecological examination (general) (routine) without abnormal findings
3. Z11.3 Encounter for screening for infections with a predominantly sexual mode of transmission
4. Z11.8 Encounter for screening for other infectious and parasitic diseases [chlamydia]
5. Z20 Contact with and (suspected) exposure to communicable diseases
6. Z22.4 Carrier of infections with a predominantly sexual mode of transmission
7. Z34 Encounter for supervision of normal pregnancy
8. Z71 Persons encountering health services for other counseling and medical advice, not elsewhere classified
9. Z72.51 - Z72.53 High-risk sexual behavior
10. O09 – Supervision of high-risk pregnancy

Procedure Codes	Description
87491	Chlamydia trachomatis, amplified probe technique
87591	Neisseria gonorrhoeae, amplified probe technique
87661	Infectious agent detection by nucleic acid (DNA or RNA); Trichomonas vaginalis, amplified probe technique

VIII. If policy criteria are met, CareSource will reimburse for the following CPT codes for diagnosis when medically necessary to test for sexually transmitted infections (STIs) if accompanied by one or more of the following ICD-10 codes:
   A. A56 Other sexually transmitted chlamydial diseases
   B. A55 Chlamydial lymphogranuloma (venereum)
   C. A74 Other diseases caused by chlamydiae
   D.
      N72 Inflammatory disease of cervix uteri
      N71.0 Acute inflammatory disease of uterus
      N71.1 Chronic inflammatory disease of uterus
      N71.9 Inflammatory disease of uterus, unspecified
      N73 Other female pelvic inflammatory diseases
      N73.9 Female pelvic inflammatory disease, unspecified
      N73.8 Other specified female pelvic inflammatory diseases
      N73.9 Female pelvic inflammatory disease, unspecified
      N74 Female pelvic inflammatory disorders in diseases classified elsewhere
      N76 Other inflammation of vagina and vulva
      N76.0 Acute Vaginitis
      N76.1 Subacute and chronic vaginitis
      N76.2 Acute vulvitis
      N76.3 Subacute and chronic vulvitis
      N76.4 Abscess of vuvla
      N76.5 Ulceration of vagina
      N76.6 Ulceration of vulva
      N76.8 Other specified inflammation of vagina and vulva
      N76.81 Mucositis (ulcerative) of vagina and vulva
      N76.89 Other specified inflammation of vagina and vulva
   E. N34 Urethritis

Chlamydia

Procedure Codes	Description
86631	Antibody;Chlamydia
86632	Antibody;Chlamydia,Igm
87110	Culture,Chlamydia
87270	Chlamydia trachomatis antigen detection by DFA
87320	Chlamydia trachomatis antigen detection by EIA
87490	Chlamydia trachomatis detect by DNA, dir probe
87491	Chlamydia trachomatis detect by DNA, amp probe

87810	Chlamydia trachomatis detect by immunoassay
87800	Detect agnt mult, dna, direc

IX. If policy criteria are met, CareSource will reimburse for the following CPT codes for diagnosis when medically necessary to test for sexually transmitted infections (STIs) if accompanied by one or more of the following ICD-10 codes:
O98 Maternal infectious and parasitic diseases classifiable elsewhere but complicating pregnancy, childbirth and the puerperium
A. A54 Gonococcal infection
B.
N72 Inflammatory disease of cervix uteri
N71.0 Acute inflammatory disease of uterus
N71.1 Chronic inflammatory disease of uterus
N71.9 Inflammatory disease of uterus, unspecified
N73 Other female pelvic inflammatory diseases
N73.9 Female pelvic inflammatory disease, unspecified
N73.8 Other specified female pelvic inflammatory diseases
N73.9 Female pelvic inflammatory disease, unspecified
N74 Female pelvic inflammatory disorders in diseases classified elsewhere
N76 Other inflammation of vagina and vulva
N76.0 Acute Vaginitis
N76.1 Subacute and chronic vaginitis
N76.2 Acute vulvitis
N76.3 Subacute and chronic vulvitis
N76.4 Abscess of vuvla
N76.5 Ulceration of vagina
N76.6 Ulceration of vulva
N76.8 Other specified inflammation of vagina and vulva
N76.81 Mucositis (ulcerative) of vagina and vulva
N76.89 Other specified inflammation of vagina and vulva
C. N34 Urethritis

Gonorrhea

Procedure Codes	Description
87590	N. gonorrhoeae by DNA, direct probe
87591	N. gonorrhoeae by DNA, amplified probe
87850	N. gonorrhoeae detection by immunoassay
87800	Detect agnt mult, dna, direc

X. If policy criteria are met, CareSource will reimburse for the following CPT codes for diagnosis when medically necessary to test for sexually transmitted infections (STIs) if accompanied by one or more of the following ICD-10 codes:
A.
A59 Trichomoniasis
A59.9 Trichomoniasis, unspecified
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

B.

N72 Inflammatory disease of cervix uteri
N71.0 Acute inflammatory disease of uterus
N71.1 Chronic inflammatory disease of uterus
N71.9 Inflammatory disease of uterus, unspecified
N73 Other female pelvic inflammatory diseases
N73.9 Female pelvic inflammatory disease, unspecified
N73.8 Other specified female pelvic inflammatory diseases
N73.9 Female pelvic inflammatory disease, unspecified
N74 Female pelvic inflammatory disorders in diseases classified elsewhere
N76 Other inflammation of vagina and vulva
N76.0 Acute Vaginitis
N76.1 Subacute and chronic vaginitis
N76.2 Acute vulvitis
N76.3 Subacute and chronic vulvitis
N76.4 Abscess of vuvla
N76.5 Ulceration of vagina
N76.6 Ulceration of vulva
N76.8 Other specified inflammation of vagina and vulva
N76.81 Mucositis (ulcerative) of vagina and vulva
N76.89 Other specified inflammation of vagina and vulva

C.

N34 Urethritis

Trichomonas vaginalis

Procedure Codes	Description
87661	Infectious agent detection by nucleic acid (DNA or RNA); Trichomonas

XI. If policy criteria are met, CareSource will reimburse for the following CPT codes for diagnosis when medically necessary to test for sexually transmitted infections (STIs) if accompanied by one or more of the following ICD-10 codes:

A. A50 Congenital syphilis
B. A65 Nonvenereal syphilis
C. A53 Other and unspecified syphilis
D. A52 Late syphilis
E. A51 Early syphilis

Syphilis

Procedure Codes	Description
86592	Syphilis test non-Trep Qual
86593	Syphilis test non-Trep Quant
86780	Treponema pallidum

XII. If policy criteria are met, CareSource will reimburse for the following CPT codes for diagnosis when medically necessary to test for sexually transmitted infections (STIs) in women if accompanied by one or more of the following ICD-10 codes:
A. B19 Unspecified viral hepatitis
B. B18 Chronic viral hepatitis
C. B17 Other acute viral hepatitisB16 Acute hepatitis B

Hepatitis B

Procedure Codes	Description
87340	Hepatitis B surface antigen detection by EIA
87341	Hepatitis b surface, ag, eia

XIII. Non-covered services

The US CDC notes that current guidelines do not support PCR testing for bacterial vaginosis or vaginal discharge. Workowski et al state that "PCR also has been used in research settings for the detection of a variety of organisms associated with BV, but evaluation of its clinical utility is uncertain."[7] The CDC does not indicate any role for PCR tests in the assessment of vaginal discharge without suspicion for C. trachomatis or N. gonorrhoeae based on history of sexual activity and presence of mucopurulent cervicitis. Otherwise, the cause of vaginal infection can be evaluated and diagnosed by pH and microscopic examination of the discharge.

A. B37.0 - B37.9 Candidiasis
B. N76.0 - N76.3 Acute, subacute, chronic vaginitis and vulvitis [bacterial vaginosis associated bacteria 2 (BVAB2), megasphaera type 2]
C. N77.1 Vaginitis, vulvitis and vulvovaginitis in diseases classified elsewhere [bacterial vaginosis associated bacteria 2 (BVAB2), megasphaera type 2]

Procedure Codes	Description
87491	Chlamydia trachomatis, amplified probe technique
87591	Neisseria gonorrhoeae, amplified probe technique
87661	Infectious agent detection by nucleic acid (DNA or RNA); Trichomonas vaginalis, amplified probe technique

CONDITIONS OF COVERAGE

AUTHORIZATION PERIOD

E. RELATED POLICIES/RULES

1. Centers for Medicare & Medicaid Services Manual – Pub. 100-3 National Coverage Determination / 210.10 – Screening for Sexually Transmitted Infections (STIs) and High-Intensity Behavioral Counseling (HIBC) to Prevent STIs
2. United States Preventive Services Task Force Recommendations

F. REVIEW/REVISION HISTORY

Date Issued:	08/10/2016
Date Reviewed:	08/10/2016
Date Revised:	09/27/2016 Additional ICD-10 Crosswalk

G. REFERENCES

[1] H. D. Nelson, B. Zakher, A. Cantor, M. Deagas, and M. Pappas, "Screening for Gonorrhea and Chlamydia: Systematic Review to Update the U.S. Preventive Services Task Force Recommendations. Evidence Synthesis No. 115. AHRQ Publication No. 13-05184-EF-1," Rockville, MD, 2014.

[2] J. A. Conry and H. Brown, "Well-Woman Task Force: Components of the Well-Woman Visit," *Obstet Gynecol,* vol. 126, pp. 697-701, Oct 2015.

[3] ACOG, "ACOG Practice Bulletin No. 31: Assessment of Risk Factors for Preterm Birth," *Obstetrics & Gynecology,* vol. 98, pp. 709-716, 2001.

[4] ACOG, "ACOG Committee Opinion no. 598: Committee on Adolescent Health Care: The initial reproductive health visit," *Obstet Gynecol,* vol. 123, pp. 1143-7, May 2014.

[5] CDC, "Recommendations for the laboratory-based detection of Chlamydia trachomatis and Neisseria gonorrhoeae--2014," *MMWR Recomm Rep,* vol. 63, pp. 1-19, Mar 14 2014.

[6] H. Weinstock, S. Berman, and W. Cates, Jr., "Sexually transmitted diseases among American youth: incidence and prevalence estimates, 2000," *Perspect Sex Reprod Health,* vol. 36, pp. 6-10, Jan-Feb 2004.

[7] K. A. Workowski, S. Berman, C. Centers for Disease, and Prevention, "Sexually transmitted diseases treatment guidelines, 2010," *MMWR Recomm Rep,* vol. 59, pp. 1-110, Dec 17 2010.

[8] CDC. (2011), (Retrieved July 24, 2016). *STDs Adolescents and Young Adults.* . Available: at http://www.cdc.gov/std/stats11/adol.htm

[9] D. M. Upchurch, W. M. Mason, Y. Kusunoki, and M. J. Kriechbaum, "Social and behavioral determinants of self-reported STD among adolescents," *Perspect Sex Reprod Health,* vol. 36, pp. 276-87, Nov-Dec 2004.

[10] B. Van Der Pol, C. S. Kraft, and J. A. Williams, "Use of an adaptation of a commercially available PCR assay aimed at diagnosis of chlamydia and gonorrhea to detect Trichomonas vaginalis in urogenital specimens," *J Clin Microbiol,* vol. 44, pp. 366-73, Feb 2006.

[11] M. B. Nye, J. R. Schwebke, and B. A. Body, "Comparison of APTIMA Trichomonas vaginalis transcription-mediated amplification to wet mount microscopy, culture, and polymerase chain reaction for diagnosis of trichomoniasis in men and women," *Am J Obstet Gynecol,* vol. 200, pp. 188 e1-7, Feb 2009.

The Payment Policy Statement detailed above has received due consideration as defined in the Payment Policy Statement Policy and is approved.