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CALIFORNIA INSURANCE COMMISSIONER

BULLETIN 2022-3

TO: **All Disability Insurers Providing Health Insurance Coverage in California**

FROM: **Insurance Commissioner Ricardo Lara**

DATE: **June 1, 2022**

RE: **Coverage Limits on Screening, Diagnosis and Treatment of Sexually Transmitted Infections**

A. Executive Summary

This Bulletin concerns health insurer obligations to cover screening, diagnosis, and treatment of sexually transmitted infections (STIs) under state law and the Affordable Care Act's requirement that health insurers cover preventive services without cost sharing. The Department has received complaints that insurers are imposing clinically inappropriate annual limits on STI screening. Insurers are instructed to review this Bulletin and take the necessary steps to assure that they provide clinically appropriate coverage of periodic STI screening, as well as diagnostic testing and treatment, and that their medical management practices comply with the law.

In Section B, this Bulletin summarizes applicable law, including relevant federal guidance on preventive services and state mandates for covering screening, diagnostic testing, and treatment of STIs that are outside the scope of preventive services. This includes requirements to cover HIV testing, basic health care services, outpatient prescription drugs, and home test kits for HIV and other STIs.

Section C of this Bulletin excerpts the text of selected U.S. Preventive Services Task Force and U.S. Health Resources and Services Administration recommendations, as well as evidence-based clinical practice guidelines on STI screening and testing, to demonstrate how an insurer should evaluate whether annual or other limits on coverage of STI screening and testing are legally permissible. This section examines six screening recommendations: (1) HIV, (2) HBV, (3) HCV, (4) syphilis, (5) chlamydia and gonorrhea screening of HIV negative persons with a cervix, and (6) chlamydia and gonorrhea screening of men who have sex with men and persons with HIV.

Examples 1 through 5 of Section C all address preventive services recommendations. Example 6 is on CDC-recommended screening of two populations that were not

included in the USPSTF recommendation that is the subject of Example 5. Example 1 explains when HIV self-tests constitute preventive services that insurers must cover without cost sharing. Examples 3 and 6 address coverage of evidence-based clinical practice guideline recommended STI screening, testing, and treatment that fall outside the scope of preventive services but constitute basic health care services or outpatient prescription drug benefits.

This Bulletin finds that imposing an annual limit on periodic risk-based STI screening contravenes the law. Insurers must cover risk-based STI screening at either the interval specified in evidence-based clinical practice guidelines, or if an interval is unspecified, at any clinically reasonable frequency. Insurers must not impose limits that function to override a provider's risk assessment with respect to covering screening tests that exceed any limits imposed.

B. Legal Requirements

1. Insurers Must Not Impose Coverage Limits on Risk-Based STI Screening that Conflict with Evidence-Based Clinical Recommendations

Pursuant to Insurance Code section 10112.2 and section 2713 of the Public Health Service Act (PHSA), non-grandfathered individual and group health insurance policies[1] must cover preventive health services without cost sharing. This includes items, services, and prescription and nonprescription medications that are "A" and "B" grade recommendations of the U.S. Preventive Services Task Force (USPSTF), as well as those recommended by guidelines for children's and women's preventive care that are supported by the U.S. Health Resources and Services Administration (HRSA). For individuals who are at increased risk of acquiring STIs, both the *HRSA Women's Preventive Services Guidelines* and USPSTF recommend certain services for preventing STIs. These services include behavioral counseling interventions for all sexually active adolescents and for adults who are at increased risk of acquiring STIs, as well as screening members of specified populations who are found to be at increased risk for infection with certain STIs.

A provider's assessment that an individual member of a specified population is at increased risk is determinative on coverage

Whether an individual member of a USPSTF or HRSA specified population is at increased risk of an STI, and therefore qualifies for a recommended service that depends on higher risk, is determined by two clinical assessments. These assessments are recommended by the Centers for Disease Control and Prevention (CDC) in the

[1] Under federal law, student health insurance is considered individual coverage and must comply with section 2713 of the Public Health Service Act (42 USC § 300gg-13), including by covering "A" and "B" grade recommendations of the USPSTF and HRSA-supported preventive services without cost sharing when delivered by network providers. *See* 45 CFR §§ 147.130, 147.145.

most recent version of its *Sexually Transmitted Infections Treatment Guidelines*.[2] The first type of clinical assessment is of behavioral risk through interviewing a patient about sexual history and risk factors for acquisition of STIs, which include local disease prevalence.[3] The second type of clinical assessment is of biological markers of risk through screening for STIs. A provider's assessment of a patient's individual risk factors ultimately determines whether clinically recommended risk-based STI prevention counseling and screening is appropriate for that patient.

The federal agencies issued similar guidance on the scope of required coverage of preventive services for members of high-risk populations under PHSA section 2713 in 2013.[4] Under the guidance, if a recommended service applies to members of a population based on increased risk and an attending provider makes that determination, the service must be covered as preventive care without cost sharing, subject to reasonable medical management. Consequently, insurers may not overrule an attending provider's determination of whether an individual is at increased risk and qualifies for STI screening under a USPSTF recommendation or HRSA guideline that applies to a population, or members of a population, based on increased risk.

Applying coverage limitations on preventive services that conflict with clinical evidence is not a reasonable medical management practice

When a USPSTF recommendation or HRSA guideline does not specify coverage parameters (i.e., the frequency, method, treatment, or setting) for the provision of a recommended preventive item or service, insurers may "rely on the relevant clinical evidence base and established reasonable medical management techniques" to determine any coverage limitations on those parameters.[5] However, an insurer cannot impose any additional limitations on a coverage parameter if the recommendation statement addresses that parameter with respect to the recommended item or service, or items or services that are necessary for furnishing the recommended item or

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[2] Kimberly A. Workowski, MD; Laura H. Bachmann, MD; Philip A. Chan, MD, *et al*. *Sexually Transmitted Infections Treatment Guidelines, 2021*. MMWR Recomm Rep July 2021;70(No. RR-4):1–187, at p. 3.
[3] *Id.*; see also CDC, Screening Recommendations by Disease (last accessed April 29, 2022).
[4] Departments of Health & Human Services, Labor, and Treasury, *FAQs About Affordable Care Act Implementation Part 12* (Feb. 20, 2013), at p. 5.

> Q7: Some USPSTF recommendations apply to certain populations identified as high-risk. Some individuals, for example, are at increased risk for certain diseases because they have a family or personal history of the disease. It is not clear, however, how a plan or issuer would identify individuals who belong to a high-risk population. How can a plan or issuer determine when a service should or should not be covered without cost-sharing?
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> Identification of "high-risk" individuals is determined by clinical expertise. Decisions regarding whether an individual is part of a high-risk population, and should therefore receive a specific preventive item or service identified for those at high-risk, should be made by the attending provider. Therefore, if the attending provider determines that a patient belongs to a high-risk population and a USPSTF recommendation applies to that high-risk population, that service is required to be covered in accordance with the requirements of the interim final regulations (that is, without cost-sharing, subject to reasonable medical management).

[5] 45 Code Fed. Regs. § 147.130(a)(4).

service.[6] When a recommendation statement is silent on one or more of these parameters, insurers must base any limits on clinical evidence for them to qualify as reasonable medical management of a coverage parameter.

Consequently, if a full recommendation statement or guideline that recommends risk-based STI screening does not specify the coverage parameters for provision of the screening, a coverage limitation on any of those parameters must align with the clinical evidence base to constitute reasonable medical management. If a recommended screening frequency is unspecified, an insurer must defer to the attending provider's assessment of whether an STI screening test is clinically appropriate due to increased risk. Therefore, the application of a coverage limitation, such as an annual limit of one screening per year, cannot result in denial of coverage or imposition of cost sharing for an STI screening that an attending provider determined was clinically appropriate for an insured based on an individual risk assessment. A coverage limitation of this nature on risk-based STI screening is not a reasonable medical management practice because it overrides the attending provider's assessment. The attending provider's determination, and not the insurer's, dictates the clinically appropriate screening interval within any periodicity limits found in evidence-based clinical practice guidelines for STI screening like the CDC's.

2. Insurers Must Cover STI Screening, Diagnosis and Treatment According to Current, Generally Accepted Standards of Care

To the extent that the most recent evidence-based clinical practice guideline recommended STI screenings exceed the preventive services benefit mandate of Insurance Code section 10112.2 or PHSA section 2713, these screenings constitute basic health care services that must be covered as clinically appropriate under Insurance Code sections 10112.27 and 10112.281.[7] Additionally, Insurance Code section 10123.91 requires that individual and group health insurance cover HIV testing, regardless of whether the testing is related to a primary diagnosis. Screenings that exceed the scope of the preventive services mandate may be subject to a policy's generally applicable cost sharing terms.

Insurers must also cover basic health care services for diagnosing and treating STIs as recommended in the most recent evidence-based clinical practice guidelines from authoritative sources because they represent current, generally accepted standards of

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[6] *Id. See also*, Departments of Health & Human Services, Labor, and Treasury, *FAQs About Affordable Care Act Implementation Part 47* (July 19, 2021), at p. 3-7 ("Plans and issuers may use reasonable medical management techniques to determine the frequency, method, treatment, or setting for the provision of a recommended preventive service only to the extent not specified in the applicable recommendation or guideline.").

[7] Insurance Code section 10112.281 requiring large group health insurance policies, including grandfathered plans, to provide coverage for basic health care services will be operative on July 1, 2022. Student blanket health insurance and non-grandfathered individual and small group health insurance policies are subject to section 10112.27. Additionally, Insurance Code section 10123.91 requires that individual and group health insurance cover HIV testing, regardless of whether the testing is related to a primary diagnosis.

care, the primary criterion for medical necessity.[8] For example, testing and treatment of symptomatic patients for STIs is not covered by the USPSTF or HRSA screening recommendations described in section C of this Bulletin. However, the CDC's guidelines include clinical recommendations on these topics that insurers must follow in designing benefits. Insurers must not impose coverage limitations on STI screening, diagnostic testing, or treatment that conflict with these or other evidence-based clinical recommendations. A prescription drug that is administered or furnished by a health care provider to treat an STI is a basic health care service, subject to medical management as regulated by the Insurance Code.[9] Further, if a policy covers outpatient prescription drugs, then the insurer must cover clinically appropriate drugs according to current, generally accepted standards of care for treating STIs.[10]

In conclusion, coverage of STI screening, testing, and treatment under the basic health care services mandate, including any quantitative or nonquantitative limits such as frequency limits or utilization review criteria, must be provided in accordance with the most recent evidence-based clinical practice guidelines from the CDC and specialty professional associations. The same rationale applies to a policy that covers outpatient prescription drugs because that policy must cover medically necessary prescription drugs, including non-formulary drugs as clinically appropriate.

3. Insurers Must Cover Home Tests Kits for Sexually Transmitted Infections, Including Combination HIV Self-Tests Without Cost Sharing

In 2021, Senate Bill 306 (Pan, Stats. 2021, ch. 486, § 5) enacted Insurance Code section 10123.208, requiring a health insurance policy that is issued, amended, or renewed on or after January 1, 2022 to cover "home test kits"[11] for sexually transmitted diseases (STDs). This statute requires coverage of home test kits that allow individuals to self-collect specimens for STDs, including HIV, remotely at a location outside of a clinical setting, when: (1) deemed medically necessary or appropriate and ordered directly by an in-network clinician; or (2) furnished through a standing order for patient use based on clinical guidelines and individual patient health needs. Insurers must also cover any laboratory costs of processing a home test kit.

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[8] *See* Cal. Ins. Code §§ 10123.135(f)(2), 10144.52(f)(1), 10169. *See also*, American Medical Association, *Medical Review: Definitions of "Screening" and "Medical Necessity" H-320.953* (last accessed April 28, 2022).

[9] *See, e.g.,* Cal. Ins. Code §§ 10123.191, 10123.1931, 10123.1933, 10123.195, 10123.196, 10123.197, and 10123.201. Assembly Bill 347 (Arambula, Stats. 2021, ch. 742, § 6) added standards for approving step therapy exception requests to subdivision (c) of Section 10123.201. These standards are not limited to outpatient prescription drugs, nor is Section 10123.191 so limited.

[10] Cal. Ins. Code §§ 10123.193(c), 10123.191(i), 10123.201(a). Note that sections 10123.191 and 10123.201 apply to all health insurance policies regardless of market segment or grandfathered status.

[11] A "home test kit" means "a product used for a test recommended by the federal Centers for Disease Control and Prevention guidelines or the United States Preventive Services Task Force that has been CLIA-waived, FDA-cleared or -approved, or developed by a laboratory in accordance with established regulations and quality standards, to allow individuals to self-collect specimens for STDs, including HIV, remotely at a location outside of a clinical setting." Cal. Ins. Code § 10123.208(b).

According to the CDC, health care providers can order home specimen collection kits that detect HIV and other STIs.[12] Several FDA-approved, CLIA-waived, rapid point-of-care (POC) HIV tests that are suitable for use in nonclinical settings are also available.[13] These tests, when ordered directly by an in-network provider or furnished through a standing order, as well as any laboratory costs of processing the tests, are covered by the benefit mandate of section 10123.208. Medical necessity and appropriateness under that statute are determined solely either by the fact of an in-network provider's order, or the furnishment of a home test kit to an insured pursuant to a standing order, meaning that insurers cannot impose quantitative frequency limits on test kits or deny claims for test kits or laboratory processing based on an asserted lack of medical necessity or appropriateness.

Combination HIV self-tests must be covered without cost sharing

Although section 10123.208 does not prohibit requiring cost sharing for STI self-test kits, combination antigen/antibody HIV self-tests[14] are preventive services under Insurance Code section 10112.2 and PHSA section 2713. Because the USPSTF and CDC recommend FDA-approved combination antigen/antibody tests for HIV screening, insurers are prohibited from imposing cost sharing on HIV self-test kits and laboratory processing when a combination antigen/antibody self-test kit is ordered by a network provider, or furnished through a standing order, to a member of the population that is covered by either the USPSTF's recommendation for HIV screening or HIV pre-exposure prophylaxis (PrEP). The same rationale applies to self-test kits for other STIs for which screening is recommended by the USPSTF.[15]

Coverage requirements for STI self-collection test kits

Insurers that have not already done so must contract with test suppliers and clinical laboratories that process mail-in STI self-collection test kits and include them in their provider directories.[16] As long as an in-network test provider and clinical laboratory cannot supply and process mail-in STI self-test kits, an insurer must cover out-of-network claims as if they were claims from in-network test providers and laboratories.[17] Further, an insurer cannot apply cost sharing to a self-test if the insured and type of test

[12] HIV home self-collection test kits are laboratory-conducted tests that are sensitive enough to detect recent HIV infection. CDC, Self-Testing (last accessed April 29, 2022). *See also* CDC, HIV Self-Testing (last accessed April 29, 2022).
[13] CDC, HIV Testing in Nonclinical Settings, HIV Testing Technologies, CLIA-waived rapid HIV tests (last accessed April 22, 2022). *See also*, FDA, Clinical Laboratory Improvement Amendments - Currently Waived Analytes, HIV-1 and HIV-2 Antigens and Antibodies (last accessed April 22, 2022).
[14] Combination antigen/antibody HIV self-tests detect antibodies to HIV-1 and HIV-2 and the HIV-1 p24 antigen (see Example C.1 below).
[15] Home test kits for CDC-recommended STI screening and diagnostic testing that fall outside the scope of USPSTF recommendations are also covered by Section 10123.108. *Supra*, n. 11.
[16] Cal. Ins. Code § 10133.15(h)(8)(F); 10 Cal. Code Regs. § 2240.1(b)(6), (b)(10).
[17] 10 Cal. Code Regs. § 2240.1(e).

are covered by a USPSTF recommendation for STI screening or PrEP.[18] Insurers must reimburse providers of STI home test kits and laboratory processing, including CLIA-waived rapid POC HIV tests that are suitable for use in nonclinical settings, when ordered directly by an in-network provider or furnished to an insured for their use through a standing order, as required by sections 10112.2 and 10123.208.

C. Examples and Conclusions

The Department has received complaints that insurers are routinely imposing clinically inappropriate annual limits on STI screening. This Bulletin excerpts the text of selected USPSTF and HRSA recommendations, as well as evidence-based clinical practice guidelines on STI screening and testing, to demonstrate how an insurer should evaluate whether quantitative frequency limits are legally permissible.[19]

The below conclusions explain whether annual limits or other quantitative frequency limits on STI screening are permissible under preventive care law, or for STI screening and diagnostic testing that does not constitute preventive services but are basic health care services, are consistent with current, generally accepted standards of care for STI screening and testing.

- Example 1 addresses preventive services coverage of HIV screening, including self-test kits and laboratory processing under SB 306.
- Example 2 addresses preventive services coverage of hepatitis B virus (HBV) screening.
- Example 3 addresses preventive services, basic health care services, and outpatient prescription drug benefit coverage of hepatitis C virus (HCV) screening, testing, and treatment.
- Example 4 addresses preventive services coverage of syphilis screening.
- Example 5 addresses preventive services coverage of chlamydia and gonorrhea screening of HIV-negative cisgender women and transgender and gender diverse people with a cervix, including pregnant persons.
- Example 6 addresses coverage of CDC-recommended chlamydia and gonorrhea screening of two populations—men who have sex with men and persons with HIV—that are not included in the corresponding USPSTF recommendation for HIV-negative persons with a cervix as of the date of this Bulletin.

It is imperative that insurers thoroughly review this Bulletin and cover screening, diagnosis, and treatment of all insureds for STIs in a clinically appropriate manner

[18] Insurers are permitted to limit preventive coverage to self-tests obtained through in-network suppliers and clinical laboratories if adequate access is provided through network channels. 45 Code Fed. Regs. § 147.130(a)(3) (but see *infra*, n. 22 on the exceptions process).

[19] The bulleted text appearing in the Appendix was pasted there from the source material, except for additions in [parentheses]. Internal cross-references and citations were omitted; **emphasis** was added. Note that the USPSTF separately recommends screening of pregnant persons for HBV and syphilis.

according to their individual risk factors or symptoms because detection is pivotal to curbing the contemporary STI epidemic.[20]

1. **Human immunodeficiency virus screening: adolescents and adults aged 15 to 65 years, adolescents and adults at increased risk, and pregnant persons (Grade "A" v. 6/2019)**

This example is based on the following USPSTF recommendation, HRSA guideline, and CDC recommendations for HIV screening:

- USPSTF brief recommendation statement
- USPSTF on patient population under consideration
- USPSTF on screening intervals
- USPSTF on screening tests
- HRSA Women's Preventive Services Guidelines (v. 12/2021)
- CDC recommendations for HIV screening (non-pregnant persons)

Preventive Care Conclusion 1: An insurer may not impose a limit of one HIV test per calendar year (or 12-month period) on HIV screening of the USPSTF or HRSA patient populations because the appropriate screening interval is determined by an attending provider based on an assessment of individual risk factors. HIV screening includes supplemental testing after a reactive assay to differentiate between HIV-1 and HIV-2 antibodies, and if necessary, an HIV-1 nucleic acid test to differentiate acute HIV-1 infection from a false positive test result.

Under the USPSTF recommendation and current, evidence-based CDC guidelines for HIV screening, an insurer may not impose a quantitative frequency limit on HIV screening of the USPSTF or HRSA patient populations that results in denial of coverage, or application of cost sharing to, periodic HIV screening as frequently as once every three months. [21]

Preventive Care and SB 306 Conclusion 1: An insurer must cover at least one FDA-approved HIV antigen/antibody combination home self-collection test kit and laboratory processing, as well as at least one rapid POC HIV antigen/antibody test that is suitable for use in nonclinical settings,[22] under these screening recommendations and the USPSTF's recommendation for HIV PrEP.

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[20] *See* CDC, *Sexually Transmitted Disease Surveillance 2020*.

[21] For HIV testing patients who are beginning or continuing on PrEP, the CDC guidelines include distinct screening frequencies for oral PrEP and injectable PrEP with cabotegravir. Testing of patients on long-acting injectable cabotegravir is more frequent (bimonthly following initiation) than for oral PrEP (quarterly). CDC, HIV Nexus Clinician Resources, Pre-Exposure Prohylaxis (PrEP) (last accessed April 29, 2022).

[22] Insurers who limit preventive services coverage to specific tests must provide "an easily accessible, transparent, and sufficiently expedient exceptions process that is not unduly burdensome" and approve requests for coverage of other available tests without cost sharing when a covered test is medically inappropriate. *See* Departments of Health & Human Services, Labor, and Treasury, *supra* note 6 at p. 2

An insurer must cover an FDA-approved combination HIV self-test for periodic HIV screening as frequently as recommended by the CDC in its most recently updated guidelines on HIV screening or PrEP without cost sharing when: (1) deemed medically necessary or appropriate and ordered directly by an in-network clinician; or (2) furnished through a standing order for patient use based on clinical guidelines and individual patient health needs.

2. **Hepatitis B virus screening: nonpregnant adolescents and adults at increased risk for infection (Grade "B" v. 12/2020)**

This example is based on the following USPSTF and CDC recommendations for hepatitis B virus (HBV) screening:

- USPSTF brief recommendation statement
- USPSTF on patient population under consideration
- USPSTF on assessment of risk
- USPSTF on screening intervals
- CDC on HBV risk factors
- CDC recommendations for HBV screening

Preventive Care Conclusion 2: An insurer may not impose a limit of one HBV test per calendar year (or 12-month period) on screening of asymptomatic, nonpregnant adolescents and adults for HBV because the appropriate screening interval is determined by an attending provider based on an assessment of individual risk factors.

Under the USPSTF recommendation and current, evidence-based CDC guidelines, an insurer may not impose a quantitative frequency limit on HBV screening of the USPSTF patient population that results in denial of coverage, or application of cost sharing to, periodic HBV screening at any clinically reasonable frequency.

3. **Hepatitis C virus screening: adults, including pregnant persons, aged 18 to 79 years (Grade "B" v. 3/2020)**

This example is based on the following USPSTF recommendation, CDC recommendations, and continually updated clinical practice guideline from the American Association for the Study of Liver Diseases (AASLD) and the Infectious Diseases Society of America (IDSA) on hepatitis C virus screening:

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and *FAQs About Affordable Care Act Part 51* (Jan. 10, 2022), at p. 12-13. And while insurers can limit coverage of preventive services to in-network providers, if a network provider cannot provide a recommended preventive item or service, the insurer "must cover the item or service when performed by an out-of-network provider, and may not impose cost sharing with respect to the item or service." 45 Code Fed. Regs. § 147.130(a)(3)(ii). Therefore, insurers who do not provide adequate access to HIV self-tests from in-network test suppliers and clinical laboratories must cover self-tests out-of-network without cost sharing when a self-test is ordered directly by an in-network provider or furnished through a standing order.

- USPSTF brief recommendation statement
- USPSTF on patient population under consideration
- USPSTF on assessment of risk
- USPSTF on screening intervals
- CDC recommendations for HCV screening
- AASLD and IDSA HCV Guidance on testing[23]

Preventive Care Conclusion 3: An insurer may not impose a limit of one test per calendar year (or 12-month period) on HCV screening of asymptomatic adults, including pregnant persons, aged 18 to 79 years without known liver disease because the appropriate screening interval is determined by an attending provider based on an assessment of individual risk factors.

In its *HCV Guidance*, the AASLD and IDSA recommend that clinicians "determine the periodicity of testing based on the risk of infection or reinfection" and test some individuals at increased risk "at least annually." Therefore, an insurer may not impose a quantitative frequency limit on HCV screening that results in denial of coverage, or application of cost sharing to, periodic HCV screening at any clinically reasonable frequency.

Basic Health Care Services Conclusion 3: A health insurer that covers basic health care services[24] must cover HCV screening and testing of individuals who are younger than 18 years of age or older than 79 years of age, or who do not otherwise qualify for the USPSTF patient population under consideration, in accordance with the CDC's guidelines and the AASLD's and IDSA's *HCV Guidance*.

An insurer may not impose a limit of one test per calendar year (or 12-month period) on HCV screening or testing that is recommended by the CDC or the *HCV Guidance* because the appropriate testing interval is determined by an attending provider based on an assessment of individual risk factors.

An insurer may not impose a quantitative frequency limit on HCV screening or testing that is recommended by the CDC or the *HCV Guidance* that results in denial of coverage for periodic HCV testing at any clinically reasonable frequency.

Outpatient Prescription Drug Benefit Conclusion 3: A health insurance policy that covers outpatient prescription drugs[25] must cover direct-acting antivirals (DAAs) for HCV infection because drug therapy with DAAs is medically necessary, "except [for] those with a short life expectancy that cannot be remediated by HCV therapy, liver transplantation, or another directed therapy."[26]

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[23] American Association for the Study of Liver Diseases and the Infectious Diseases Society of America, *HCV Guidance: Recommendations for Testing, Managing, and Treating Hepatitis C*, HCV Testing and Linkage to Care, at p. 12-15 (last updated Oct. 5, 2021).
[24] Insurance Code, *supra* n. 7.
[25] Insurance Code, *supra* n. 10.
[26] AASLD and IDSA, HCV *Guidance*, *supra* n. 23 at p. 24.

4. **Syphilis screening: nonpregnant adults and adolescents at increased risk (Grade "A" v. 6/2016, update in progress 2/22)**

This example is based on the following USPSTF and CDC recommendations for syphilis screening:

- USPSTF brief recommendation statement
- USPSTF on patient population under consideration
- USPSTF on assessment of risk
- USPSTF on screening interval
- CDC recommendations for syphilis screening

Preventive Care Conclusion 4: An insurer may not impose a limit of one test per calendar year (or 12-month period) on syphilis screening of asymptomatic, nonpregnant adolescents and adults who are at increased risk for syphilis infection because the appropriate screening interval is determined by an attending provider based on an assessment of individual risk factors.

Under the USPSTF recommendation and current, evidence-based CDC guidelines, an insurer may not impose a quantitative frequency limit on syphilis screening of the USPSTF patient population that results in denial of coverage, or application of cost sharing to, periodic syphilis screening at any clinically reasonable frequency.

5. **Chlamydia and gonorrhea screening: sexually active women, including pregnant persons (Grade "B" v. 9/21)**

This example is based on the following USPSTF and CDC recommendations for chlamydia and gonorrhea screening:

- USPSTF brief recommendation statement
- USPSTF on patient population under consideration
- USPSTF on assessment of risk
- USPSTF on screening intervals
- CDC recommendations for chlamydia and gonorrhea screening of USPSTF population

Preventive Care Conclusion 5a: An insurer may not impose a limit of one test per calendar year (or 12-month period) on chlamydia or gonorrhea screening of asymptomatic, sexually active adolescents and adults with a cervix who are under 25 years of age, including pregnant persons, because the appropriate anatomical sites and screening interval are determined by an attending provider based on an assessment of individual risk factors. Chlamydia and gonorrhea screening includes retesting of an asymptomatic patient following treatment.

Under the USPSTF recommendation and current, evidence-based CDC guidelines, an insurer may not impose a quantitative frequency limit on chlamydia or gonorrhea screening of the USPSTF patient population that results in denial of coverage, or

application of cost sharing to, periodic chlamydia or gonorrhea screening at any clinically reasonable frequency.

Preventive Care Conclusion 5b: An insurer may not impose a limit of one test per calendar year (or 12-month period) on chlamydia or gonorrhea screening of asymptomatic, sexually active adults with a cervix who are 25 years of age and older, including pregnant persons, because the appropriate anatomical sites and screening interval are determined by an attending provider based on an assessment of individual risk factors. Chlamydia and gonorrhea screening includes retesting of an asymptomatic patient following treatment.

Under the USPSTF recommendation and current, evidence-based CDC guidelines, an insurer may not impose a quantitative frequency limit on chlamydia or gonorrhea screening of the USPSTF patient population that results in denial of coverage, or application of cost sharing to, periodic chlamydia or gonorrhea screening at any clinically reasonable frequency.

6. **CDC-recommended chlamydia and gonorrhea screening: men who have sex with men and persons with HIV**

When the USPSTF updated its recommendation for chlamydia and gonorrhea screening in 2021, it concluded that the evidence was insufficient to assess the balance of benefits and harms of screening in sexually active men. However, the 2021 CDC recommendations for chlamydia and gonorrhea screening of men are stratified by sexual behavior and risk. CDC recommends screening men who have sex with men (MSM) for chlamydia and gonorrhea at anatomic sites exposed to infection at least annually, and every three to six months if at increased risk. CDC also recommends screening persons with HIV for chlamydia and gonorrhea, which is a population the USPSTF did not consider in updating its recommendation.[27]

The CDC recommends the following chlamydia and gonorrhea screening of asymptomatic MSM and persons with HIV:

- Men who have sex with women (MSW) [asymptomatic screening not recommended; suggested for chlamydia in high prevalence clinical settings]
- Men who have sex with men (MSM), and transgender and gender diverse persons [with male anatomy] who have sex with men
- Persons with HIV
- Screening recommendations for MSM, Importance of rectal and pharyngeal testing

Basic Health Care Services Conclusion 6a: These CDC screening recommendations, which are not preventive services because they fall outside the scope of the USPSTF recommendations for HIV-negative persons with a cervix, constitute basic health care

[27] USPSTF, *Chlamydia and gonorrhea: screening* (Sept. 2021) ("The USPSTF did not review evidence on screening for chlamydia and gonorrhea in persons living with HIV or taking HIV preexposure prophylaxis. The CDC provides recommendations for these and other specific groups.").

services that an insurer must cover in accordance with the recommendations because they represent current, generally accepted standards of care.

Basic Health Care Services Conclusion 6b: An insurer may not impose a limit of one test per calendar year (or 12-month period) on chlamydia or gonorrhea screening of MSM or persons with HIV because the appropriate anatomical sites and screening interval are determined by an attending provider based on an assessment of individual risk factors. Chlamydia and gonorrhea screening includes retesting of an asymptomatic patient following treatment.

Under current, evidence-based CDC guidelines, an insurer may not impose a quantitative frequency limit on chlamydia or gonorrhea screening of MSM that results in denial of coverage for periodic chlamydia or gonorrhea screening as frequently as once every three months.

Under current, evidence-based CDC guidelines, an insurer may not impose a quantitative frequency limit on chlamydia or gonorrhea screening of persons with HIV that results in denial of coverage for periodic chlamydia or gonorrhea screening at any clinically reasonable frequency.

In conclusion, an insurer that imposes limits on coverage of screening, testing, and treatment for STIs that conflict with current, generally accepted standards of care found in evidence-based CDC and specialty association clinical practice guidelines is not providing clinically appropriate coverage for basic health care services or outpatient prescription drugs. If an insurer's network providers cannot provide geographically accessible or timely access to a covered benefit, an insurer must approve and arrange for the care from an available and accessible out-of-network provider and either cover the services without cost or subject to the policy's in-network cost-sharing terms, as applicable.[28]

Insurers that perform utilization review or otherwise impose coverage limits on STI screening should review the CDC's recommendations on *The Detection of STIs in Special Populations* and evaluate whether their criteria comport with current, generally accepted standards of care and provide equitable access to coverage of clinically appropriate screening for all covered persons. Because benefit designs that impose annual limits on STI screening conflict with current, generally accepted standards of care, insurers who impose annual limits or other clinically inappropriate limits must stop doing so.

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Questions concerning this Bulletin may be directed to Jessica Ryan, Attorney III, at jessica.ryan@insurance.ca.gov.

[28] Cal. Ins. Code § 10112.2; 10 Cal. Code Regs. § 2240.1(e); 45 Code Fed. Regs. § 147.130(a)(3)(ii).

Appendix to Bulletin 2022-3
Compiled Source Material

1. **Human immunodeficiency virus screening: adolescents and adults aged 15 to 65 years, adolescents and adults at increased risk, and pregnant persons (Grade "A" v. 6/2019)**

   - USPSTF brief recommendation statement:
     - The USPSTF recommends that clinicians screen for HIV infection in adolescents and adults aged 15 to 65 years. Younger adolescents and older adults who are at increased risk of infection should also be screened.
     - The USPSTF recommends that clinicians screen for HIV infection in all pregnant persons, including those who present in labor or at delivery whose HIV status is unknown.
   - USPSTF on patient population under consideration:
     - This recommendation applies to adolescents, adults, and all pregnant persons regardless of age. Based on the age-stratified incidence of HIV infection and data on sexual activity in youth, the USPSTF recommends screening for HIV infection beginning at age 15 years. Adolescents younger than 15 years and adults older than 65 years should be screened if they have risk factors for HIV infection.
   - USPSTF on screening intervals:
     - The USPSTF found insufficient evidence to determine appropriate or optimal time intervals or strategies for repeat HIV screening. **Repeat screening is reasonable for persons known to be at increased risk of HIV infection**, such as sexually active men who have sex with men; persons with a sex partner who is living with HIV; or persons who engage in behaviors that may convey an increased risk of HIV infection, such as injection drug use, transactional sex or commercial sex work, having 1 or more new (i.e., since a prior HIV test) sex partners whose HIV status is unknown, or having other factors that can place a person at increased risk of HIV infection (see the Assessment of Risk section). Repeat screening is also reasonable for persons who live or receive medical care in a high-prevalence setting, such as a sexually transmitted disease clinic, tuberculosis clinic, correctional facility, or homeless shelter**. The CDC recommends annual screening in persons at increased risk but recognizes that clinicians may wish to screen high-risk men who have sex with men more frequently (e.g., every 3 or 6 months) depending on the patient's risk factors, local HIV prevalence, and local policies.** Routine rescreening may not be necessary for persons who have not been at increased risk since they last tested negative for HIV.
   - USPSTF on screening tests:
     - **Current CDC guidelines recommend testing for HIV infection with an antigen/antibody immunoassay approved by the US Food and Drug Administration that detects HIV-1 and HIV-2 antibodies and the HIV-1 p24 antigen, with supplemental testing after a reactive assay to differentiate between HIV-1 and HIV-2 antibodies.** If supplemental testing

for HIV-1/HIV-2 antibodies is nonreactive or indeterminate (or if acute HIV infection or recent exposure is suspected or reported), **an HIV-1 nucleic acid test is recommended to differentiate acute HIV-1 infection from a false-positive test result.**
    - Antigen/antibody tests for HIV are highly accurate, with reported sensitivity ranging from 99.76% to 100% and specificity ranging from 99.50% to 100%, and results can be available in 2 days or less. **Rapid antigen/antibody tests are also available.**
    - When using a rapid HIV test for screening, positive results should be confirmed. Pregnant women presenting in labor with unknown HIV status should be screened with a rapid HIV test to get results as soon as possible.
- HRSA Women's Preventive Services Guidelines (v. 12/2021):
    - WPSI recommends all adolescent and adult women, ages 15 and older, receive a screening test for HIV at least once during their lifetime. Earlier or additional screening should be based on risk, and rescreening annually or more often may be appropriate beginning at age 13 for adolescent and adult women with an increased risk of HIV infection.
    - A screening test for HIV is recommended for all pregnant women upon initiation of prenatal care with rescreening during pregnancy based on risk factors. Rapid HIV testing is recommended for pregnant women who present in active labor with an undocumented HIV status.
- CDC recommendations for HIV screening (non-pregnant persons):
    - CDC and USPSTF recommend HIV screening at least once for all persons aged 15–65 years.
    - Persons at higher risk for HIV acquisition, including sexually active gay, bisexual, and other MSM, should be screened for HIV at least annually. Providers can consider the benefits of offering more frequent screening (e.g., every 3–6 months) among MSM at increased risk for acquiring HIV.
    - Providers should use a laboratory-based antigen/antibody (Ag/Ab) combination assay as the first test for HIV, unless persons are unlikely to follow up with a provider to receive their HIV test results; in those cases screening with a rapid POC test can be useful.[29]

2. Hepatitis B virus screening: nonpregnant adolescents and adults at increased risk for infection (Grade "B" v. 12/2020)[30]

- USPSTF brief recommendation statement:
    - The USPSTF recommends screening for hepatitis B virus (HBV) infection in adolescents and adults at increased risk for infection.
- USPSTF on patient population under consideration:

[29] For PrEP, CDC recommends laboratory testing or for same-day prescribing, "[a]dministering a rapid, point-of-care, FDA-approved fingerstick HIV antigen/antibody blood test and drawing blood to send for laboratory testing. PrEP can be prescribed or continued based on a negative rapid antigen/antibody test result while awaiting laboratory test results." CDC, HIV Nexus Clinician Resources, Pre-Exposure Prophylaxis (PrEP) (last accessed April 28, 2022).
[30] *See also*, USPSTF, *Hepatitis B Virus Infection in Pregnant Women: Screening* (July 2019).

    - This recommendation applies to asymptomatic, nonpregnant adolescents and adults at increased risk for HBV infection, including those who were vaccinated before being screened for HBV infection. The USPSTF has made a separate recommendation on screening in pregnant women.
- USPSTF on assessment of risk:
    - The CDC classifies HBV endemicity levels by prevalence of positive HBsAg (high [8%], moderate [2%-7%], or low [<2%]). The estimated prevalence of HBV infection in the general US population is 0.3% to 0.5%, which makes it reasonable to screen adolescents and adults born in countries or regions with an HBsAg prevalence of 2% or greater (regardless of vaccination history in their country of origin) and adolescents and adults born in the US who did not receive the HBV vaccine as infants and whose parents were born in regions with an HBsAg prevalence of 8% or greater (regardless of their biological mother's HBsAg status).
    - HBV screening should also be offered to other risk groups defined by clinical and behavioral characteristics in which prevalence of positive HBsAg is 2% or greater. Persons from such risk groups include persons who have injected drugs in the past or currently; men who have sex with men; persons with HIV; and sex partners, needle-sharing contacts, and household contacts of persons known to be HBsAg positive. Some persons with combinations of risk factors who are not members of risk factor groups listed above may also be at increased risk for HBV infection. Clinicians should therefore consider the populations they serve when making screening decisions.
- USPSTF on screening intervals:
    - For patients with negative HBsAg results who have not received the HBV vaccine series, periodic screening may be useful for those who report continued risk for acquiring HBV transmission, such as persons who continue to inject drugs and men who have sex with men. **Clinical judgment should be used to determine screening frequency.** The USPSTF found no evidence to determine optimal screening intervals.
- CDC on HBV risk factors:
    - The primary risk factors associated with infection among adolescents and adults are unprotected sex with an infected partner, having multiple partners, men having sex with men, having history of other STIs, and injecting drug use. In addition, studies have demonstrated other modes of HBV transmission, including premastication and lapses in health care infection control procedures, as less common sources of transmission.
- CDC recommendations for HBV screening:
    - Women at increased risk (having had more than one sex partner in the previous 6 months, evaluation or treatment for an STI, past or current injection-drug use, and an HBsAg-positive sex partner).
    - Men [who have sex with women] at increased risk (i.e., by sexual or percutaneous exposure).
    - All MSM [men who have sex with men] should be tested for HBsAg, HBV core antibody, and HBV surface antibody.
    - Test [persons with HIV] for HBsAg and anti-HBc and/or anti-HBs.

3. **Hepatitis C virus screening: adults, including pregnant persons, aged 18 to 79 years (Grade "B" v. 3/2020)**

- USPSTF brief recommendation statement:
  - The USPSTF recommends screening for hepatitis C virus (HCV) infection in adults aged 18 to 79 years.
- USPSTF on patient population under consideration:
  - This recommendation applies to all asymptomatic adults [including pregnant persons] aged 18 to 79 years without known liver disease.
- USPSTF on assessment of risk:
  - Although all adults aged 18 to 79 years should be screened, a number of risk factors increase risk. The most important risk factor for HCV infection is past or current injection drug use. In the US, recent increases in HCV incidence have predominantly been among young persons who inject drugs (PWID). Approximately one-third of PWID aged 18 to 30 years are infected with HCV, and 70% to 90% of older PWID are infected. Clinicians may want to consider screening in adolescents younger than 18 years and in adults older than 79 years who are at high risk (eg, past or current injection drug use).
  - Pregnant adults should be screened. HCV prevalence has doubled in women aged 15 to 44 years from 2006 to 2014. From 2011 to 2014, 0.73% of pregnant women tested had an HCV infection, with a 68% increase in the proportion of infants born to HCV-infected mothers. Approximately 1700 infected infants are born annually to 29,000 HCV-infected mothers. Because of the increasing prevalence of HCV in women aged 15 to 44 years and in infants born to HCV-infected mothers, clinicians may want to consider screening pregnant persons younger than 18 years.
- USPSTF on screening intervals:
  - Most adults need to be screened only once. **Persons with continued risk for HCV infection (eg, PWID) should be screened periodically.** There is limited information about the specific screening interval that should occur in persons who continue to be at risk for new HCV infection or how pregnancy changes the need for additional screening.
- CDC recommendations for HCV screening:
  - CDC recommends hepatitis C screening at least once in a lifetime for all adults aged ≥18 years and for all women during each pregnancy, except in settings where the prevalence of HCV infection is <0.1%. One-time hepatitis C testing is also recommended regardless of age, setting, or recognized conditions or exposures (e.g., HIV infection, history of injecting drug use, or children born to women with HCV infection). **Routine periodic HCV testing is recommended for persons with ongoing risk factors (e.g., injecting drug use or hemodialysis).**
- AASLD and IDSA HCV Guidance on testing:
  - One-time, routine, opt out HCV testing is recommended for all individuals aged 18 years or older. [Rating I, B.]
  - One-time HCV testing should be performed for all persons less than 18 years old with activities, exposures, or conditions or circumstances associated with

an increased risk of HCV infection. [Rating I, B.] [See link for risk activities, exposures, and other conditions and circumstances.]
    - Prenatal HCV testing as part of routine prenatal care is recommended with each pregnancy. [Rating I, B.]
    - **Periodic repeat HCV testing should be offered to all persons with activities, exposures, or conditions or circumstances associated with an increased risk of HCV exposure.** [Rating IIa, C.] [See link for risk activities, exposures, and other conditions and circumstances.]
    - **Annual HCV testing is recommended for all persons who inject drugs, for HIV-infected men who have unprotected sex with men, and men who have sex with men taking pre-exposure prophylaxis (PrEP).** [Rating IIa, C.]
    - Because of shared transmission modes, persons with HIV infection are at risk for HCV. Annual HCV testing is recommended for sexually active HIV-infected adolescent and adult men who have sex with men. The presence of concomitant ulcerative sexually transmitted infections, proctitis related to sexually transmitted infections, or high-risk sexual or drug use practices may warrant more frequent testing. Sexual transmission is particularly a risk for HIV-infected men who have unprotected sex with men.
    - Evidence regarding the frequency of HCV testing in persons at risk for ongoing exposures to the virus is lacking. **Clinicians should, therefore, determine the periodicity of testing based on the risk of infection or reinfection.** Because of the high incidence of HCV infection among PWID and HIV-infected men who have unprotected sex with men, HCV testing at least annually using an assay that detects HCV RNA (ie, a quantitative HCV-RNA test) if they have been previously exposed, is recommended among such individuals.

4. **Syphilis screening: nonpregnant adults and adolescents at increased risk (Grade "A" v. 6/2016, update in progress 2/22)**[31]

- USPSTF brief recommendation statement:
    - The USPSTF recommends screening for syphilis infection in persons who are at increased risk for infection.
- USPSTF on patient population under consideration:
    - This recommendation applies to asymptomatic, nonpregnant adults and adolescents who are at increased risk for syphilis infection. Screening for syphilis in nonpregnant populations is an important public health approach to preventing the sexual transmission of syphilis and subsequent vertical transmission of congenital syphilis.
- USPSTF on assessment of risk:
    - The USPSTF recommends screening for syphilis in persons who are at increased risk for infection. Based on 2014 surveillance data, men who have sex with men (MSM) and men and women living with HIV have the highest risk for syphilis infection.

[31] *See also*, USPSTF, *Syphilis Infection in Pregnant Women: Screening* (Sept. 2018).

    - When deciding which other persons to screen for syphilis, clinicians should be aware of the prevalence of infection in the communities they serve, as well as other sociodemographic factors that may be associated with increased risk of syphilis infection. Factors associated with increased prevalence that clinicians should consider include history of incarceration, history of commercial sex work, certain racial/ethnic groups, and being a male younger than 29 years, as well as regional variations that are well described.
- USPSTF on screening interval:
    - The optimal screening frequency for persons who are at increased risk for syphilis infection is not well established. **Men who have sex with men or persons living with HIV may benefit from more frequent screening. Initial studies suggest that detection of syphilis infection in MSM or persons living with HIV improves when screening is performed every 3 months compared with annually.**
- CDC recommendations for syphilis screening:
    - Screen asymptomatic adults [women and men who have sex with women] at increased risk (history of incarceration or transactional sex work, geography, race/ethnicity, and being a male younger than 29 years) for syphilis infection.
    - Screen sexually active MSM at least annually; every 3-6 months if at increased risk.
    - Consider screening [transgender and gender diverse people] at least annually based on reported sexual behaviors and exposure.
    - For sexually active individuals with HIV, screen at first HIV evaluation, and at least annually thereafter; More frequent screening might be appropriate depending on individual risk behaviors and the local epidemiology.

5. Chlamydia and gonorrhea screening: sexually active women, including pregnant persons (Grade "B" v. 9/21)

- USPSTF brief recommendation statement:
    - The USPSTF recommends screening for chlamydia in all sexually active women 24 years or younger and in women 25 years or older who are at increased risk for infection.
    - The USPSTF recommends screening for gonorrhea in all sexually active women 24 years or younger and in women 25 years or older who are at increased risk for infection.
- USPSTF on patient population under consideration:
    - This recommendation applies to asymptomatic, sexually active adolescents and adults, including pregnant persons. In this recommendation statement, the recommendations are stratified by "men" and "women," although the net benefit estimates are driven by biological sex (ie, male/female) rather than gender identity. Persons should consider their sex at birth and current anatomy (especially presence of a cervix/vagina) and consult with their own clinician, if necessary, to determine which recommendation best applies to them.
- USPSTF on assessment of risk:

    - Age is a strong predictor of risk for chlamydial and gonococcal infections, with the highest infection rates in women occurring during ages 15 to 24 years. Women 25 years or older are at increased risk if they have a new sex partner, more than 1 sex partner, a sex partner with concurrent partners, or a sex partner who has an STI; practice inconsistent condom use when not in a mutually monogamous relationship; or have a previous or coexisting STI. Exchanging sex for money or drugs and history of incarceration also are associated with increased risk. Clinicians should consider the communities they serve and may want to consult local public health authorities for information about local epidemiology and guidance on determining who is at increased risk.
- USPSTF on screening intervals:
    - **In the absence of studies on screening intervals, a reasonable approach would be to screen patients whose sexual history reveals new or persistent risk factors since the last negative test result**.
- CDC recommendations for chlamydia and gonorrhea screening of USPSTF population:
    - Cisgender women, and transgender and gender diverse people with a cervix: Sexually active women under 25 years of age; 25 years of age and older if at increased risk (those who have a new sex partner, more than one sex partner, a sex partner with concurrent partners, or a sex partner who has an STI [or for gonorrhea, transactional sex]). Retest approximately 3 months after treatment. Rectal chlamydial testing can be considered in females based on reported sexual behaviors and exposure, through shared clinical decision between the patient and the provider. Pharyngeal and rectal gonorrhea screening can be considered in females based on reported sexual behaviors and exposure, through shared clinical decision between the patient and the provider.
    - Pregnant women: All pregnant women under 25 years of age; Pregnant women, 25 years of age and older if at increased risk (those who have a new sex partner, more than one sex partner, a sex partner with concurrent partners, or a sex partner who has an STI). Retest during the 3rd trimester for women under 25 years of age or at risk. Pregnant women with chlamydial infection should have a test of cure 4 weeks after treatment and be retested within 3 months. Pregnant women with gonorrhea should be retested within 3 months.

6. CDC-recommended chlamydia and gonorrhea screening: men who have sex with men and persons with HIV

- Men who have sex with women (MSW) [asymptomatic screening not recommended; suggested for chlamydia in high prevalence clinical settings]:
    - There is insufficient evidence for screening among heterosexual men who are at low risk for infection [for chlamydia and gonorrhea], however, screening young men [for chlamydia] can be considered in high prevalence clinical settings (adolescent clinics, correctional facilities, STI/sexual health clinic).

- Men who have sex with men (MSM), and transgender and gender diverse persons [with male anatomy] who have sex with men:
    - At least annually for sexually active MSM at sites of contact (urethra, rectum, [pharynx for gonorrhea]) regardless of condom use. Every 3 to 6 months if at increased risk (i.e., MSM on PrEP, with HIV infection, or if they or their sex partners have multiple partners).
- Persons with HIV:
    - For sexually active individuals, screen at first HIV evaluation, and at least annually thereafter. More frequent screening might be appropriate depending on individual risk behaviors and the local epidemiology.
- Screening recommendations for MSM, Importance of rectal and pharyngeal testing:
    - Rectal and pharyngeal testing by NAAT for gonorrhea and chlamydia is recognized as an important sexual health consideration for MSM. Rectal gonorrhea and chlamydia are associated with HIV infection, and men with repeat rectal infections can be at substantially higher risk for HIV acquisition. Pharyngeal infections with gonorrhea or chlamydia might be a principal source of urethral infections. … Approximately 70% of gonococcal and chlamydial infections might be missed if urogenital-only testing is performed among MSM because most pharyngeal and rectal infections are asymptomatic. …
    - A detailed sexual history should be taken for all MSM to identify anatomic locations exposed to infection for screening. Clinics that provide services for MSM at high risk should consider implementing routine extragenital screening for N. gonorrhoeae and C. trachomatis infections, and screening is likely to be cost-effective.