

CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-03 Medicare National Coverage Determinations	Centers for Medicare & Medicaid Services (CMS)
Transmittal 141	Date: January 26, 2012
	Change Request 7610

SUBJECT: Screening for Sexually Transmitted Infections (STIs) and High Intensity Behavioral Counseling (HIBC) to Prevent STIs (ICD-10)

I. SUMMARY OF CHANGES: Effective for claims with dates of service on and after November 8, 2011, CMS will cover screening for chlamydia, gonorrhea, syphilis, and hepatitis B with the appropriate FDA-approved lab tests used consistent with FDA-approved labeling and in compliance with CLIA regulations when ordered by a primary care provider and performed by an eligible Medicare provider for these services. This revision to the Medicare National Coverage Determinations Manual is a national coverage determination (NCD). NCDs are binding on all carriers, fiscal intermediaries,[contractors with the Federal government that review and/or adjudicate claims, determinations, and/or decisions], quality improvement organizations, qualified independent contractors, the Medicare appeals council, and administrative law judges (ALJs) (see 42 CFR section 405.1060(a)(4) (2005)). An NCD that expands coverage is also binding on a Medicare advantage organization. In addition, an ALJ may not review an NCD. (See section 1869(f)(1)(A)(i) of the Social Security Act.)

EFFECTIVE DATE: November 8, 2011

IMPLEMENTATION DATE: February 27, 2012 – Non-shared system edits, July 2, 2012 - Shared system changes, CWF provider screen, HICR, and MCS MCSDT changes

Disclaimer for manual changes only: The revision date and transmittal number apply only to red italicized material. Any other material was previously published and remains unchanged. However, if this revision contains a table of contents, you will receive the new/revised information only, and not the entire table of contents.

II. CHANGES IN MANUAL INSTRUCTIONS: (N/A if manual is not updated)

R=REVISED, N=NEW, D=DELETED-*Only One Per Row.*

R/N/D	CHAPTER / SECTION / SUBSECTION / TITLE
N	1/210.10/Screening for Sexually Transmitted Infections (STIs) and High-Intensity Behavioral Counseling (HIBC) to Prevent STIs

III. FUNDING:

For Fiscal Intermediaries (FIs), Regional Home Health Intermediaries (RHHIs) and/or Carriers:

No additional funding will be provided by CMS; Contractor activities are to be carried out within their operating budgets.

For Medicare Administrative Contractors (MACs):

The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC Statement of Work. The contractor is not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the Contracting Officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the Contracting Officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

IV. ATTACHMENTS:

Business Requirements

Manual Instruction

**Unless otherwise specified, the effective date is the date of service.*

Attachment - Business Requirements

Pub. 100-03	Transmittal: 141	Date: January 26, 2012	Change Request: 7610
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SUBJECT: Screening for Sexually Transmitted Infections (STIs) and High Intensity Behavioral Counseling (HIBC) to Prevent STIs (ICD-10)

Effective Date: November 8, 2011

Implementation Date: February 27, 2012 – Non-shared system edits
July 2, 2012 - Shared system changes, CWF provider screen, HICR, and MCS
MCSDT changes

I. GENERAL INFORMATION

A. Background: Pursuant to §1861(ddd) of the Social Security Act, the Centers for Medicare and Medicaid Services (CMS) may add coverage of "additional preventive services" through the National Coverage Determination (NCD) process. The preventive services must meet all of the following criteria:

- (1) Reasonable and necessary for the prevention or early detection of illness or disability.
- (2) Recommended with a grade of A or B by the United States Preventive Services Task Force (USPSTF).
- (3) Appropriate for individuals entitled to benefits under Part A or enrolled under Part B.

The CMS reviewed the USPSTF recommendations and supporting evidence for screening for STIs and HIBC to prevent STIs and determined that the criteria listed above were met, enabling the CMS to cover these preventive services. Thus, effective November 8, 2011, CMS shall cover screening for the indicated STIs and HIBC to prevent STIs. The covered screening lab tests must be ordered by the primary care provider and the HIBC must be provided by primary care providers in primary care settings such as by the beneficiary's family practice physician, internal medicine physician or nurse practitioner in the doctor's office.

A new HCPCS code, *G0445, high-intensity behavioral counseling to prevent sexually transmitted infections, face-to-face, individual, includes: education, skills training, and guidance on how to change sexual behavior, performed semi-annually, 30 minutes*, has been created for use when reporting HIBC to prevent STIs effective November 8, 2011, to be included in the January 2012 Medicare Physician Fee Schedule Database (MPFSDB) and Integrated Outpatient Code Editor (IOCE) updates.

Code G0445 may be paid on the same date of service as an annual wellness visit, evaluation and management (E&M) code, or during the global billing period for obstetrical care, but only one G0445 may be paid on any one date of service. If billed on the same date of service with an E&M code, the E&M code should have a distinct diagnosis code other than the diagnosis code used to indicate high/increased risk for STIs for the G0445 service. An E&M code should not be billed when the sole reason for the visit is HIBC to prevent STIs.

The appropriate screening diagnosis code (ICD-9 V74.5 – screening, bacterial – sexually transmitted, or V73.89 – screening, disease or disorder, viral, specified type NEC) with the screening lab tests identified in this CR will indicate that the test is a screening test and is therefore covered by Medicare as specified in the NCD.

Diagnosis code V69.8 (Other problems related to life style) is used to indicate that the beneficiary is at high/increased risk for STIs. Providers should also use V69.8 for sexually active adolescents when billing G0445 counseling services.

Diagnosis codes V22.0 – supervision of normal first pregnancy, V22.1 – supervision of other normal pregnancy, or V23.9 – supervision of unspecified high-risk pregnancy, are to be used in addition to the above coding instructions when appropriate.

For services provided on an annual basis, this is defined as a 12-month period.

B. Policy: CMS will cover screening for chlamydia, gonorrhea, syphilis and hepatitis B with the appropriate FDA approved/cleared laboratory tests, used consistent with FDA approved labeling and in compliance with the Clinical Laboratory Improvement Act (CLIA) regulations, when ordered by the primary care physician or practitioner, and performed by an eligible Medicare provider for these services.

- Screening for chlamydia and gonorrhea:
 - Pregnant women who are 24 years old or younger when the diagnosis of pregnancy is known, and then repeat screening during the third trimester if high-risk sexual behavior has occurred since the initial screening test.
 - Pregnant women who are at increased risk for STIs when the diagnosis of pregnancy is known, and then repeat screening during the third trimester if high-risk sexual behavior has occurred since the initial screening test.
 - Women at increased risk for STIs annually.
- Screening for syphilis:
 - Pregnant women when the diagnosis of pregnancy is known, and then repeat screening during the third trimester and at delivery if high-risk sexual behavior has occurred since the previous screening test.
 - Men and women at increased risk for STIs annually.
- Screening for hepatitis B:
 - Pregnant women at the first prenatal visit when the diagnosis of pregnancy is known, and then re-screening at the time of delivery for those with new or continuing risk factors.

CMS will also cover up to two individual - 20 to 30 minute, face to face counseling sessions annually for Medicare beneficiaries for HIBC to prevent STIs for all sexually active adolescents and for adults at increased risk for STIs, if referred for this service by a primary care provider and provided by a Medicare eligible primary care provider in a primary care setting. HIBC is defined as a program intended to promote sexual risk reduction or risk avoidance which includes each of these broad topics, allowing flexibility for appropriate patient-focused elements:

- education,
- skills training,
- guidance on how to change sexual behavior.

The high/increased risk individual sexual behaviors, based on the USPSTF guidelines, include any of the following:

- Multiple sex partners
- Using barrier protection inconsistently
- Having sex under the influence of alcohol or drugs
- Having sex in exchange for money or drugs
- Age (24 years of age or younger and sexually active for women for chlamydia and gonorrhea)
- Having an STI within the past year
- IV drug use (hepatitis B only)
- In addition for men – men having sex with men (MSM) and engaged in high risk sexual behavior, but no regard to age

In addition to individual risk factors, community social factors such as high prevalence of STIs in the community populations should be considered in determining high/increased risk for chlamydia, gonorrhea, syphilis, and in recommending HIBC.

High/increased risk sexual behavior for STIs is determined by the primary care provider by assessing the patient’s sexual history which is part of any complete medical history, typically part of an annual wellness visit or prenatal visit and considered in the development of a comprehensive prevention plan. The medical record should be a reflection of the service provided.

For the purposes of this NCD, a primary care setting is defined as the provision of integrated, accessible health care services by clinicians who are accountable for addressing a large majority of personal health care needs, developing a sustained partnership with patients, and practicing in the context of family and community. Emergency departments, inpatient hospital settings, ambulatory surgical centers, independent diagnostic testing facilities, skilled nursing facilities, inpatient rehabilitation facilities, clinics providing a limited focus of health care services, and hospice are examples of settings not considered primary care settings under this definition.

For the purposes of this NCD, a “primary care physician” and “primary care practitioner” will be defined consistent with existing sections of the Social Security Act (§1833(u)(6), §1833(x)(2)(A)(i)(I) and §1833(x)(2)(A)(i)(II)).

§1833(u)

(6) Physician Defined.—For purposes of this paragraph, the term “physician” means a physician described in section [1861\(r\)\(1\)](#) and the term “primary care physician” means a physician who is identified in the available data as a general practitioner, family practice practitioner, general internist, or obstetrician or gynecologist.

§1833(x)(2)(A)(i)

(I) is a physician (as described in section [1861\(r\)\(1\)](#)) who has a primary specialty designation of family medicine, internal medicine, geriatric medicine, or pediatric medicine; or

(II) is a nurse practitioner, clinical nurse specialist, or physician assistant (as those terms are defined in section [1861\(aa\)\(5\)](#)).

NOTE: See Pub. 100-03 NCD Manual, section 210.10, and Pub. 100-04, Claims Processing Manual, Chapter 18, section 170.

II. BUSINESS REQUIREMENTS TABLE

Use “Shall” to denote a mandatory requirement

Number	Requirement	Responsibility (place an “X” in each applicable column)									
		A / B M A C	D M E M A C	F I I E R	C A R I E R	R H H I S S	Shared-System Maintainers				OTHER
						F I S	M C S	V M S	C W F		
7610-03.1	Effective for dates of service on and after November 8, 2011, contractors shall pay claims for screening for chlamydia, gonorrhea, syphilis, and hepatitis B, and	X		X	X						

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A / B	D M E	F I	C A R R I E R	R H H I	Shared-System Maintainers				OTHER
		M A C	M A C		I E R	I S S	F I S	M C S	V M S	C W F	
	for HIBC to prevent STIs for Medicare beneficiaries subject to criteria in Pub. 100-03, NCD Manual, section 210.10 and Pub 100-04, Claims Processing Manual, Chapter 18, section 170, for claims processing instructions. Refer to CR 7610-04 for detailed business requirements.										

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A / B	D M E	F I	C A R R I E R	R H H I	Shared-System Maintainers				OTHER
		M A C	M A C		I E R	I S S	F I S	M C S	V M S	C W F	
7610-03.2	A provider education article related to this instruction will be available at http://www.cms.hhs.gov/MLNMattersArticles/ shortly after the CR is released. You will receive notification of the article release via the established "MLN Matters" listserv. Contractors shall post this article, or a direct link to this article, on their Web site and include information about it in a listserv message within one week of the availability of the provider education article. In addition, the provider education article shall be included in your next regularly scheduled bulletin. Contractors are free to supplement MLN Matters articles with localized information that would benefit their provider community in billing and administering the Medicare program correctly.	X		X	X						

IV. SUPPORTING INFORMATION

Section A: For any recommendations and supporting information associated with listed requirements, use the box below: N/A

X-Ref Requirement Number	Recommendations or other supporting information:

Section B: For all other recommendations and supporting information, use this space: N/A

V. CONTACTS

Pre-Implementation Contact(s):

Deirdre O'Connor, Coverage, 410-786-3263, deirdre.oconnor@cms.hhs.gov,
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Wanda Belle, Coverage, 410-786-7491, wanda.belle@cms.hhs.gov,
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Post-Implementation Contact(s):

Contact your Contracting Officer's Technical Representative (COTR) or Contractor Manager, as applicable.

VI. FUNDING

Section A: For *Fiscal Intermediaries (FIs)*, *Regional Home Health Intermediaries (RHHIs)*, and/or *Carriers*:

No additional funding will be provided by CMS; contractor activities are to be carried out within their operating budgets.

Section B: For *Medicare Administrative Contractors (MACs)*:

The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC Statement of Work. The contractor is not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the Contracting Officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the Contracting Officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

Medicare National Coverage Determinations Manual

Chapter 1, Part 4 (Sections 200 – 310.1)

Coverage Determinations

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(Rev. 141, 01-26-12)

210.10 - Screening for Sexually Transmitted Infections (STIs) and High Intensity Behavioral Counseling (HIBC) to Prevent STIs

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(Rev. 141, Issued: 01-26-12, Effective: 11-08-2011, Implementation: 02-27-12)

A. General

Sexually transmitted infections (STIs) are infections that are passed from one person to another through sexual contact. STIs remain an important cause of morbidity in the United States and have both health and economic consequences. Many of the complications of STIs are borne by women and children. Often, STIs do not present any symptoms so can go untreated for long periods of time. The presence of an STI during pregnancy may result in significant health complications for the woman and infant. In fact, any person who has an STI may develop health complications. Screening tests for the STIs in this national coverage determination (NCD) are laboratory tests.

Under §1861(ddd) of the Social Security Act (the Act), the Centers for Medicare & Medicaid Services (CMS) has the authority to add coverage of additional preventive services if certain statutory requirements are met. The regulations provide:

§410.64 Additional preventive services

(a) Medicare Part B pays for additional preventive services not described in paragraph (1) or (3) of the definition of “preventive services” under §410.2, that identify medical conditions or risk factors for individuals if the Secretary determines through the national coverage determination process (as defined in section 1869(f)(1)(B) of the Act) that these services are all of the following: (1) reasonable and necessary for the prevention or early detection of illness or disability, (2) recommended with a grade of A or B by the United States Preventive Services Task Force, (3) appropriate for individuals entitled to benefits under Part A or enrolled under Part B.

(b) In making determinations under paragraph (a) of this section regarding the coverage of a new preventive service, the Secretary may conduct an assessment of the relation between predicted outcomes and the expenditures for such services and may take into account the results of such an assessment in making such national coverage determinations.

The scope of the national coverage analysis for this NCD evaluated the evidence for the following STIs and high intensity behavioral counseling (HIBC) to prevent STIs for which the United States Preventive Services Task Force (USPSTF) has issued either an A or B recommendation:

- *Screening for chlamydial infection for all sexually active non-pregnant young women aged 24 and younger and for older non-pregnant women who are at increased risk,*
- *Screening for chlamydial infection for all pregnant women aged 24 and younger and for older pregnant women who are at increased risk,*
- *Screening for gonorrhea infection in all sexually active women, including those who are pregnant, if they are at increased risk,*

- *Screening for syphilis infection for all pregnant women and for all persons at increased risk,*
- *Screening for hepatitis B virus (HBV) infection in pregnant women at their first prenatal visit,*
- *HIBC for the prevention of STIs for all sexually active adolescents, and for adults at increased risk for STIs.*

B. Nationally Covered Indications

CMS has determined that the evidence is adequate to conclude that screening for chlamydia, gonorrhea, syphilis, and hepatitis B, as well as HIBC to prevent STIs, consistent with the grade A and B recommendations by the USPSTF, is reasonable and necessary for the early detection or prevention of an illness or disability and is appropriate for individuals entitled to benefits under Part A or enrolled under Part B.

Therefore, effective for claims with dates of services on or after November 8, 2011, CMS will cover screening for these USPSTF-indicated STIs with the appropriate Food and Drug Administration (FDA)-approved/cleared laboratory tests, used consistent with FDA-approved labeling, and in compliance with the Clinical Laboratory Improvement Act (CLIA) regulations, when ordered by the primary care physician or practitioner, and performed by an eligible Medicare provider for these services.

Screening for chlamydia and gonorrhea:

- *Pregnant women who are 24 years old or younger when the diagnosis of pregnancy is known, and then repeat screening during the third trimester if high-risk sexual behavior has occurred since the initial screening test.*
- *Pregnant women who are at increased risk for STIs when the diagnosis of pregnancy is known, and then repeat screening during the third trimester if high-risk sexual behavior has occurred since the initial screening test.*
- *Women at increased risk for STIs annually.*

Screening for syphilis:

- *Pregnant women when the diagnosis of pregnancy is known, and then repeat screening during the third trimester and at delivery if high-risk sexual behavior has occurred since the previous screening test.*
- *Men and women at increased risk for STIs annually.*

Screening for hepatitis B:

- *Pregnant women at the first prenatal visit when the diagnosis of pregnancy is known, and then rescreening at time of delivery for those with new or continuing risk factors.*

In addition, effective for claims with dates of service on or after November 8, 2011, CMS will cover up to two individual 20- to 30-minute, face-to-face counseling sessions annually for Medicare beneficiaries for HIBC to prevent STIs, for all sexually active adolescents, and for adults at increased risk for STIs, if referred for this service by a primary care physician or practitioner, and provided by a Medicare eligible primary care provider in a primary care setting. Coverage of HIBC to prevent STIs is consistent with the USPSTF recommendation.

HIBC is defined as a program intended to promote sexual risk reduction or risk avoidance, which includes each of these broad topics, allowing flexibility for appropriate patient-focused elements:

- *education,*
- *skills training,*
- *guidance on how to change sexual behavior.*

*The **high/increased risk** individual sexual behaviors, based on the USPSTF guidelines, include any of the following:*

- *Multiple sex partners*
- *Using barrier protection inconsistently*
- *Having sex under the influence of alcohol or drugs*
- *Having sex in exchange for money or drugs*
- *Age (24 years of age or younger and sexually active for women for chlamydia and gonorrhea)*
- *Having an STI within the past year*
- *IV drug use (for hepatitis B only)*
- *In addition for men – men having sex with men (MSM) and engaged in high risk sexual behavior, but no regard to age*

In addition to individual risk factors, in concurrence with the USPSTF recommendations, community social factors such as high prevalence of STIs in the community populations should be considered in determining high/increased risk for chlamydia, gonorrhea, syphilis, and for recommending HIBC.

High/increased risk sexual behavior for STIs is determined by the primary care provider by assessing the patient’s sexual history which is part of any complete medical history, typically part of an annual wellness visit or prenatal visit and considered in the development of a comprehensive prevention plan. The medical record should be a reflection of the service provided.

*For the purposes of this NCD, a **primary care setting** is defined as the provision of integrated, accessible health care services by clinicians who are accountable for addressing a large majority of personal health care needs, developing a sustained partnership with patients, and practicing in the context of family and community. Emergency departments, inpatient hospital settings, ambulatory surgical centers, independent diagnostic testing facilities, skilled nursing facilities, inpatient rehabilitation facilities, clinics providing a limited focus of health care services, and hospice are examples of settings not considered primary care settings under this definition.*

*For the purposes of this NCD, a “**primary care physician**” and “**primary care practitioner**” will be defined based on existing sections of the Social Security Act (§1833(u)(6), §1833(x)(2)(A)(i)(I) and §1833(x)(2)(A)(i)(II)).*

§1833(u)

(6) Physician Defined.—For purposes of this paragraph, the term “physician” means a physician described in section 1861(r)(1) and the term “primary care physician” means a physician who is identified in the available data as a general practitioner, family practice practitioner, general internist, or obstetrician or gynecologist.

§1833(x)(2)(A)(i)

*(I) is a physician (as described in section 1861(r)(1)) who has a primary specialty designation of family medicine, internal medicine, geriatric medicine, or pediatric medicine; or
(II) is a nurse practitioner, clinical nurse specialist, or physician assistant (as those terms are defined in section 1861(aa)(5));*

C. Nationally Non-Covered Indications

Unless specifically covered in this NCD, any other NCD, or in statute, preventive services are non-covered by Medicare.

D. Other

Medicare coinsurance and Part B deductible are waived for these preventive services.

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. See the claims processing manual for further instructions on claims processing.

For services provided on an annual basis, this is defined as a 12-month period.

(This NCD last reviewed November 2011.)