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Evidence-Statements for Recommended Clinical Preventive Service Benefits

Overview:

The scientific evidence behind each of the 46 screening, testing, counseling, immunization, preventive medication, and (preventive) treatment benefit recommendations.

Abdominal Aortic Aneurysm, Screening

Alcohol Misuse, Screening and counseling

Aspirin Therapy for the Prevention of Cardiovascular Disease, Counseling

Breast Cancer

Breast Cancer, *Screening*

Breast Cancer Genetic Risk Assessment and BRCA Mutation Testing, *Counseling, testing, and preventive treatment*

Breast Cancer, *Counseling and preventive medication*

Cervical Cancer, Screening

Childhood Health Promotion

Child Development, *Screening*

Dental Caries, *Preventive medication*

Immunizations

Lead, Elevated Blood Level, *Screening*

Newborn Hearing, *Screening*

Newborn Screening for Genetic and Endocrine Disorders, *Screening, medical foods, and treatment*

Vision, *Screening*

Colorectal Cancer, Screening

Contraceptive Use, Counseling and preventive intervention

Depression, Screening

Diabetes (type 2), Screening

Healthy Diet, Counseling

Healthy Pregnancy

Alcohol Misuse, *Screening and counseling*

Asymptomatic Bacteriuria, *Screening*

Breastfeeding, *Counseling*

Folic Acid Supplementation, *Counseling and preventive medication*

Group B Streptococcal Disease (GBS), *Screening and preventive medication*

Hepatitis B Virus (HBV), *Screening, immunization, and treatment*

Human Immunodeficiency Virus (HIV), *Screening, counseling, and preventive medication*

Influenza, *Immunization*

Preeclampsia, *Screening*

Prenatal Diagnosis of Chromosomal Abnormalities and Neural Tube Defects (NTDs), *Screening and testing*

Rh (D) Incompatibility, *Screening and preventive medication*

Rubella, *Screening*

Syphilis, *Screening*

Tetanus, *Immunization*

Tobacco Use Treatment, *Screening and counseling*

Hypertension, Screening and treatment

Immunizations (Child, Adolescent, Adult)

Lipid Disorders, Screening, counseling, and treatment

Motor Vehicle-Related Injury Prevention, Counseling

Obesity, Screening, counseling, and treatment

Osteoporosis, Screening and treatment

Sexually Transmitted Infections (STIs)

Counseling to Prevent STIs, *Counseling*

Chlamydia, *Screening*

Gonorrhea, *Screening*

Human Immunodeficiency Virus (HIV), *Screening and counseling*

Syphilis, *Screening*

Tobacco Use Treatment, Screening, counseling, and treatment

Tuberculosis, Screening



EVIDENCE-STATEMENT:

TOBACCO USE TREATMENT (Screening, Counseling, and Treatment)

**Why This Chapter is
Important for
Employers:
An Overview**

- Tobacco use is the leading cause of preventable death in the United States. Each year, approximately 440,000 individuals die as a result of smoking¹, accounting for 20% of all deaths in the United States annually.²
- In the United States the direct medical costs associated with smoking total \$75.5 billion per year.² Smoking also costs an estimated \$92 billion per year in lost productivity due to sickness and premature death.³
- Smokers who successfully stop smoking reduce their potential medical costs associated with cardiovascular disease by an average of \$47 during the first year and approximately \$853 during the following 7 years (in year 1995 dollars).⁴
- Cost analyses have shown that tobacco-cessation benefits, from an employer's perspective, are cost-saving.⁵ An employer's cost to implement a tobacco-cessation program becomes cost-neutral at 3 years and begins to save healthcare dollars at 5 years.⁶
- Screening for tobacco use allows clinicians to identify tobacco users and offer them effective cessation treatments such as counseling and pharmacotherapy (nicotine replacement products or cessation medications). Counseling and pharmacotherapy have each been proven to double quit rates.⁷

Clinical Preventive Service Recommendations

**U.S. Preventive
Services Task Force
Recommendation
(USPSTF)**

The U.S. Preventive Services Task Force (USPSTF) strongly recommends that clinicians screen all adults for tobacco use and provide tobacco cessation interventions for those who use tobacco products.⁸

**Evidence Rating: A
(Strongly
Recommended/
Good Evidence)**

The USPSTF found good evidence that brief smoking cessation interventions, including screening, brief behavioral counseling (less than 3 minutes), and pharmacotherapy delivered in primary care settings, are effective in increasing the proportion of smokers who successfully quit smoking and remain abstinent after 1 year. The USPSTF and the Surgeon General's Report on the Health Consequences of Smoking found good evidence that smoking cessation lowers the risk for heart disease, stroke, cancer, and lung disease.⁹⁻¹⁰ The USPSTF concluded that there is good evidence that even small increases in the quit rates from tobacco cessation counseling and/or medication would produce important health benefits.⁸

The USPSTF strongly recommends that clinicians screen all pregnant women for tobacco use and provide augmented pregnancy-tailored counseling to those who smoke.⁸

The USPSTF found good evidence that extended or augmented smoking cessation counseling (5 to 15 minutes) using messages and self-help materials tailored for pregnant smokers, compared with brief generic counseling interventions alone, substantially increases abstinence rates during pregnancy and leads to increased birth weights. Although relapse rates are high in the post-partum period, the USPSTF concluded that reducing smoking during pregnancy is likely to have substantial health benefits for both the baby and the expectant mother.

<p>CDC Recommendation</p>	<p>The <i>Community Guide to Preventive Services</i> strongly recommends providing coverage for tobacco dependence treatment and initiating provider reminder systems to enhance treatment.¹¹</p>
<p>Evidence Rating: Strongly Recommended/ Strong Evidence</p>	<p>Recommendations are based on the strength of the evidence of effectiveness found through a systematic review of published studies conducted by a team of experts on behalf of the Task Force. Strong evidence indicates that there are a number of supportive studies that recommend the action.¹²</p>
<p>Other Recommended Guidance U.S. Public Health Service</p>	<p>The U.S. Public Health Service Clinical Practice Guideline, <i>Treating Tobacco Use and Dependence</i> (PHS Guideline) strongly recommends screening for tobacco use and providing tobacco cessation treatment (including counseling and/or medication).¹³ The U.S. Public Health Service found good evidence that benefits covering screening for tobacco use and providing cessation treatment (counseling and pharmacotherapy) to those who use tobacco are effective in increasing the proportion of smokers who successfully quit and remain abstinent at one year.⁷</p>
<p>Evidence Rating: Strongly Recommended/ Strong Evidence</p>	<p>Recommendations are based on research from multiple, well-designed randomized clinical trials, directly relevant to the recommendation that yielded a consistent pattern of findings.</p>
<p>Centers for Medicare and Medicaid Services (CMS)</p>	<p>The Centers for Medicare and Medicaid Services (CMS) recommends that physicians provide tobacco screening, counseling, and treatment services. Medicare provides coverage for 2 cessation attempts per year. Each attempt includes a maximum of 4 intermediate or intensive counseling cessations for a total maximum benefit of 8 counseling sessions in a 12-month period. Medicare Part D covers all smoking cessation medications that are prescribed by a physician.¹³</p>
<p>Evidence Rating:</p>	<p>CMS Mandate</p>
<p>Information Sources</p>	<p>The recommendations and supporting information contained in this document came from several sources, including the:</p> <ul style="list-style-type: none"> • Center for Medicaid and Medicare Services (CMS) • Centers for Disease Control and Prevention (CDC) • <i>Community Guide to Preventive Services</i> • George Washington University, Center for Health Services Research and Policy • Partnership for Prevention • Peer-reviewed research • U.S. Preventive Services Task Force (USPSTF) • U.S. Public Health Service (PHS) • U.S. Surgeon General <p>The background and supporting information contained in this document is a compilation of research findings. All information presented in this document should be attributed to its referenced source and should not be considered a reflection of other organizations cited in the text.</p>

Condition/Disease Specific Information

Epidemiology of Condition/Disease

Tobacco use contributes to many diseases and is the primary underlying cause of death in the United States. Each year, approximately 440,000 individuals die as a result of smoking¹, accounting for 20% of all deaths in the United States annually.² Approximately 155,000 of these deaths result from cancer, 80,000 result from ischemic heart disease, and 17,000 result from cerebrovascular disease.

Among the estimated 43.4% (91.5 million) of persons alive in 2003 who had ever smoked, 50.3% (45.9 million) were former smokers and 49.7% (45.4 million) were current smokers. Current smokers make up 20.9% of the adult population in the United States. If these current smokers continue smoking, half will die due to their tobacco use.²

Tobacco use also affects the health of non-smokers. Second-hand smoke exposure at work or at home (also called environmental tobacco smoke) increases non-smokers' risk of developing heart disease by 25% to 30% and increases their risk of lung cancer by 20% to 30%.¹⁴ Second-hand smoke exposure contributes to the deaths of 38,000 people each year; 3,000 die as a result of lung cancer and 35,000 die as a result of cardiovascular disease.² In addition, each year in the United States 300,000 children suffer from respiratory tract infections and asthma as a result of being exposed to secondhand smoke.¹⁵ Smoking during pregnancy is particularly dangerous because it increases the risks of premature birth, miscarriage, stillbirth, and low birth weight.¹⁰ Prenatal tobacco use resulted in an estimated 1,007 infant deaths annually between 1995 and 1999.¹⁶

There is substantial evidence that smoking cessation improves health by lowering an individual's risk for diseases caused by smoking such as heart disease, stroke, and cancer.¹ Yet despite the documented risks of smoking, 20.8% of the United States population continues to smoke.² Seventy percent (70%) of smokers say they want to quit and each year 41% of smokers make a quit attempt of at least 24 hours.⁶ Without assistance, only 7% are abstinent at 1 year.¹⁷

Condition/Disease Risk Factors

There are numerous risk factors for cigarette smoking, including: younger age, male sex, race, a lower level of education, and low socioeconomic status.¹⁸

Young adults (18 to 24-year-olds and 25 to 44-year-olds) are more likely to smoke than older adults (45 to 64-year-olds and persons above the age of 65).¹⁸ Nearly 80% of all adult smokers began smoking before they were 18 years old, and it is estimated that more than 2,000 adolescents become daily smokers each day.¹⁹ During 2005, 23% of high school students smoked cigarettes daily.²⁰

Men are also at increased risk of tobacco use; while 23.4% of men smoke cigarettes, only 18.5% of women smoke.¹⁸

The prevalence of cigarette smoking by race is highest among American Indians/Alaska Natives (33.%), followed by whites (22.2 %), African-Americans (20.2%), Hispanics (15%), and Asians [excluding Native Hawaiians and other Pacific Islanders] (11.3%).¹⁸

Approximately 39.6% of adults with a General Education Development (GED) diploma and 34% of adults with 9 to 11 years of education smoke, while only 11.7% of adults who complete an undergraduate degree and 8% of adults who complete a graduate college degree smoke.¹⁸ Cigarette smoking is also more common among adults who live below the poverty level (29.1%) than among those living at or above the poverty level (20.6%).¹⁸

Value of Prevention

Economic Burden of Condition/Disease

The cost of smoking-related illnesses and the loss of productivity associated with smoking are considerable. In the United States, the direct medical costs associated with smoking are \$75.5 billion per year.³ During 1997 to 2001, these expenditures plus productivity losses exceeded \$167 billion per year.³

Individuals who smoke have higher total medical expenses than do nonsmokers due to their higher burden of illness. Men who smoke incur \$15,800 and women who smoke incur \$17,500 more in lifetime medical expenses than do nonsmokers (in year 2002 dollars).³

Workplace Burden of Condition/Disease

In addition to direct medical costs, smokers incur higher costs related to disability, lost productivity, and absenteeism than do nonsmokers. For example, men who smoke use 4 more sick days per year than do nonsmoking males, and women who smoke use 2 more sick days per year than do nonsmoking females.⁶ In 1999, lost productivity due to smoking and smoking-related illnesses cost employers \$1,897 per smoking employee. Excess medical expenses due to smoking and smoking-related illnesses cost employers \$1,850 per smoking employee (both figures are adjusted to year 2002 dollars).³

Economic Benefit of Preventive Intervention

Smokers who successfully stop smoking reduce potential medical costs associated with cardiovascular disease by about \$47 during the first year and by about \$853 during the following 7 years (in year 1995 dollars).^{4,21} An annual drop of 1 percentage point in smoking prevalence among pregnant women would prevent 1,300 low birth weight live births and save 21 million in direct medical costs in the first year of a smoking cessation program.²² Besides the savings in healthcare costs, economic benefits of preventive intervention include reductions in absenteeism costs, on-the-job productivity loss, life-insurance costs, and costs associated with fire and property damage due to smoking.^{6,23}

Estimated Cost of Preventive Intervention

The cost of implementing a comprehensive tobacco cessation program including screening, counseling, and treatment, will vary by location and provider base, but is generally considered to be low. Research has shown

that the average cost of providing a comprehensive tobacco cessation program for all employees ranges from 10 cents to 40 cents per member, per month.²⁴

In 2004, the private-sector cost of screening for tobacco use averaged \$39; approximately 95% of all paid claims fell within the range of \$0 to \$129.²⁵ In 2004, the private-sector cost of counseling averaged \$39 per session; approximately 95% of all paid claims fell within the range of \$0 to \$134 per session.²⁵

The cost of pharmacological interventions vary depending on type and dosage. The average wholesale price (AWP) of a 1-month supply of bupropion ranges from \$86.54 to \$196.07 depending on the brand and type chosen; a 1-month supply of varenicline (Chantix™) is \$89.60.²⁶

**Cost-Effectiveness
and/or Cost-Benefit
Analysis of
Preventive
Intervention**

Research has shown that tobacco screening and cessation-treatment efforts are cost-effective from a societal perspective. Cost analyses have shown that the provision of tobacco-cessation benefits are cost-saving from an employer's perspective.¹² The cost to employers of implementing a tobacco cessation program equalizes at 3 years and begins to save healthcare dollars at 5 years.⁶

Smokers who successfully stop smoking reduce potential medical costs associated with cardiovascular disease (including heart attack and stroke) by about \$47 during the first year and by about \$853 during the following 7 years.⁴ In fact, treating tobacco use ranked the highest among adult preventive services in terms of health impact, cost-effectiveness and cost, yet, according to a recent study by the Partnership for Prevention, the service is provided to less than 35% of tobacco users.¹²

The most cost-effective population to target for smoking cessation programs is pregnant women.⁴ Pregnant women incur an additional \$704 in neonatal healthcare costs compared to nonsmokers. Clinical trials have shown that, for every \$1 invested in smoking cessation programs for pregnant women, \$7.75 are saved in short-term medical costs and an additional \$7.63 (in year 2002 dollars) are saved in long-term costs by preventing disability among low birth weight infants who survive.⁵

The manner in which tobacco cessation programs are crafted influences their cost-effectiveness. For example, reducing the patient out-of-pocket costs for effective cessation therapies provides a net benefit of \$362 to \$1,449 per enrollee.²⁷ In fact, subsidizing the out-of-pocket expense for patients who wish to quit smoking increases the use of effective cessation therapies, increases the number of people who attempt to quit, and — most importantly — increases the number of people who quit successfully.²⁸

Preventive Intervention Information

Preventive Intervention: Purpose of Screening, Counseling, and Treatment

Screening for tobacco use allows clinicians to identify tobacco users and offer them effective cessation treatments such as counseling and pharmacotherapy (nicotine replacement products or cessation medications). Counseling and pharmacotherapy have each been proven to double quit rates.⁷

Despite the strong evidence supporting tobacco use screening, cessation counseling, and medication use, and the fact that 70% of smokers report they want to quit smoking, few adults receive recommended care for tobacco use treatment. For example, only 71.2% of smokers are advised to quit by their providers and only 39% of smokers are offered prescription medication or counseling to support the quitting process.²⁹⁻³⁰

Benefits and Risks of Intervention

The benefit of screening for tobacco use and cessation counseling and treatment is substantial. Smoking cessation is proven to lower an individual’s risk for diseases caused by smoking such as heart disease, stroke, and cancer.¹ There are no documented risks to screening for tobacco use.

The benefit of providing smoking-cessation coverage is considerable. As mentioned above, subsidizing the out-of-pocket expense for patients who wish to quit smoking increases the use of effective cessation therapies, increases the number of people who attempt to quit, and — most importantly — increases the number of people who quit successfully.²⁸ Additional workplace interventions, such as establishing smoke-free workplaces, add even more benefit. Smoke-free workplaces and the provision of comprehensive coverage presumably act together to reduce smoking, and they have been demonstrated to increase quit attempts.¹¹

Initiation, Cessation, and Interval Screening

All adults should be screened for tobacco use at every provider visit. Adults who screen positive for tobacco use should be advised to quit and offered counseling and medication at every medical encounter.¹⁰ There is limited evidence on the efficacy of screening and counseling children and adolescents for tobacco use. However, because most adult smokers began smoking during their teenage years, the USPSTF recommends that clinicians screen and counsel this population at their discretion.¹⁰

Counseling

At least two courses of 4 to 6 counseling sessions of at least 30 minutes each should be provided annually, for a total of 12 sessions per calendar year until the patient successfully quits smoking. Some patients may require additional sessions.

Treatment

Guidelines for the duration of medication treatment are specified in the PHS Guideline and differ depending on the medication type.¹⁰

Patients identified as recently quit should be eligible for up to 4 additional counseling sessions and/or 4 to 8 weeks of medication to maintain tobacco abstinence (depending on the medication).¹⁰

Intervention Process Screening

The USPSTF¹⁰ and the PHS Guideline⁷ recommend the use of the “5-A’s” behavioral counseling framework for tobacco screening and counseling. This framework is composed of 5 steps aimed at engaging the patient in a discussion about their tobacco use and their intention to quit:

- **Ask** about tobacco use.
- **Advise** the patient to quit through clear and personalized messages.
- **Assess** the patient’s willingness to quit.
- **Assist** to quit, develop a quit plan, and set a quit date.
- **Arrange** for medications and support services.

Counseling

The PHS Guideline recommends several effective methods of tobacco cessation counseling including brief counseling (3 minutes or under), intensive counseling (5 to 15 minutes), telephone based counseling (4 to 6 sessions), and tailored counseling (with information and support specific to the population, e.g., pregnant women).⁷ The USPSTF further recommends that clinicians provide problem-solving guidance for smokers to develop a quit plan and to overcome common barriers to quitting. Practices that complement the 5-A framework include provision of medications, motivational interviewing or other methods of intensive counseling, referral for those who may need extra help, and referral to telephone quitlines.¹⁰

The USPSTF and the PHS Guideline note that there is a dose-response relationship between the intensity and frequency of counseling and tobacco abstinence rates.^{7,10} For example, brief counseling interventions (under 3 minutes) are more effective than no counseling, but intensive counseling sessions (5 to 15 minutes) are more effective than brief counseling sessions. The more time a patient is exposed to counseling, the more likely it is that the patient will be successful in quitting.⁷ Although there is limited evidence on the optimal amount of counseling, there is evidence that counseling up to 300 minutes per course of treatment has the most effectiveness.⁷

Treatment

Counseling and pharmacotherapy have each been proven to double quit rates⁷: therefore, a tobacco use treatment benefit should include brief counseling (in-person) and intensive counseling (in-person or telephonic) as described above, and:

- All first-line FDA-approved over-the-counter (OTC) and prescription nicotine replacement products such as nicotine replacement gum, patches, lozenges, inhalers, and nasal sprays.
- All FDA-approved tobacco cessation prescription medications such as bupropion (e.g., Wellbutrin[®] and Zyban[®])⁷ and varenicline (Chantix[™]).

Because reducing out-of-pocket costs for tobacco use treatment medications and nicotine replacement products has proven to further reduce quit rates²⁷, FDA-approved medications/products should not be subject to the deductible and copayments should be reduced or eliminated.

Prescription and Over-the-Counter Tobacco Cessation Medications Approved by the Food and Drug Administration (FDA)

Type	Form	Common Brand Name(s)	Availability
Nicotine Replacement Therapy	Gum	Nicorette®	Over-the-counter (OTC)
	Patch	Nicoderm® Habitrol® Prostep® Nicotrol®	OTC and prescription
	Inhaler	Nicotrol®	Prescription
	Nasal Spray	Nicotrol®	Prescription
	Lozenge	Commit®**	OTC
Bupropion SR[Ⓢ]	Pill	Zyban® Wellbutrin®	Prescription
Varenicline	Pill	Chantix™***	Prescription

**Received FDA approval in October 2002; therefore not addressed in the 2000 PHS Guidelines.

*** Received FDA Approval in May 2006; therefore not addressed in the 2000 PHS Guidelines.

Some populations of smokers require specialized and tailored interventions. For example, pregnant women who smoke should be offered tailored and intensive counseling (5 to 15 minutes) and self-help materials as brief counseling has been found to be less effective in this population.⁷ The PHS Guideline recommends that pharmacotherapy be considered on a case-by-case basis for tobacco cessation during pregnancy.⁷

Strength of Evidence for the Clinical Preventive Service

The level of evidence supporting the recommendations contained in this chapter is described below.

Evidence-Based Research:

U.S. Preventive Services Task Force (USPSTF)

Strength of Evidence: A (Strongly Recommended/Good Evidence)

- The USPSTF found good evidence to recommend that clinicians screen all adults for tobacco use and provide tobacco cessation interventions (counseling, medication, and follow-up) for those who use tobacco products.⁸
- The USPSTF found good evidence to recommend that clinicians screen all pregnant women for tobacco use and provide augmented pregnancy-tailored counseling to those who smoke.⁸

The Centers for Disease Control and Prevention (CDC)

Strength of Evidence: Strong Evidence (Systematic review of published studies conducted by a team of experts).

- The *Community Guide to Preventive Services*¹ strongly recommends establishment of provider reminder systems within health care systems,

provision of telephone counseling services and establishment of effective media campaigns.

U.S. Public Health Service (USPHS)

Strength of Evidence: Strong Evidence (Research from multiple, well designed randomized clinical trials, directly relevant to the recommendation that yielded a consistent pattern of findings).

- The Public Health Service Clinical Practice Guideline, *Treating Tobacco Use and Dependence* (PHS Guideline)³ strongly recommends screening for tobacco use and providing tobacco cessation treatment (counseling and medication).

Recommended Guidance:

The Centers for Medicare and Medicaid Services (CMS)

Strength of Evidence: CMS Mandated

- CMS recommends that physicians provide tobacco screening, counseling, and treatment services. Medicare provides coverage for two cessation attempts per year. Each attempt includes a maximum of 4 intermediate or intensive counseling cessations for a total maximum benefit of 8 counseling sessions in a 12-month period. Medicare Part D covers all smoking cessation medications that are prescribed by a physician.¹³

Authored by:

Rosenthal AC, Campbell KP, Chattopadhyay S. Tobacco use treatment evidence-statement: screening, counseling, and treatment. In: Campbell KP, Lanza A, Dixon R, Chattopadhyay S, Molinari N, Finch RA, editors. *A Purchaser's Guide to Clinical Preventive Services: Moving Science into Coverage*. Washington, DC: National Business Group on Health; 2006.

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