

California Society of Addiction Medicine "The Voice for Treatment"

Minimum Insurance Benefits for Patients with Nicotine and Tobacco Use Disorder

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TOBACCO IS THE LEADING PREVENTABLE CAUSE OF DEATH AND DISEASE IN THE UNITED STATES

Tobacco is the leading preventable cause of mortality in the United States, accounting for 480,000 premature deaths annually.¹ Nicotine is the psychoactive drug found in tobacco products and now also in electronic nicotine delivery systems (ENDS) including e-cigarettes. Nicotine is highly addictive, causing physical dependence, tolerance and withdrawal. Nicotine has the highest prevalence of all substance-related disorders in the United States.² Approximately 17% of the U.S. population are cigarette smokers;³ while smoking rates have declined steadily overall in the US since 1965, prevalence remains high among individuals in addiction treatment, ranging from 77%-93%.⁴ Annually, tobacco costs the nation at least \$130 billion in medical care costs for adults and more than \$1,500 billion in lost productivity, accounting for a major economic burden on employers, health plans and government.⁶ Given the immense health benefits of quitting smoking as well as the public health benefits, quit attempts must be supported.

THE EVIDENCE FOR TOBACCO TREATMENT IS COMPELLING

Quitting tobacco greatly reduces smoking-related morbidity and mortality, both in the short-term and long-term. Additionally, quitting tobacco has indirect benefits on the nearly 42,000 deaths resulting from secondhand smoke exposure.^{1,3} Quitting smoking is possible as is demonstrated by the strong evidence base that has developed over the last 50 years. Today there are more former smokers than current smokers.¹

The 2008 update to the *Public Health Service Clinical Practice Guideline on Treating Tobacco Use and Dependence* recommends providing evidence-based tobacco cessation treatment to all smokers.⁵ Effective cessation treatments include individual, group, and telephone counseling and seven FDA-approved medications. Counseling (such as the 5 A's approach) and medications are effective in increasing quit rates when used separately and even more effective when used together. While even brief cessation advice/counseling by health care providers is effective, more frequent, intense and lengthier sessions produce more robust effects. The seven FDA approved medications including five nicotine replacement therapies (NRTs) and two non-NRT medications, bupropion SR (brand name Zyban if used for tobacco cessation and Wellbutrin if used as an antidepressant) and varenicline (brand name Chantix) have all been proven effective. Combinations of medications work best. Furthermore, medication combinations with psychosocial treatments have the best outcomes.

Tobacco Use Disorder, listed in the Diagnostic and Statistical Manual, Fifth Edition (DSM-5) as a *Substance Related and Addictive Disorder*, is a chronic, relapsing illness.⁶ Quitting smoking often requires multiple quit attempts.^{1,7} While 68.8% of current US smokers reported in 2010 that they wanted to quit completely,⁸ (and about half try to quit each year), less than 10% succeed, in part because less than 1/3 of smokers who try to quit use proven cessation treatments. In 2010, less than half of smokers who saw a health professional in the past year reported receiving advice to quit.⁸

COVERAGE AND COST EFFECTIVENESS OF TREATMENT

Comprehensive cessation coverage (including counseling and medications) increases use of evidence-based cessation treatments and increases quit rates. Cessation treatments are both clinically effective and, relative to treatment of other diseases, is highly cost-effective. Increased follow up (frequency and duration) results in better long-term quit rates.⁵

An example of a state case study is Massachusetts, which offered a nearly comprehensive cessation benefit to Medicaid enrollees in 2006.⁹ The included benefits provided up to two 90-day courses per year of one of the seven FDA-approved cessation medications (with copayments of \$1 or \$3), and up to 16 individual or group counseling sessions. In the first 2 ½ years post-implementation, 37% of smokers in the Massachusetts Medicaid program (more than 70,000 persons) used the benefit and the smoking rate in this population fell from 38% to 28%. Furthermore, annualized hospitalizations for heart attacks and other acute heart disease diagnoses among Medicaid enrollees who used the benefit there was \$3.12 in medical savings for cardiovascular conditions.¹¹

Full tobacco cessation coverage, compared to no or partial coverage, increases utilization of effective treatments and increases quit rates.^{5,12,13}

EVIDENCE-BASED BEST PRACTICES

The Centers for Disease Control (CDC) has put forth recommendations on optimal insurance coverage for tobacco cessation.^{5,14}

- 1. Coverage should be comprehensive, covering all evidencebased cessation treatments, including counseling and both over-the-counter and prescription medications.
 - a. Individual, group, and telephone counseling
 - b. All FDA-approved cessation medications and any future medications approved for this purpose by the FDA
 - c. At least two quit attempts per year
 - d. At least four counseling sessions of at least 10 minutes each per attempt
- 2. Coverage should eliminate or minimize barriers to accessing these treatments.
 - a. Reducing out-of-pocket costs for evidence-based cessation treatments increases use of these treatments and increases the number of tobacco users who quit.¹⁵
 - b. Comprehensive cessation coverage eliminates or minimizes barriers to accessing cessation treatments such as copayments, coinsurance, deductibles, annual or lifetime dollar limits, or prior authorization.¹⁶
- 3. Coverage should be heavily promoted to tobacco users and health care providers, and include monitoring utilization of the coverage, since high utilization is essential for a cessation benefit to have its intended impact.
 - a. Awareness increases use of cessation treatments. In the Massachusetts case example, the benefit was heavily promoted to Medicaid enrollees and providers using tailored communication channels.
 - b. It is easier to promote standard, comprehensive coverage; if coverage varies widely, it is more difficult for providers and patients to understand what is covered for any given patient.

CSAM RECOMMENDATIONS FOR MINIMUM INSURANCE COVERAGE

Given that half of all current smokers will die from a tobacco-related disease and because the evidence for treatment is so compelling, yet underused, in part due to insurance barriers, we recommend the following coverage based on evidence presented in this document. Minimum insurance coverage should include full coverage for:

- 1. Screening for tobacco/nicotine use in all visits.
- 2. Regular physician visits for initial evaluation and follow-up counseling. Given that tobacco use disorder has such a large prevalence and health impact, there should be no exclusions on the type of physician providing counseling. For example, physician coverage should not be limited to primary care, as many smokers may see other providers like psychiatrists more often. We recommend a minimum of four follow up visits, whereas eight or more visits produce quit rates of about 25%.^{5,17}

- 3. Coverage of the seven FDA approved medications alone or in combination; limits on the medications or use of one or the other should be eliminated as the FDA has recently concluded that individuals can use combination NRT, that NRT can be used while still smoking and that NRT can be used for longer periods of time. Also, medication combinations such as NRT and bupropion SR produce improved quit rates.5 There should not be a requirement for prior authorization on any of the seven FDA approved medications.
- 4. Combination of counseling and medication is recommended for minimum coverage. However, a counseling program should not be required as a precondition for medications and vice-versa.
- 5. Use of procedures such as cotinine urine/serum testing or CO monitors which may be helpful in monitoring progress as well as enhancing motivation.
- 6. Continued coverage of highly effective state quitlines.¹⁸
- 7. Group smoking cessation options should also be covered as needed to supplement individual counseling.
- 8. Patient should be allowed a minimum of two completely covered quit attempts annually (including medications and counseling). There cannot be a lifetime limit on quit attempts.
- 9. The recommendations apply to all tobacco products. As research and data emerge about alternative nicotine products such as ENDS, coverage recommendations will need to be updated, perhaps to include coverage of cessation from Electronic Nicotine Delivery Systems (ENDS).

APPENDIX: EVIDENCE-BASED CONSENSUS TREATMENT RECOMMENDATIONS FOR TOBACCO OPTIMAL INSURANCE COVERAGE

- 1. Comprehensive, covering all evidence-based cessation treatments, including counseling and both over-the-counter and prescription medications.^{5, 7, 14, 15}
- 2. Eliminates or minimizes barriers to accessing these treatments.^{5,} 7, 14, 15
- 3. Is heavily promoted to tobacco users and health care providers, and includes monitoring utilization of the coverage, since high utilization is essential for a cessation benefit to have its intended impact.^{5, 7, 14,16}

CHOICE OF MEDICATIONS

Seven FDA approved medications, including five nicotine replacement therapies (NRTs), a partial nicotine agonist, varenicline (brand name Chantix), and buproprion SR (an antidepressant with both dopaminergic and norepinephrine activity, brand name Zyban if used for tobacco cessation and Wellbutrin if used as an antidepressant). Combinations of medications work best. All insurance plans should cover nicotine patch, nicotine gum, nicotine lozenge, nicotine inhaler, nasal spray, varenicline and bupropion.⁵

MEDICATION TREATMENT DURATION

Pharmacologic treatment should not be limited. The FDA supports

use of longer term nicotine replacement therapies as well as combinations. Decisions concerning treatment duration should be made jointly by clinicians, other members of the treatment team, and patients. Decisions should be based on accumulated data and medical experience, as well as patient participation in treatment and past quit attempts, rather than on regulatory or general administrative policy because long-term use of medication may be more effective than short-term use. Studies have shown that many patients use medications for 1-5 years or longer and are successful. Continued use of medication is preferable to a return to smoking.⁵

DOSAGE AND COMBINATION THERAPY

Dosage requirements must be determined on an individual basis. Dosage should be individually adjusted based on heaviness of smoking, serum cotinine levels, and withdrawal symptoms. It is critical to successful patient management to determine a medication dosage that will minimize withdrawal symptoms and craving and decrease or eliminate tobacco use. Maximums are recommended but on occasion even these need to be exceeded based on clinical judgment and experience as in the case of multiple patches. For example, evidence shows that combination therapy with patch and short acting nicotine replacement is more effective than mono nicotine therapy.⁵

REGULAR PHYSICIAN VISITS FOR EVALUATION AND FOLLOW UP OF TOBACCO USE DISORDER

Patient-treatment matching begins with a thorough assessment to determine each patient's needs. Then these needs are matched to appropriate levels of care and types of services. All patients should be asked about tobacco use in a non-judgmental manner. Assessment should include the extent, nature, and duration of patients' tobacco use and other substance use and their treatment/quit histories, as well as their medical, psychiatric, and psychosocial needs and functional status. For relapse prevention, stress management, weight, social support and discussion of withdrawal/triggers, regular visits for evaluation and follow-up are essential. Many smokers require multiple quit attempts as nicotine and tobacco use disorders are chronic relapsing illnesses that often require repeated intervention and multiple quit attempts. For patients who smoke and who are not yet ready to quit, motivational interviewing should be employed.

LAB WORK AND DIAGNOSTIC TESTING

Lab work and diagnostic tests are necessary for safely and effectively treating tobacco use disorders. Carbon monoxide testing can motivate cessation; research on this is ongoing. Cotinine levels can be used to adjust levels of nicotine replacement.

EVIDENCE-BASED TREATMENT REQUIRES COMBINATION OF MEDICATION AND COUNSELING

Medication combinations with psychosocial treatments have the best outcomes. The combination of medication and counseling is more effective for smoking cessation than either alone. Therefore, whenever feasible and appropriate, both counseling and medication should be provided to patients trying to quit smoking. Providing tobacco dependence treatments (both medication and counseling) as a paid or covered benefit by health insurance plans has been shown to increase the proportion of smokers who use cessation treatment, attempt to quit, and successfully quit. Therefore, treatments shown to be effective in the guideline should be included as covered services in public and private health benefit plans.⁵

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