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TOBACCO DEPENDENCE
TREATMENT TOOLKIT

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TOBACCO DEPENDENCE TOOLKIT

Please be advised throughout this document that the treatment of tobacco dependence refers to all forms of tobacco and tobacco products, including but not limited to, combustible tobacco such as traditional cigarettes, cigars, pipes, smokeless oral tobacco products *(i.e. snus, snuff, pouches, loose leaf, plugs, twists, and dissolvable tobacco products such as orbs, pellets, sticks, or strips)*, electronic cigarettes *(eg, e-cigarettes)* vaping and heated tobacco products *(i.e. heat not burn tobacco)*.

All tobacco product use causes tobacco dependence. Nicotine is the addictive substance in all tobacco products. No distinction between the treatment of these products is intended unless otherwise specified.

EXECUTIVE SUMMARY/OVERVIEW

Tobacco dependence is a severe chronic disease that causes disability and premature death. Nicotine, the addictive drug in tobacco products, changes brain structure and function such that the brain does not work normally without nicotine on board. The goal of tobacco dependence treatment is to help the brain learn to function without nicotine.

Most of the research on tobacco dependence treatment has focused on conventional cigarette smokers. As nicotine is the addictive substance in tobacco products, treatments shown to be effective for smokers can reasonably be applied to individuals addicted to other tobacco products.

Tobacco dependence most commonly starts in adolescence. Tobacco dependence is one of the few chronic diseases that is actively promoted to our youth and where efforts at control are actively fought by an industry that makes billions of dollars addicting young people. The tobacco industry has a long history of designing products to maximize their addictiveness and their appeal to youth.

Severity of tobacco dependence varies. For some people dependence can be mild, whereas for others it can be very severe. One way to describe the severity of the compulsion to use tobacco, as proposed by DiFranza et al, is wanting, craving, and needing. Wanting is a mild desire to smoke that is short lived and easily ignored. Craving is a stronger urge to smoke that is more persistent and difficult to ignore. Needing is an intense and urgent desire to smoke that is unpleasant and unremitting.

Nicotine withdrawal symptoms are not limited to cravings. Sometimes these symptoms are not recognized as withdrawal. Irritability, frustration, anger, increased appetite/weight gain, tremors, depression, anhedonia, insomnia, anxiety, and difficulty concentrating are all symptoms of nicotine withdrawal. In severely addicted individuals, withdrawal symptoms can be so severe as to meet criteria for major psychiatric illness.

EXECUTIVE SUMMARY/OVERVIEW

Strategies for Treating Tobacco Dependence

There are two complementary strategies for treating tobacco dependence.

1. *Cope with the nicotine withdrawal.*
2. *Supress the withdrawal and overcome the reinforcing effects of nicotine (with medications).*

Use of any of the US Food and Drug Administration (FDA)-approved medications for tobacco dependence improves cessation rates, regardless of severity level of tobacco dependence. FDA-approved first-line medications for tobacco dependence include varenicline, bupropion, and nicotine replacement therapy (NRT) products *(i.e. nicotine patch, nicotine gum, nicotine lozenge, nicotine oral inhaler, nicotine nasal spray).*

Among the FDA-approved medications, varenicline is the most effective single agent. The combination of varenicline with NRT and/or bupropion is more effective than varenicline alone. Courses of treatment longer than 12 weeks are more effective than shorter courses of treatment. While this strategy is underused, starting treatment before the tobacco-dependent person is ready to stop substantially increases stop smoking rates and engages more patients.

Electronic cigarettes should not be recommended for tobacco dependence treatment. Electronic cigarettes are a tobacco product, not an FDA-approved medication. By rapidly releasing nicotine to the brain, electronic cigarettes create and maintain addiction. Unlike the FDA-approved NRT medications, electronic cigarettes are neither a safe nor effective product to use. Further, because it is an unregulated product, the clinician cannot be assured of quality control in the manufacturing process. Instances of explosions and fires of electronic cigarettes are not an uncommon occurrence. Recommending an unapproved, unregulated product may also expose the clinician to legal liability.

PHARMACOTHERAPY

The goal of pharmacotherapy is to control withdrawal symptoms and reduce the rewarding effects of tobacco. How much medication to begin with initially will depend on the severity of the addiction, the individual's ability to tolerate withdrawal, and the individual's readiness to accept medication. On follow-up, medication is adjusted based on adequacy of control of nicotine withdrawal and adverse events, if any. Individuals with more severe addiction and those with less ability to tolerate withdrawal will need more medication and longer courses of medication. When withdrawal is well controlled and the patient is no longer using tobacco products, the medications can be gradually stepped down. If withdrawal is not well controlled and/or if the patient is still using tobacco products, the medication should be stepped up, intensified, or additional medications added. It is important to remember that tobacco dependence is a chronic, relapsing, life-threatening disease. If necessary, the clinician should feel just as comfortable continuing medications for the tobacco dependent patient as they feel continuing medications for patients with other chronic conditions *(eg, diabetes, hypertension, asthma).*

MOTIVATIONAL INTERVIEWING

Motivational Interviewing (MI) is an evidence-based approach to behavior change. It is defined as a collaborative, goal-oriented style of communication with particular attention to the language of change. It is designed to strengthen personal motivation for and commitment to a specific goal by eliciting and exploring the person's own reasons for change. It uses intrinsic motivation and reflective listening in rolling with resistance, building decisional balance, and managing roadblocks to reach a successful change of negative behaviors. Originally developed to treat those with alcohol use disorder, MI has been shown to have a statistically significant effect on abstinence rates for smoking cessation as compared with controls. MI can be utilized in counseling tobacco-dependent patients with the goal of helping them toward being ready to change the behavior, not specifically to quit using tobacco.

A few key elements highlight the perspective of MI. Motivation to change is determined by the patient, not externally imposed by the practitioner. The focus should be on the patient's view of the situation with acceptance, empathy, affirmation, and support of their autonomy. It assumes that the patient already has internal motivation and resources and owns the responsibility for resolving their ambivalence.

These motivations can be revealed using evocative questions.

In this process the provider kindly explores and helps the patient to build their own "why" by inquiring about the patient's motivations and ideas. The provider-patient relationship is seen more as a collaborative and encouraging partnership rather than the expert-recipient relationship.

When Practicing MI, the Provider Should Develop Five Primary Counseling Skills

Express empathy. The provider should be non-judgmental and use listening instead of lecturing. Ambivalence about tobacco cessation should be accepted. Accurately understanding the patient point of view can facilitate change.

Develop discrepancy. Assist the patient in identifying a difference between their behavior and desired change. Motivation for change in lifestyle occurs when patients can recognize that what they are doing will not help them achieve a future goal.

Avoid argumentation. Discouraged patients will tell a provider what they want to hear. Carefully diffusing a patient's defensiveness and changing strategies when resistance to change is demonstrated can be more effective.

Roll with resistance. Reframe the patient's statements and invite them to consider alternative perspectives while valuing the patient as being their own reason for change. *(eg, "It may be that after our discussion you decide that it's worth it to you to continue to smoke. It might be that it is too difficult to make that change right now and that decision is yours to make".)*

Support self-efficacy. Provide encouragement to increase the patient's self-confidence in their ability to change behavior.

Engaging in MI Starts With Core Skills Using OARS

O: Open-ended questions allow for longer answers and should start with "what", "where", "how" or "tell me" *(eg, "What would change in your life if you stopped smoking?")*

A: Affirmations offer patient support and encouragement to increase their self-perception, provide genuine appreciation, and validate strengths. These build rapport and reduce negativity. *(eg, "You're really working hard on this!")*

R: Reflective listening is used to repeat what the patient says and allows the patient to feel heard. It also allows the provider to clarify and confirm perceptions. *(eg, "It's hard to imagine coping with stress without a cigarette").*

S: Summarizing allows the provider to link together ideas and emphasize positive changes. Items to summarize include reasons for change, confidence in ability to change, values, goals, and intrinsic motivation. *(eg, "You can't imagine quitting because you would not be able to smoke with your friends and at the same time you are worried about how it is affecting you").*

The provider should attend to the language of change by identifying what is being said against making the change *(sustain talk)* and in favor of change *(change talk)* and, when appropriate, encourage a movement away from sustain talk to change talk. Change talk can be elicited by first assessing the importance, confidence, or readiness to change using OARS.

A provider may simply start with a scale question, *(eg, "On a scale of 1 to 10, with 1 being not important at all and 10 being extremely important, how important is it to you to quit smoking?")* This can then be followed up with evoking the reason the patient is at that particular number, *(eg, "Why are you at a 6?" or "Why not a 1-2?", and then "What would it take for you to get to a higher number?")* In the case of a patient who is ambivalent about cessation, it can be helpful to direct them towards making a positive decision.

During the conversation, the provider should notice and reinforce change talk and readiness to quit. As the patient identifies desires, ability, reasons and the need to quit smoking, these will lead to commitment and then change in behavior.

Examples of phrases to recognize include:

Desire – *"I wish," "I want"*

Ability – *"I think I could cut out smoking during my lunch break"*

Reasons – *"Smoking keeps me from keeping up with my kids"*

Need – *"I must be healthier for my son"*

In response to change talk, the provider should elaborate, affirm, reflect, and summarize. Depending on the situation, the provider may then have the opportunity to support the patient to consolidate commitment to change through planning that explores how to achieve the change. One such example would be offering a menu of options and eliciting patient choice by asking, *"Which option seems most possible?"*

Provider proficiency in MI is not substantially increased by reading about it or viewing video examples of the do's and don'ts. If, after reviewing this chapter, the reader is interested in achieving proficiency in MI, this can be increased by attending a 2-day clinical MI training workshop and substantially increased by attending a workshop followed by supervisory feedback or individual coaching sessions.

TESTING/ DIAGNOSTICS

Fortunately, there are several types of diagnostics *(both paper and pencil and via devices)* are available for assessing tobacco use and addiction.

Simply stated, drug addiction can be defined as a loss of control in substance use. If a patient wants to stop tobacco use *(and consistently more than 70% do want to stop)*, needs to stop tobacco, and cannot stop using tobacco, that's tobacco addiction. If a tobacco consumer is experiencing medical sequalae caused by their tobacco, and they can't stop, that's addiction. By definition, cardiac and pulmonary patients who continue to smoke are addicted! A patient experiencing severe shortness of breath with radiologically confirmed COPD and demonstrated moderate to severe airways obstruction and a significantly reduced DLCO who is aware that tobacco perpetuates these problems and continues to smoke is severely addicted.

Quantification of Biochemical Tobacco Consumption and Addiction

As mentioned, tobacco addiction and dependence can be assessed with both medical diagnostics and paper and pencil tests. Unfortunately, while it does provide one important clinical data point, counting cigarettes is inadequate and biochemically inaccurate for treatment planning.

Studies have shown that patients lack the ability to accurately recall the number of cigarettes they smoke. Benowitz and colleagues demonstrate that simple reduction in the number of cigarettes per day simply changes the tobacco user's smoking characteristics. Benowitz and others have found that changing the way smokers actually smoke such as inhaling more forcefully and deeply, taking more puffs per cigarette, holding each puff in the lungs longer, etc., can actually increase nicotine consumption by 200%. Biochemical assessment assists with accurate quantification, medication management, and assessment of therapeutic progress.

MEDICAL DIAGNOSTICS FOR ASSESSMENT OF TOBACCO ADDICTION

Carbon Monoxide/Carboxyhemoglobin Assessments

The tobacco treatment profession has long acknowledged the importance of independent assessments of smoking status. The tool most widely used to do this is the carbon monoxide (CO) monitor. Carbon monoxide monitors measure expired breath CO *(and by calculation, the percentage of blood hemoglobin bound to carbon monoxide molecules)* in an easy and noninvasive way *(Jarvis, Russell, & Saloojee, 1980*). However, CO is not produced by electronic cigarettes, smokeless tobacco, or heat not burn tobacco products. Other techniques are necessary to quantify non-combustible tobacco consumption.

CO level feedback can enhance the effect of brief quit advice and smoking cessation rates. Baseline expired CO measurements are also a valuable clinical tool in assessing the severity of dependence and likelihood of cravings during abstinence *(West, 1985)*. There is some evidence that expired CO measurements correlate with levels of plasma nicotine and the severity of tobacco dependency *(Lee, Malson, Waters, Moolchan, & Pickworth, 2003).*

Various CO Monitor Manufacturers

https://www.mdd.org.uk/products/co-check-pro/

https://mdspiro.com/products/breath-co/

https://vitalograph.com/product/162449/breathco

https://intelliquit.org/products/fim-expired-breath-carbon-monoxide-co-cohb-tester

https://www.biospace.com/article/releases/asia-s-first-prescription-digital-therapeutic-approved-in-japan-nicotine-addiction-treatment-app-with-co-checker-receives-regulatory-approval-cureapp-inc-/?s=85&utm_source=dlvr.it&utm_medium=twitter

Various Nicotine and Nicotine Metabolite Assays

Until recently nicotine and related metabolite assays were expensive, inconvenient and time consuming, rending point-of-care testing impractical. Nicotine and metabolite quantification also helps determine the level of tobacco addiction and tobacco consumption.

Better NRT dose matching has been accomplished by measuring baseline cotinine *(a nicotine metabolite)* levels while smoking and titrating NRT to this baseline intake and/or subsequent levels.

Studies show the percentage of replacement of nicotine compared with baseline or intake levels is inversely correlated with withdrawal symptoms and positively correlated with quit rates. In addition, nicotine assays can also guide clinicians towards successful tobacco treatment with varenicline and bupropion.

Insurance reimbursement for assessing tobacco dependence with nicotine and nicotine metabolites

G0480 Drug test, definitive.....$114.43

G0659 Drug test, without calibration.....$62.14

80307 Drug test, presumptive chemical analyzer.....$62.14

80305-QW Drug test, presumptive direct optical observation.....$12.60

These numbers are based on the US national average in first quarter 2021.

Additional telehealth codes and further third-party payments may be applicable. See the chapter on Insurance billing and telehealth for more information.

IntelliQuit

Smartphone enabled, cloud-based nicotine bio-monitoring. Quantitative total nicotine equivalents nicotine and nicotine metabolites results returned to user's smartphone in seconds. IntelliQuit can biochemically assess tobacco consumption remotely via telehealth protocols or in person or in office.

https://www.IntelliQuit.org

NicAlert

https://nymox.com/products#nicalert

https://www.fishersci.com/shop/products/nymox-corporation-nicalert-nicotine-test-nicalert-nicotine-test/23385500

Semi-quantitative (results are read 0-6) immunochromatographic assay monoclonal antibody-coated gold particles and a series of avidity traps.

NicQuick Urine Cotinine

https://drugtestsinbulk.com/nicotine-test.html?gclid=EAIaIQobChMIz8PC_pzu6wIVBYbICh3JtAfsEAQYASABEgJNFvD_BwE

Qualitative lateral flow immunoassay returning results positive for tobacco or negative for tobacco only. Qualitative results inhibit the clinician's ability to quantify either addiction, consumption, titration of medications, and therapeutic progress accurately.

Expert Opinion

Measurement of nicotine levels or TNEs can aid treatment planning and medication titration while assessing biochemical reduction in consumption and abstinence. Expired end-tidal breath CO (EtCO) and TNE assays are powerful tools to assess both tobacco dependence and therapeutic progress regarding all tobacco product use. After baseline measurements, adaptive treatment protocols can be implemented based on changing clinical findings, patient preferences, and clinician input over the course of the treatment.

Generally, if the tobacco dependent patient is prescribed a non-nicotine medication *(eg varenicline)*, frequent EtCO and TNE measurements should both decrease over time, with corresponding decreases in combustible tobacco and nicotine consumption towards tobacco abstinence.

In contrast, successful administration of NRTs or successful combination pharmacotherapies *(NRT(s) plus varenicline and/or bupropion)* would result in a relatively rapid decrease in EtCO due to a reduction in combustible tobacco, while TNEs should remain relatively constant due to the therapeutic nicotine from NRTs.

For example, even with smokers with no desire to quit or reduce their smoking, FDA-approved NRT suppressed nicotine intake from cigarettes in a dose-dependent manner up to as much as 40%. Cigarettes, nicotine intake, and CO decreased by 26.3%, 36%, and 28%, respectively.

- *With NRTs, after initial high % replacement as treatment continues, TNE assays begin to decrease during downward titration of NRT towards abstinence.*
- *Tobacco treatment with non-nicotine medications, such as varenicline, both EtCO and TNE measurements should decrease, corresponding to decreases in traditional cigarettes (including cigars and pipes) and decreases in nicotine consumption.*
- *EtCO and TNEs enable personalized tobacco treatment and the titration of medications towards optimal efficacy.*

EPIGENETICS-DNA METHYLATION

Every day, the average smoker ingests between 20 and 30 micrograms of toxic polyaromatic hydrocarbons (PAHs), which are immediately absorbed into the blood stream. The toxic effects of smoking remain in DNA for months or even longer. As the patient stops smoking, gene modification returns to normal. When white blood cells encounter PAHs, they turn on key enzymes. Smoke Signature® measures methylation at cg05575921 of *AHRR,* which gene-the key site controlling these enzymatic cascades. The more someone smokes, the more this site is demethylated. Cigarette consumption is precisely determined by using digital poymerase chain reaction technology, using this information to accurately determine the exact numbers of cigarettes consumed. Requiring only a single drop of blood or saliva samples, Smoke Signature offers a quick, easy-to-perform assessment that precisely quantifies consumption for a period of 60 days or longer by measuring the precise level of DNA methylation and consequently how much the patient smokes.

Smoke Signature was developed by Behavioral Diagnostics Inc., a company established in 2009 at the University of Iowa to advance epigenetic methods for detecting and measuring patterns of cigarette consumption. More than fifty studies support the validity of this test.

https://bdmethylation.com/smoking-signature-purchase/

Passive Motion Detection of Combustible Cigarettes

SmokeBeat, is an artifical intelligence machine learning–powered remote patient monitoring platform that uses wearable wristband enabled gesture detection to monitor smoking habits for improving cessation efficacy. The SmokeBeat user app enables health-care professionals and smokers to track smoking habits and receive relevant messaging regarding their smoking. SmokeBeat date and time stamps each cigarette the patient smokes in real time with GPS physical location. Just-in-time text notifications are available highlighting and addressing problem times such as eating, drinking, awakening, etc.

Somatix: https://somatix.com/for-smoking-cessation/

Insurance reimbursement for assessing tobacco dependence via real-time passive motion smoking determinations

CPT Codes Description Frequency Reimbursement

99453 Initial Set-up & Education One-time.....$21.00

99454 Data collections & alerts Monthly.....$69.00

99457 Patient data management Monthly.....$54.00

Interactive communication, 20 minutes

99458 Patient data management Monthly.....$43.00

Interactive communication, additional 20 minutes

99091 Patient data management Monthly.....$59.00

Without interactive communication, 30+ minutes

(cannot be billed with 99457 & 99458)

These numbers are based on the US national average as of January 5th 2021.

PAPER AND PENCIL TESTS FOR TOBACCO DEPENDENCE

Modified Penn State Cigarette/e-Cigarette Dependence Index

1. How many cigarettes [vaping times] per day do you usually smoke or vape? [assume that one vape "time" consists of around 15 puffs or lasts around 10 minutes])

SCORING:

0–4 times/day = 0

5–9 times/day = 1

10–14 times/day = 2

15–19 times/day = 3

20–29 times/day = 4

30 or more times/day = 5

2. On days that you can smoke or vape freely, how soon after you wake up do you smoke or vape for the first time of the day?

SCORING:

0–5 mins = 5

6–15 mins = 4

16–30 mins = 3

31–60 mins = 2

61–120 mins = 1

121+ mins = 0

3. How many nights per week do you typically awaken to smoke or vape?

SCORING:

0–1 nights per week = 0

2–3 nights per week = 1

4 or more nights per week = 2

TOTAL SCORING:

0–1 = not dependent

2-4 = low dependence

5-7 = medium dependence

8-10 = high dependence

11-12 = very high dependence

SCORING INSTRUCTIONS:

Add up responses to all items. A score of 5 or more indicates a significant dependence, while a score of 4 or less shows a low to moderate dependence.

The Fagerström Test for Nicotine Dependence-Smokeless Tobacco *(FTND-ST)*

(Please note: all questions refer to any form of smokeless oral tobacco)

1. How soon after you wake up to do you place your first dip?

Within 5 min	3
6–30 min	2
31–60 min	1
After 60 min.	0

2. How often do you intentionally swallow tobacco juice?

Always	2
Sometimes	1
Never	0

3. Which chew would you hate to give up most?

The first one in the morning	1
Any other	0

4. How many cans/ pouches per week do you use?

More than 3 cans/pouches	2
2–3 cans/pouches	1
1 or less cans/pouches	0

5. Do you chew more frequently during the first hours after awakening than during the rest of the day?

Yes	1
No	0

6. Do you chew if you are so ill that you are in bed most of the day?

Yes	1
No	0

SCORING INSTRUCTIONS:

Add up responses to all items. A score of 5 or more indicates a significant dependence, while a score of 4 or less shows a low to moderate dependence.

TREATMENT BASICS FOR PHARMACOLOGY:

Neurotransmitter Mechanisms Regulating Nicotine Addiction and Tobacco Treatment Medications Mechanisms of Action.

Inhalation of smoke or vapor from a cigarette, heated tobacco products, or e-cigarette releases nicotine from the tobacco or e-cigarette liquid. Smokeless tobacco products release nicotine directly into the mouth, and nicotine is absorbed through the buccal mucosa. Traditional cigarette smoke carries nicotine into the lungs in both a vapor phase and on the surface of tar particles, where it is rapidly absorbed into the pulmonary venous circulation. Nicotine then enters the arterial circulation and within approximately 7 seconds rapidly enters the brain, where it binds to nicotinic cholinergic receptors (NAch). One of the effects of NAch binding is the release of neurotransmitters.

One prominent neurotransmitter is dopamine. Dopamine causes pleasurable feelings and is critical for the reinforcing effects of nicotine and other drugs of abuse. These reinforcing effects also promote the self-administration of nicotine. Specifically, nicotine releases dopamine in the mesolimbic area, the corpus striatum, and the frontal cortex. The dopaminergic neurons in the ventral tegmental area of the midbrain and in the nucleus accumbens are critical in drug-induced rewards, and these have an important role in the feelings of pleasure and reward.

Nicotine changes the user's brain chemistry and causes the sensation of pleasure while reducing feelings of stress and anxiety. Smoking controls mood and improves concentration, reaction time, and performance of certain tasks. Improvement in withdrawal symptoms is probably the primary reason for this enhanced performance and heightened mood. Tobacco abstinence causes the emergence of withdrawal symptoms: irritability, depressed mood, restlessness, difficulty concentrating, and anxiety. The intensity of these mood disturbances can be similar to that found in psychiatric outpatients. Anhedonia — lack of pleasure in things and events — can also occur with withdrawal from nicotine, and can be similar to the withdrawal from other drugs of abuse.

The basis of nicotine addiction is believed to be a combination of positive reinforcements, including improvement in mood and the avoidance of withdrawal symptoms. Effective medications address one or both of positive reinforcements and withdrawal symptoms.

The 7 FDA-approved tobacco treatment medications have different mechanisms of action. While these mechanisms of action are not fully understood, NRTs are, of course, agonists for the nicotine in tobacco. Varenicline is a partial agonist, partial antagonist at the alpha 4 beta 2 nicotine receptor. While bupropion inhibits reuptake of dopamine, noradrenaline, and serotonin in the central nervous system, it is also a non-competitive nicotine receptor antagonist *(other antidepressant medications do not have this effect on nicotine receptors).*

Expert Opinion

There is perhaps no topic in the field of tobacco cessation treatment more controversial and contentious than the use of alternative tobacco products as harm reduction options to cessation. These alternative tobacco products include, but are not limited to, electronic cigarettes (e-cigarettes), vaping, and heat-not-burn products.

It is the consensus of the toolkit authors that further data are needed before definitive determinations of safety and efficacy of present or future e-cigarette/vaping products can be made. There is no evidence yet to include alternative products such as e-cigarettes as effective tobacco harm reduction or tobacco dependence treatment.

The European Respiratory Society position paper shares the following:

The tobacco harm reduction strategy is based on well-meaning, but incorrect, or undocumented claims or assumptions. The human lungs are created to breathe clean air, not "reduced levels of toxins and carcinogens," and the human body is not meant to be dependent on addictive drugs.

Alternative nicotine delivery products are primarily manufactured by the tobacco industry, and the tobacco industry has a strong economic interest in spreading these products to as many individuals as possible: smokers as well as nonsmokers. The tobacco industry has manufactured so-called "safer" tobacco products (ie, filter, light, low-tar cigarettes) since the 1950s, and none of them have improved smokers' health. Alternative nicotine delivery products are the tobacco industry's adaptation to declining tobacco consumption and acceptability of smoking and increased regulation of cigarettes.

1. *The tobacco harm reduction strategy is based on incorrect claims that smokers cannot or will not quit smoking.*
2. *The tobacco harm reduction strategy is based on undocumented assumptions that alternative nicotine delivery products are highly effective as a smoking cessation aid.*
3. *The tobacco harm reduction strategy is based on incorrect assumptions that smokers will replace conventional cigarettes with alternative nicotine delivery products.*
4. *The tobacco harm reduction strategy is based on undocumented assumptions that alternative nicotine delivery products are generally harmless.*
5. *Alternative nicotine delivery products can have a negative impact on public health even if "stick-by-stick" they turn out to be less harmful than conventional cigarettes.*
6. *Smokers see alternative nicotine delivery products as a viable alternative to the use of evidence-based smoking cessation services and smoking cessation pharmacotherapy.*
7. *The tobacco harm reduction strategy is based on incorrect claims that we cannot curb the tobacco epidemic.*

Pisinger C, Dagli E, Filippidis FT, et al. ERS and tobacco harm reduction. Eur Respir J. 2019;54:1902009 [https://doi.org/10.1183/13993003.02009-2019].

Tobacco Treatment Medication Prescribing Chart**

These highlights do not include all information needed for safe and effective use. See full prescribing information.

Medication	Nicotine Replacement Therapies (NRT)*					Bupropion (SR or XL) (Zyban, Wellbutrin)	Varenicline (Chantix, Champix) ***
	Transdermal Nicotine Patch (Long-acting NRT)	Nicotine Polacrilex gum (Short-acting NRT)	Nicotine Lozenge (Short-acting NRT)	Nicotine Nasal Spray (Short-acting NRT)	Nicotine Inhaler (Short-acting NRT)		
Suggested Regimen	<= 10 cig/d, start with 14mg/qd x 6 wks or longer >10 cig/d, start with 21mg/qd x 6 wks or longer If needed smokers <= 10 cig/d feel comfortable prescribing 21mg/qd	1st cig >30 mins after awakening, 2 mg/hr 1st cig =<30 mins after awakening, 4 mg/hr If needed for smokers <= 10 cig/d, feel comfortable prescribing 4mg gum	1st cig >30 mins after awakening, 2 mg/hr 1st cig =<30 mins after awakening, 4 mg/hr If needed for smokers <= 10 cig/d, feel comfortable prescribing 4mg lozenges	1-2 sprays per nostril/hr, PRN. Increase to 5 sprays per nostril per hr (max 80 sprays total) x 3 mos	4 puffs/min x 20-30 mins per cartridge PRN	Days 1-3: 150mg po qam then Day 4 to 12 weeks (or end of treatment): 150mg SR bid or 300mg XL po qam	Start >= 1 week before target quit date 0.5mg po qam x 3days then 0.5mg po bid x 4days then 1 mg po bid x 11 weeks to 6 months Target quit date can be delayed or extended if needed.
Precautions	Pregnancy Class D Uncontrolled HTN Skin disorders (patch) MRI (patch) Advise starting with highest does patch Except c/ patients <100 lbs. TMJ disease, dental work, dentures (gum) Na++ restricted diet (gum, loz, nasal spray, inhaler) Sinusitis, rhinitis (nasal spray) Reactive airways disease (nasal spray, inhaler)					Pregnancy Class C Uncontrolled HTN Severe cirrhosis/ abnormal LFTs-dos-adjustment required Mild-mod hepatic & mod-sever renal impairment-consider dose adjustment	Pregnancy Class C Seizure disorder CrCL <30 or dialysis-dose adjustment required May increase risk of CV events in pts c/ CVD
Potential Contrain-dications	MI w/I 2 wks Serious cardiac arrhythmia Unstable angina					MAO inhibitor in past 14 days Seizure disorder or risk, bulimia/ anorexia Abrupt iscontinuation of EtOH or sedatives Serious head trauma	Known hx of serious hypersensitivity or skin reactions to varenicline
Potential Adverse Effects	Be advised most patients receive too little (not too much) nicotine from their NRTs Possible symptoms of too much nicotine (eg, nausea, headache, dizziness, tachycardia (patch) Skin irritation, insomnia (nausea, headache, dizziness, insomnia are also tobacco withdrawal symptoms) Hiccups, heartburn (gum, loz) Nasal irritation, tearing, sneezing (nasal spray) Mouth and throat irritation (inhaler)					Insomnia, dry mouth, headaches, pruritis, pharyngitis, tachycardia, seizures, neuropsychiatric effects & suicide risk (Black-boxed warnings removed Dec 16, 2016)	Nausea, insomnia, abnormal dreams, constipation, neuropsychiatric effects, seizures, suicide risk and cardiovascular events (Black-boxed warnings removed Dec 16, 2016)

*In 2013, the FDA did not identify any safety risks associated with longer-term NRT products. Tailor treatment to patient's needs.
** Virtually every FDA medication can be combined with every other in various permutations and combinations.
*** Champix is a trade name used outside the USA. Alternatively, patients can use varenicline to reduce cigs per day ad lib or to delay their target quit day for 35 days until they feel comfortable quitting.

Tobacco Treatment Medications Brief Instructions

Product	Brief Instructions
Nicotine Patch	Apply 1 patch to clear, dry, hairless skin like upper or inner arm, upper back, shoulders, lower back or hip. Avoid moisturizers or moisturizing soap and wash hands after use. Replay daily after working, rotate site daily, do not apply patch at bedtime. Store patches at room temperature. See Clinical Pearls for more information.
Nicotine Gum	Chew slowly until a peppery taste or mild tingle occurs *(approximately 15 slow chews or about 1 minute)* then park for 1 minutes between the cheek and gum. Then repeat placing gum in another mouth area between cheek and gum. Avoid eating or drinking *(anything except water)* for at least 15 minutes before and after the gum use. See Clinical Pearls for more information.
Nicotine Lozenge	Allow lozenge to dissolve slowly without chewing or swallowing. Avoid eating or drinking *(anything except water)* for at least 15 minutes before and after the lozenge use. Be advised mini-lozenges dissolve faster than the larger nicotine lozenges. See Clinical Pearls for more information.
Nicotine Nasal Spray	Blow nose prior to spraying. Insert nasal spray into nostril as far as comfortable, angle toward outside wall of nostril. Actuate spray by pushing hard and fast on the bottom of the glass bottom. Do not sniff sprayed liquid while spraying or immediately afterwards to avoid irritation and sneezing. See Clinical Pearls for more information.
Nicotine Inhaler	Inhale cartridge vapor using shallow puffs into mouth not past the back of throat to assist nicotine absorption and decrease irritation. Store cartridges at room temperature. See Clinical Pearls for more information.
Bupropion (SR or XL)	Take with food. Take one 150mg pill x 3 days then 150mg SR BID *(2nd pill >= 8 hours after 1st pill but early in AM to avoid insomnia OR (instead of 150mg SR BID)* 300mg XL qam. See Clinical Pearls for more information.
Varenicline	Take with full meals and a full glass of water. Do not take at bedtime. 0.5mg po qam x 3days then 0.5mg po bid x 4days then 1 mg po bid x 11 weeks to 6 months. See Clinical Pearls for more information.

Possible Patient Questions and Possible Responses

Can I use these medicines if I am not ready to quit completely?

Absolutely! You do not have to stop tobacco to start these medicines. You can continue to use tobacco. Using these medications may increase your motivation to quit and help you cut down prior to stopping. Let's start with a medication while you try to reduce your tobacco consumption by half.

Can I become addicted to the nicotine in the NRTs?

Nicotine from these medications is much less harmful than the nicotine you get from tobacco, and these medications deliver nicotine much slower than the nicotine you get from cigarettes. There is a very small chance of becoming dependent on the nicotine nasal spray but the nasal spray, is still much safer than smoking.

What do I do if the patch does not stick?

Place the patch on non hairy skin and press and hold the patch for at least 10 seconds. Do not use moisturizing soaps or skin lotions prior to applying the patch. You can use medical tape to help the patch adhere better.

I have dental work dentures, so should I use the nicotine gum?

You should use the nicotine lozenges or mini-lozenges. It is best to avoid the gum if you've had major dental work, have braces, dentures, or temporary crowns.

Can I use the patch, gum, lozenges, inhalers, and/or nasal spray at the same time?

Yes, all these FDA medications can be used together. Let's start with one and we can always add another or change medications if needed.

What should I do if I slip or relapse?

Continue with your medications even if you slip. Using these medications is safe and can increase your chancing of stopping. The harms of smoking when taking these medications is not greater than the harms of smoking alone.

How long should I stay on these medications?

Remember you didn't get to where you are using tobacco in weeks or even months. Our goal is to help you stop tobacco, and let's not worry how long you'll need these medications. As your nicotine withdrawal symptoms decrease the medications can be gradually stepped down.

What should I do if I don't think this medicine is helping?

We have many medications we can use to help you. Our goal is to help you feel normal while you cut down and then stop tobacco product use. Cutting down, or having fewer or more mild tobacco withdrawals like reduced cravings means the medication is working. You might need more medication to control your nicotine withdrawal symptoms. Two *(or sometimes even 3)* FDA-approved tobacco dependence treatment medication can work better than just one. If in doubt, call my office.

TREATMENT BASICS FOR NON PHARMACOLOGICAL METHODS

Quick and Simple Behavioral Techniques for the Clinician Treating the Tobacco Dependent

It is important to realize that any clinician treating tobacco dependent patients does not have to become a reincarnation of Sigmund or Anna Freud to achieve a successful outcome. Using simple, time-honored and evidence-based techniques can help attain therapeutic progress.

Cigarette Logs

Direct all tobacco users to self-quantify tobacco consumption in real-time with a log. For example, a smoker of combustible cigarettes should record every single smoked cigarette on a cigarette log *(either on their smartphone or with paper and pencil)* contiguous to the smoking. Logging their smoked cigarettes in real-time *(while smoking)* helps quantify consumption accurately and helps the smoker and their act of smoking become more mindful versus automatically, habitually without thought or cognizance. You can't change something if you can't measure the change. Cigarette logs are also extremely helpful to the clinician in determining therapeutic progress.

Cough-ey Butt Jars

Direct all combustible *(and oral smokeless tobacco)* users to dispose of all cigarette ashtrays and instead deposit the remainders of the smoked tobacco products *(cigarette butts and ashes)* in a clean glass or plastic jar with a screw-top filled about one-third with water. The sense of smell is extremely powerful. The olfactory receptor gene superfamily is the largest in the human genome containing more than 390 functional genes. Direct the patient to unscrew the top from the cough-ey jar and inhale the odor deeply. The malodorous experience can be extremely helpful in breaking the patient's positive association with tobacco.

Oral Substitutes/Hydration

Drinking water is a superb coping technique. Snacking on crunchy, nutrient dense, low calorie foods such as chopped peppers, celery, or carrots can be extremely helpful. Using cinnamon sticks, plastic straws, and sugarless gum/ candy are also excellent oral substitutes.

After Quitting, Maintain a Clean Mouth Taste

Advise your patients to visit their dentist for a teeth cleaning. Gentle brushing and gargling after meals can help the former tobacco patient resist urges and is a helpful substitute behavior. Sugarless chewing gum can also be helpful.

Post Prandial Urges

Many tobacco users report strong after-meal cravings. Advise patients to avoid lingering at the table after a meal. Instead instruct them to get up and do the dishes, go for a walk or brush their teeth.

Avoid Other Smokers, Vapers and Tobacco Users

Not only is it psychologically challenging to remain tobacco free around other users, but research has demonstrated that even inhaling second-hand smoke from other smokers can fire the patient's nicotine receptors stimulating the urge to smoke. Advise patients that at social gatherings they can simply walk away from tobacco users. If offered a cigarette, vaping product, pouch, pinch, or wad recovering tobacco users should simply say, "No thank you, I don't use tobacco", rather than "I just quit."

Avoid Smoking Places, People and Things Associated With Your Tobacco Use

Try to spend time in places where tobacco use is difficult or impossible such as libraries, museums, art galleries, movie theaters, and public transportation venues.

Physical Exercise

If the tobacco patient is ambulatory and able, studies show physical activity is an extremely effective coping technique. Many ex smokers use quitting tobacco as a stepping-stone to better health. Have your patients start slow and with your advice. They can increase the length, frequency, and intensity of their exercise program as they become more fit. Exercise reduces stress, tension, and tobacco urges. If possible, stretching or isometric exercises or a short set of push-ups during an urge can overcome thoughts of tobacco.

Mindfulness Meditation

Mindfulness meditation training has been shown to be effective for smoking cessation. Mindfulness is the skill that facilitates awareness and acceptance of experiences, including distressing thoughts non judgmentally and observing them without reacting, avoiding, grasping, or taking actions to change them.

Advise your patients: One puff, vape, dip, or pouch is too many, and a million is too few

Even one puff can fill approximately half the nicotine receptors in the human brain. Advise all former tobacco patients that, once they are abstinent, even one puff, or one dose of tobacco can "prime the pump" neurophysiologically to use tobacco again. Paradoxically, patients should be instructed not to focus on "no tobacco for forever"! The therapeutic goal is more immediate: don't use tobacco right now. When the goal of abstaining right now is repeatedly attained, forever takes care of itself.

Chat

Connect with a National Cancer Institute Live Help *(https://livehelp.cancer.gov/app/chat/chat_launch)* information specialist. Get immediate information and answers about quitting smoking. LiveHelp is available Monday through Friday from 9:00 a.m. to 9:00 p.m. Eastern time. LiveHelp also is available in Spanish. El servicio de LiveHelp también está disponible en español en el siguiente enlace: *https://LiveHelp-es.cancer.gov*

Phone 800-QUIT-NOW (800-784-8669)

All states have quit-lines with counselors who are trained specifically to help smokers quit. Your tobacco-dependent patients can call this number to connect directly to your state's quit-line. Hours of operation and services vary from state to state.

877-44U-QUIT (877-448-7848)

The National Cancer Institute's trained counselors provide information and support for quitting in English and Spanish. Call Monday through Friday 9:00 a.m. to 9:00 p.m. Eastern time.

Avoid Alcohol

Alcohol is an excellent solvent because it dissolves willpower. For newly minted tobacco-abstinent patients, it is a good idea to avoid alcoholic beverages. When the patient does consume alcohol, recommend that they not drink to intoxication and have a plan if the urge to use tobacco arises such as walking away or drinking water instead.

Slips Happen

A slip doesn't have to become a relapse. Explain to your patients to continue their medications even if they slip. Tobacco treatment medications help ensure that any slips are short-lived. The patient should try to understand what caused the slip: Was it alcohol or situational stress, transient or constant withdrawal symptoms, or was the tobacco patient with other tobacco users? Slips should also prompt the clinician to examine the efficacy of the treatment plan. Perhaps the patient can benefit from an additional or different medication. Either way, advise the tobacco patient that quitting is a process, a therapeutic journey. Like any journey, a problem along the way doesn't not mean all the progress achieved is for naught. It doesn't mean that the patient has to start from the beginning; rather, it means that they can learn much from their slips or difficulties in quitting to help them reach success.

TREATMENT PEARLS/CLINICAL VIGNETTES/CASE STUDIES:

Clinical Pearls

Contrary to popular opinion, virtually every FDA-approved medication can be used prior to the day the tobacco-using patient actually decides to quit. In addition, tobacco treatment specialists have used all seven medications in almost every permutation and combination. It is important to remember that no adverse events caused by any FDA-approved medication or combination of medications come anywhere close to approaching the tobacco-caused morbidity and mortality of more than 1,200 Americans per day. Indeed, the data demonstrate that almost no patients die as a direct result of tobacco treatment medications. While these FDA-approved medications received their approvals as "smoking cessation aids," they are effective for all tobacco product use. Please be advised that many of these recommendations are off-label.

The FDA has approved three Quit methods with varenicline. These include the Fixed Quit, Flexible Quit, and Gradual Quit. The Gradual Quit is for patients who are not able or willing to quit abruptly *(quitting right now),* and the Flexible Quit is for patients who want more time to quit between days 8 and 35 after starting varenicline. While the Fixed Quit is for patients who want to quit within a week, be advised that varenicline requires 4 days to reach steady-state. As such, if 1mg bid is started on day 8, it may be appropriate to wait until day 12 to initiate a quit attempt. Consequently, every smoker, regardless of motivation to quit, can be engaged and treated.

For patients exhibiting a sub optimal response to varenicline 1mg twice a day, there is evidence that increasing the dose to 3 mg/d may increase efficacy and quit rates.

Varenicline is a partial agonist and partial antagonist at the alpha 4 beta 2 nicotine receptor. As such, it is not uncommon that some tobacco patients, while enjoying the therapeutic benefit continue to smoke. Many of these patients will benefit from faster NRTs such as the nicotine nasal spray.

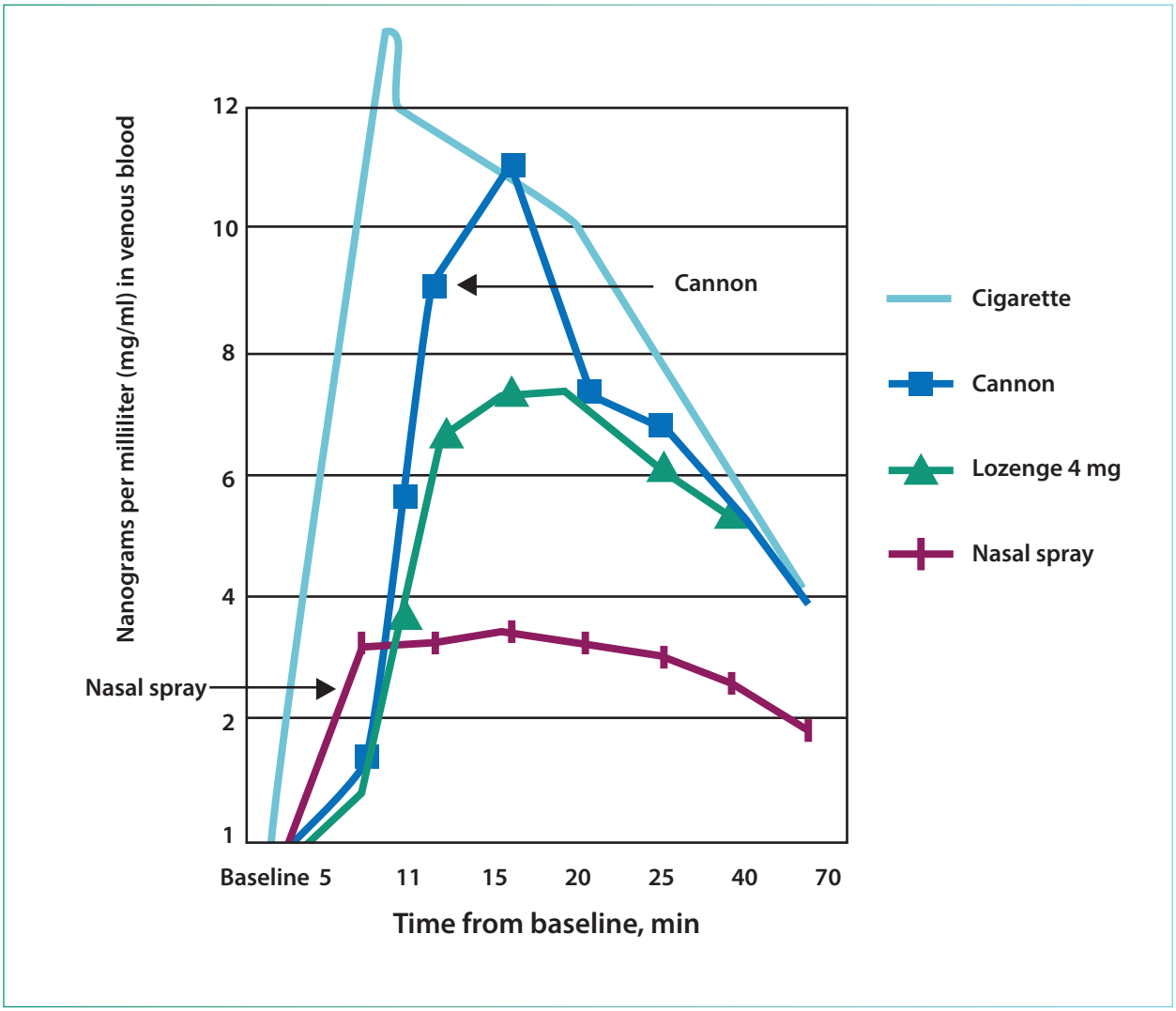
A nicotine nasal spray dose of one spray in each nostril delivers 1 mg nicotine, which reaches a maximum concentration within 12 to 15 minutes. In addition to delivering nicotine more rapidly than any other single FDA-approved NRT to assist the suboptimal effect of varenicline in reducing cravings and cigarette per day, within minutes nicotine nasal spray dosing can differentiate between tobacco withdrawal symptoms and adverse events/side effects.

Alternatively, nicotine nasal spray can be delivered by spraying directly onto the buccal mucosa between the cheeks and gums or sublingually.

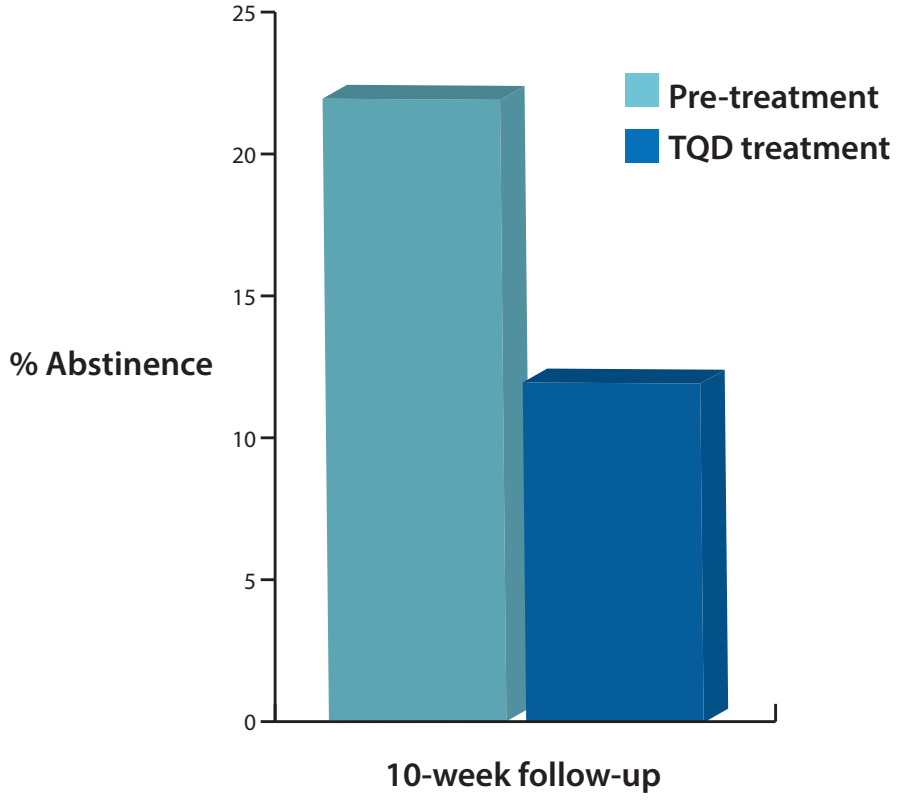
Nicotine polacrilex gum and lozenges and the nicotine inhaler deliver nicotine directly to the buccal mucosa. Absorption is attenuated in an acidic environment. As such, oral nicotine delivery can be "turbocharged" when the patient gargles and rinses their mouth with a baking soda-water solution prior to nicotine gum, lozenge, or inhaler administration.

A study of 190 treatment-seeking smokers found that the mean baseline blood nicotine level was 19.3 ng/mL; with a mean nicotine "boost" of 10.9 ng/mL within 3 minutes of smoking a single cigarette *(Patterson et al., 2003).*

While the Nicotrol nicotine inhaler delivery is relatively low and slow *(hence unsatisfying pharmacologically compared with cigarettes)*, Robert West and colleagues found that five Nicotrol cartridges assembled in what they describe as a "cannon" delivers less harmful nicotine with a nicotine plasma profile more similar to a cigarette. The cartridges can be assembled and held together with cellophane tape or a rubber band, and 40 puffs performed within 10 minutes delivers 11 ng/mL at the 15-minute mark.

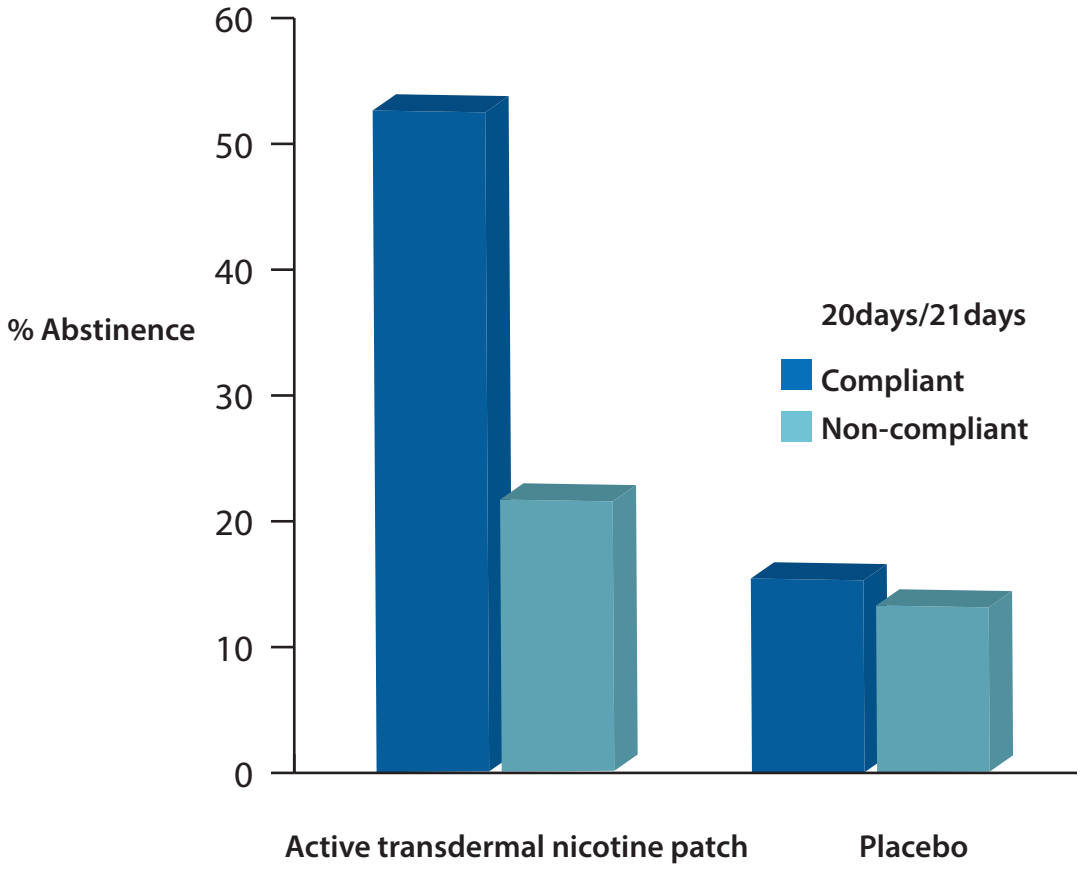


Pre-treatment *(i.e. application prior to a target quit date)* of transdermal nicotine patches can double biochemically confirmed quit rates.

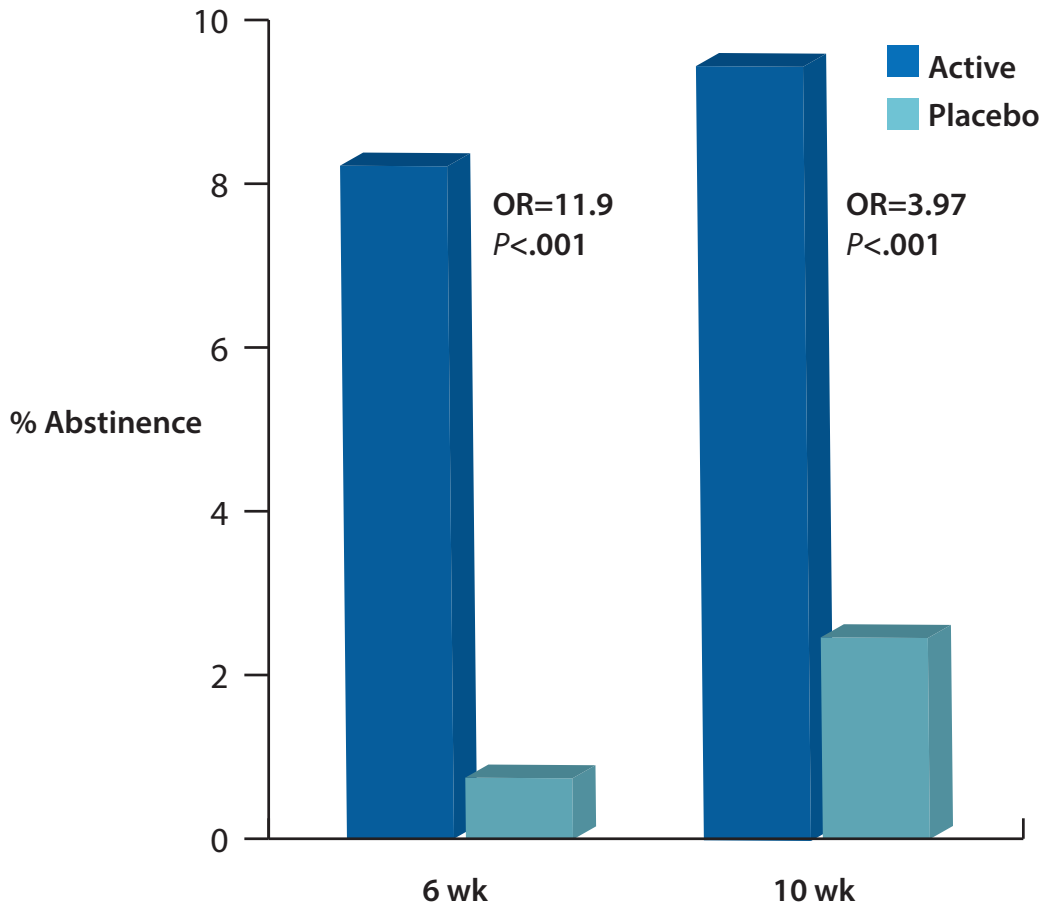


Pre-cessation treatment with Nicotine Patch Significantly increases Abstinence Rates Relative to Conventional Treatment. Rose, JE Herskovic, JE, Behm FM, Westman, EC. Presented at the SRNT Annual Conference 2007.

Wearing transdermal nicotine patches continuously increases quit rates. Missing more than 1 day in 3 weeks greatly lowers biochemically confirmed quit rates. Educate all patients that medications can't work if they are not used.

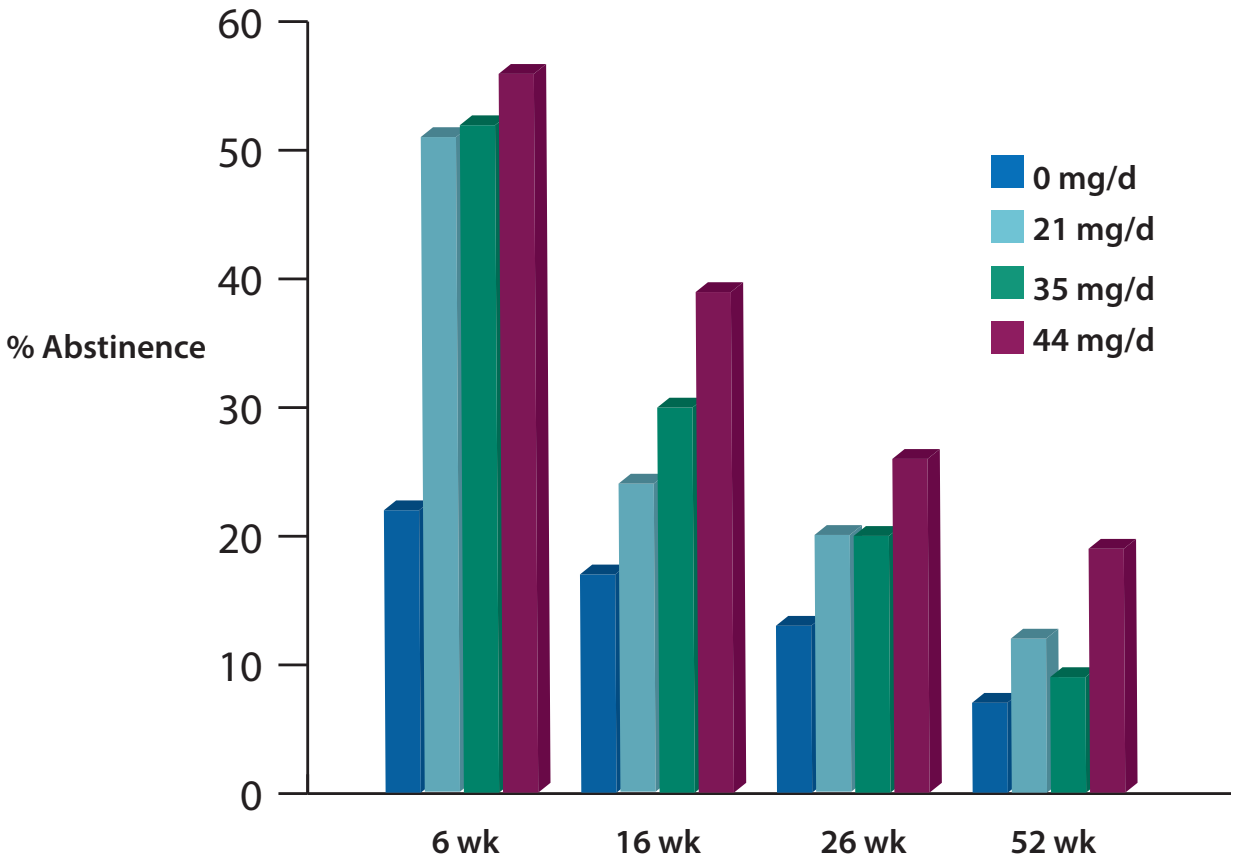


Continually wearing transdermal nicotine patches after smoking lapse promotes recovery toward biochemically confirmed abstinence.

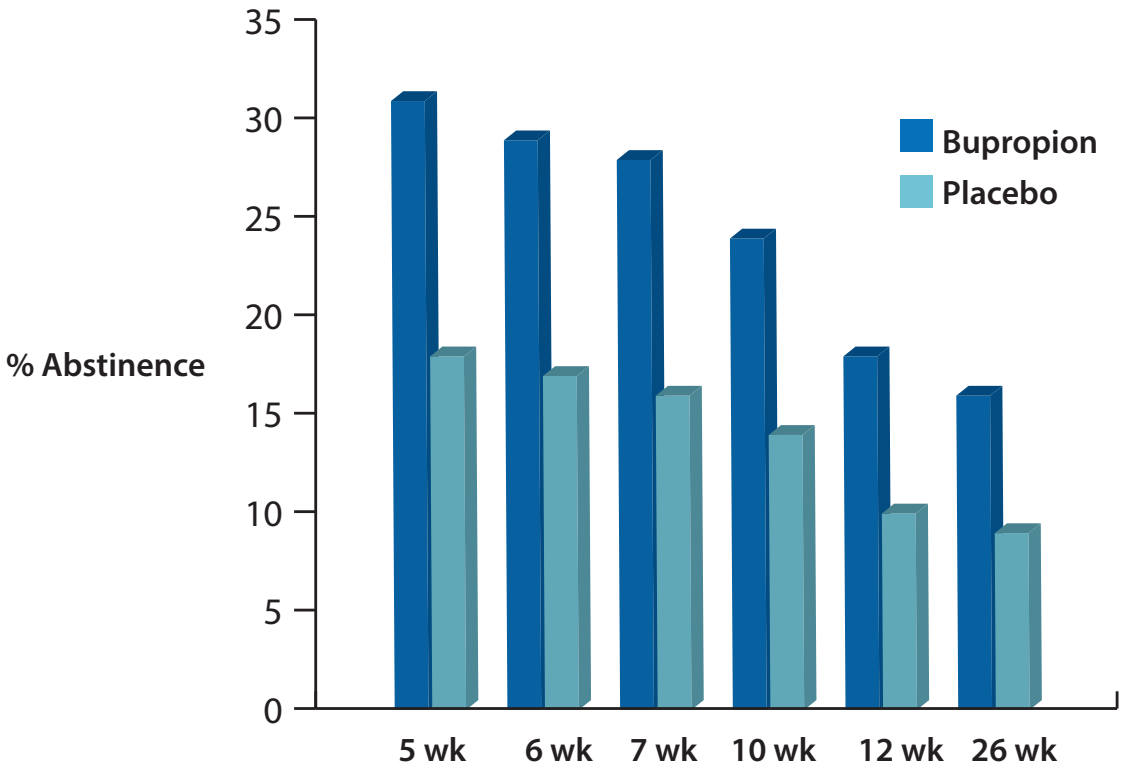


Active patch use *(versus placebo)* increased the likelihood of recovery from a lapse both at 6 weeks [8.3% versus 0.8%; relative risk (RR) = 11.0, P < 0.001] and at 10 weeks (9.6% versus 2.6%; RR = 3.7, P < 0.001).

Patients wearing higher-dose nicotine patches (≥21mg x 2) may work better. Higher nicotine delivery is safe and effective for persons with severe tobacco dependence.

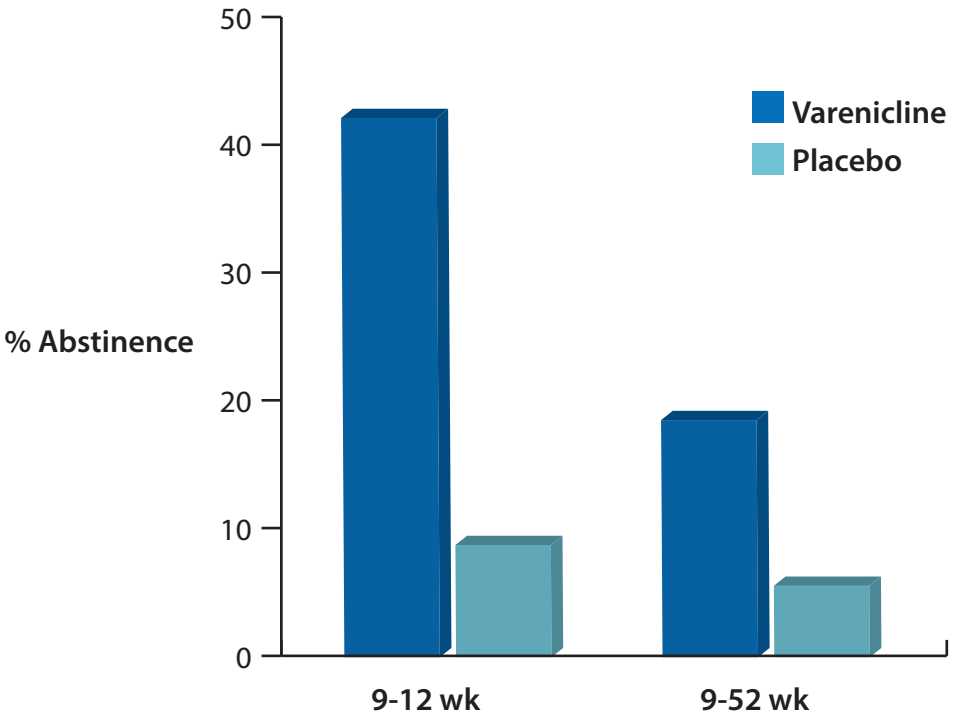


Bupropion helps even heavily tobacco-addicted, previously diagnosed with mild to moderate COPD patients achieve biochemically confirmed quit rates.

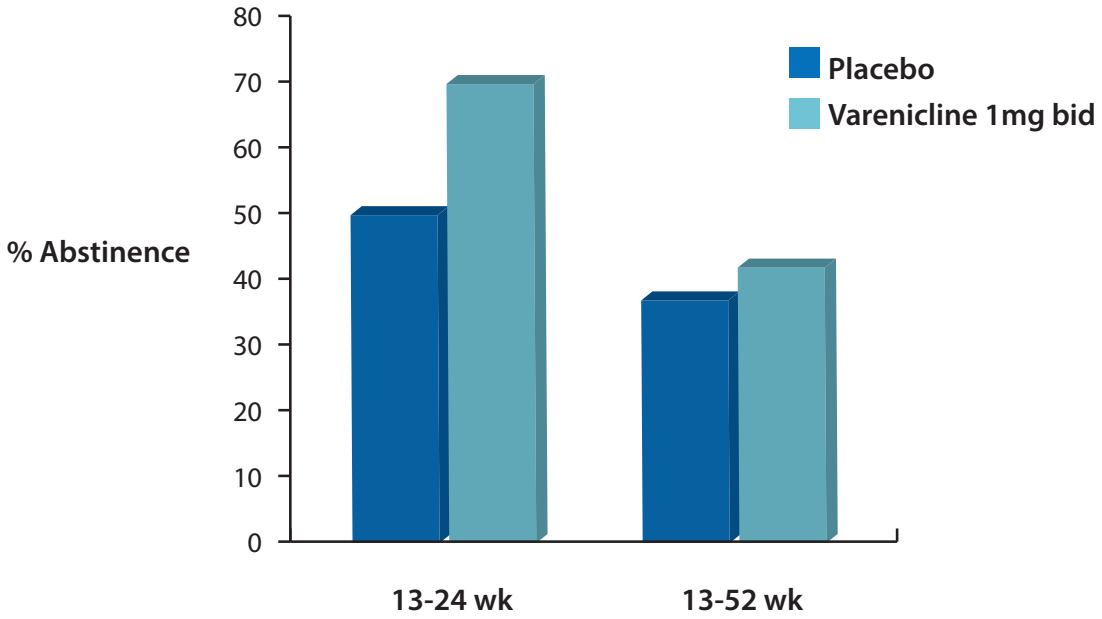


Bupropion increases the motivation to quit in unmotivated smokers over placebo. Bupropion decreased the time to a quit attempt from an average of 118 days with placebo to 64 days. With unmotivated smokers, bupropion increased biochemically-confirmed quit rates 75% *(14% vs 8%)*. Bupropion reduced tobacco consumption over placebo as measured by urinary cotinine levels prior to quitting *(20% vs 6%)*.

Varenicline helps heavily addicted smokers with COPD attain biochemically confirmed quit rates.



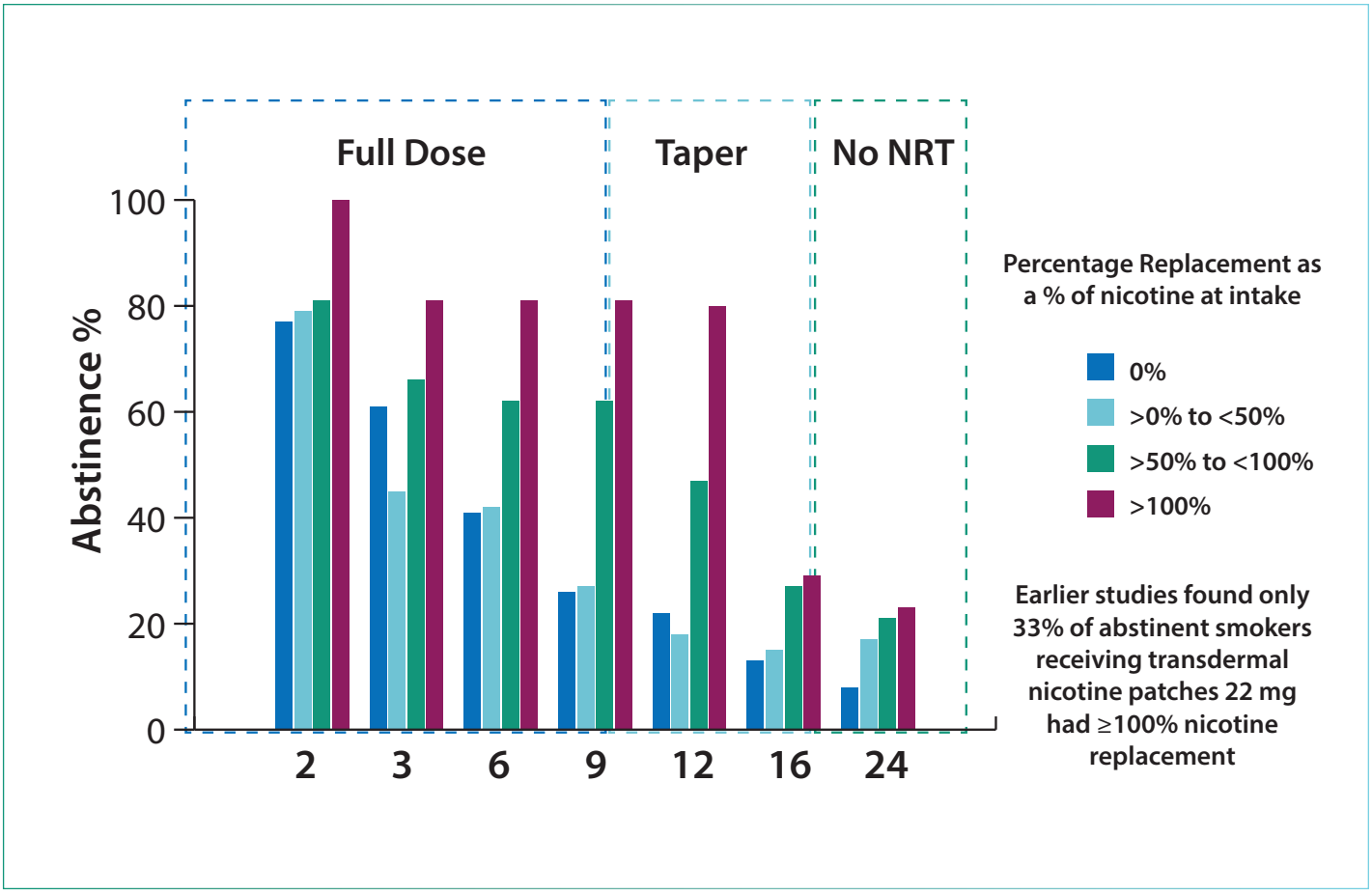
Extended administration of varenicline *(52 weeks)* is safe and may increase biochemically confirmed quit rates.



Better NRT dose matching has been accomplished by measuring baseline cotinine levels while smoking and titrating NRT to this baseline intake and/or subsequent levels.

Studies show a percentage replacement of nicotine is inversely correlated with withdrawal symptoms and positively correlated with quit rates.

Cotinine/nicotine metabolite assays can guide successful treatment. Increasing nicotine replacement as a percentage of nicotine metabolites measured at baseline or intake increases treatment success.



SPECIAL POPULATIONS

Parents and/or Household Members of Your Patient

Tobacco product use by parents harms the health of their children. Pediatricians have an important role in counseling and/or offering tobacco dependence treatment to the parents of their patients. The health of their child may motivate the parent much more than their own health. The parent may see their child's pediatrician much more than their own physician. Often the parent may not have their own health insurance. Counseling and treatment *(or referral for treatment)* of the parent's tobacco dependence is an important role for the pediatrician, because it will benefit the child and other children in the family, reduce the risk for future pregnancy complications from tobacco product use or exposure, and it will benefit the parents themselves.

Similarly, if the patient is a spouse, household member or close family member to a smoker, offering a path for effective tobacco dependence treatment that your patient can bring back to their loved one will help both your patient and their loved ones.

Key Point:

- *Pediatricians can and should counsel and/or offer tobacco dependence treatment to parents/ caregivers of their patients.*

Adolescents

Treatment of tobacco dependence in adolescents is challenging. Nicotine dependence is but one part of the problem. Social influences, beliefs, underestimation of risk, and easy access to products designed to appeal to adolescents are others. Psychiatric co-morbidities and other substance abuse may also be contributors.

The most effective smoking cessation interventions for adolescents have been behaviorally based group programs that focus on problem-solving skills and providing support and encouragement. Behaviorally based approaches, although beneficial, have been less effective for adolescents with moderate or high levels of nicotine dependence.

Most clinical trials of pharmacotherapy of tobacco dependence in adolescents failed to show benefit, being limited by either short treatment courses or non adherence to the study medication. Behavioral factors need to be addressed such as motivation, refusal skills, and the role of tobacco products in the adolescent's social relationships. Medications for tobacco dependence treatment that are FDA approved for use in adults can be used for moderate to severely nicotine-dependent adolescents; however the practitioner needs to be aware that non adherence is common and often limits medication effectiveness and that no tobacco treatment medication is FDA-approved for patients younger than 18 years of age.

The most effective approach, however, is primary prevention. Close to 90% of adult smokers start tobacco product use in adolescence. We, as a society need to stop developing and marketing tobacco products that appeal to youth. As providers, we need to counsel young people from as early in life as possible so that they can understand about the harmful effects of using any type of tobacco product, how quickly they can get addicted, and the importance of not using or trying any tobacco products, including electronic cigarettes. Messages should be clear, personally relevant, and age appropriate. Ask them to make a commitment to be tobacco-free and help them identify their own reasons for being tobacco-free.

Key Points:

- *Treatment of nicotine and tobacco dependence in adolescents is difficult.*
- *In addition to nicotine addiction, social influences, underestimation of risk, and easy access to products are important factors in maintaining tobacco and nicotine product use.*
- *Pharmacotherapy for tobacco dependence that is effective for adults can be prescribed for adolescents, ; however, nonadherence is common.*

Patients With Psychiatric Disorders

Tobacco dependence is very common among patients with psychiatric disorders, and it is commonly the cause of premature death for these patients. Tobacco dependence is often more difficult to treat in patients with psychiatric disorders, because as they are often less able to manage the symptoms of nicotine withdrawal, including depression, anxiety, irritability, anhedonia, and difficulty concentrating. Further more, poorly controlled nicotine withdrawal may exacerbate their psychiatric comorbidities. Often patients with psychiatric disorders consume more nicotine per cigarette than nonpsychiatric smoking patients.

Although there had been concern of bupropion and varenicline causing or exacerbating psychiatric comorbidities, a recent, very large clinical trial has shown that the rate of psychiatric adverse events was not much different in treatment groups compared with placebo. The cause of psychiatric adverse events is often the inadequately controlled nicotine withdrawal, not the tobacco-dependence treatment medications. Close follow up and monitoring of treatment are important to ensure adequate control of nicotine withdrawal.

Key Points:

- *FDA-approved medications for tobacco dependence can be used for psychiatric patients. They do not greatly increase the risk for psychiatric adverse events.*
- *Psychiatric patients may not be able to tolerate nicotine withdrawal symptoms. They often need more intensive pharmacotherapy to suppress their withdrawal symptoms.*
- *Contrary to popular opinion, smokers with psychiatric challenges also want to become tobacco-free.*

Patients With Substance Abuse

Nicotine and tobacco dependence are common in persons addicted to other substances of abuse and tobacco is associated with an increased risk of substance abuse relapse. Nicotine and tobacco are often reported as more difficult to stop than other substances such as heroin, cocaine, and alcohol. Substance abusers who have their tobacco dependence treated often find it easier to reduce or stop their other substances of abuse. Patients in substance abuse treatment programs are often interested in having their tobacco dependence treated.

Key Points:

- *Treatment of tobacco dependence can improve outcomes for the treatment of other substance abuse.*
- *Tobacco dependence treatment should be offered as part of the treatment of other substance abuse.*

Pregnant Women

Tobacco product use during pregnancy has definite adverse effects on the fetus. These harms include orofacial clefts, fetal growth restriction, placenta previa, abruptio placentae, preterm pre-labor rupture of membranes, low birth weight, increased perinatal mortality, ectopic pregnancy, and decreased maternal thyroid function. Children born to women who smoke during pregnancy are at an increased risk of respiratory infections, asthma, infantile colic, bone fractures, and childhood obesity. Stopping tobacco product use at any point in gestation benefits the pregnant woman and her fetus.

It is safest for the woman and her pregnancy if she is able to stop tobacco product use without medications. Counseling strategies that have been shown to benefit pregnant women include helping her develop a sense of self-monitoring and control, learn to manage cravings, manage situations of stress and anxiety, promote self-efficacy, set goals, and plan actions.

Continued tobacco product use is the most harmful for the woman and her pregnancy. Pharmacotherapy of tobacco dependence with any of the FDA-approved medications should be considered for women who are not able to stop tobacco product use without medication. Varenicline, the most effective single agent for tobacco dependence, has not shown teratogenicity in several small studies. There are limited data on bupropion use in pregnancy;however, there is no known risk of fetal anomalies or adverse impacts on pregnancy with bupropion use. Although nicotine has definite adverse effects on the fetus, some women may be more likely to accept nicotine replacement as harm reduction because it is not adding a drug that they are not already using.

At present, there is no reliable scientific evidence that electronic cigarette use *(also called vaping)* is a safer alternative to cigarette smoking and should not be recommended as tobacco dependence treatment.

There are also legal liability issues for any clinician who advises patients to use a product that is not FDA-approved, especially for products that have no manufacturing standards, that commonly contain chemicals known to be hazardous to inhale, are known to cause severe acute disease *(such as e-cigarette or vaping product use-associated lung injury [EVALI]),* and are associated with increased risk for severe cardiopulmonary chronic conditions.

Pregnant women who use electronic cigarettes should be given the same counseling and/or treatment to help them stop as would be given to a woman dependent on any other tobacco product.

Many women who do stop smoking during pregnancy relapse after delivery. The post-partum period is a particularly important time to monitor the mother, counsel her about strategies to avoid relapse, and initiate pharmacotherapy if needed. For the breast feeding mother, bupropion use is associated with low levels of detection in breastmilk that are unlikely to cause adverse effects in infants. There is no published information available on varenicline use during lactation. Nicotine, however, does cross into breast milk. NRT for breast-feeding women can be considered as a harm reduction strategy if other strategies have been declined or have been ineffective.

Key Points:

- *Tobacco product use during pregnancy leads to substantial harms for the mother and fetus.*
- *Relapse of tobacco dependence after delivery is common.*
- *It is best for the pregnant woman to stop smoking without medication.*
- *If pharmacotherapy is needed for the tobacco dependent pregnant woman, varenicline and/or bupropion is preferred.*

HARMS OF ELECTRONIC CIGARETTES

Expert Opinion

Electronic cigarette or vaping products are commonly perceived – and promoted– as a safer alternative to smoking. Accumulating evidence, however, demonstrates that electronic cigarettes are not a safe product and that dual use of electronic cigarettes plus combustible tobacco may be more hazardous than use of combustible tobacco alone.

Multiple large epidemiologic studies have demonstrated that smokers who also use electronic cigarettes are less likely to stop smoking than those who don't use electronic cigarettes. Among former smokers, those who use electronic cigarettes are more likely to relapse to smoking than those who don't.

Severe acute harms from e-cigarette use include injuries and burns from product explosions and acute nicotine poisoning from the concentrated nicotine solution used in the products. Severe acute respiratory diseases have been described in e-cigarette users, including eosinophilic pneumonia, hypersensitivity pneumonitis, diffuse alveolar hemorrhage, lipoid pneumonia, organizing pneumonia, and severe asthma. The Centers for Disease Control and Prevention has identified many cases of leading to hospitalization and death. Although most of the cases were associated with use of tetrahydrocannabinol (THC)-containing products, 29% of fatal cases and 14% of all reported cases describe exclusive use of nicotine containing e-cigarette products.

Laboratory studies and large epidemiologic studies show increased risk for cardiovascular disease in e-cigarette users. Increased rates of respiratory diseases, including bronchitis, emphysema, and asthma, are observed in e-cigarette users. Laboratory animal studies show decreased defenses against bacterial and viral pathogens in animals exposed to electronic cigarette emissions.

Increased rates of cancer have been demonstrated in laboratory animals exposed to electronic cigarette, emissions and carcinogenic substances that are linked to bladder cancer have been shown to accumulate in the urine of human electronic cigarette users.

Dual use of electronic cigarette and combustible tobacco products is the most common pattern of use. Dual use exposes the user to the toxins in combustible tobacco and to additional toxins unique to electronic cigarettes. Large epidemiologic studies have shown that dual users had worse general health scores, more breathing difficulty, and had a higher risk of stroke than combustible tobacco only users.

Further more, e-cigarettes are an unregulated consumer product and best manufacturing processes are not necessarily followed. It is not uncommon for e-cigarettes to explode or burst into flames, causing serious injury.

TREATMENT FOR E-CIGARETTES/SMOKELESS TOBACCO USERS

Expert Opinion

As the reader may be aware, e-cigarettes and vaping devices are relatively new tobacco products. Please be advised that these vaping treatment protocols are empirically based and have not been subjected to rigorous clinical trials. Smokeless tobacco treatments have been investigated in relatively few studies.

Smokeless tobacco products are used by approximately 5.9 million American adults, or about 2.4% of the US population. A total of 64% of smokeless tobacco users report the desire to quit.

Neither varenicline, bupropion, nor any NRT is specifically approved for smokeless tobacco, e-cigarette vaping, or heat not burn tobacco products, yet all seven FDA-approved medications are effective treatments for all tobacco product use. Specifically, research has demonstrated that varenicline significantly increases smokeless tobacco abstinence after 6 months. Severson and colleagues found that mini-lozenges 4 mg were also very helpful in treating smokeless tobacco dependence. Ebbert and others found that high dose of nicotine patches *(42mg/day)* safe and increases short-term tobacco abstinence rates among smokeless tobacco users who use ≥3 cans/pouches per week. High-dose nicotine patch therapy is associated with significant long-term attenuation of weight gain. Studies of higher-dose nicotine patch therapy *(≤63 mg/day; three individual transdermal nicotine patches 21 mg/day)* in smokeless tobacco users have demonstrated a dose-dependent reduction in tobacco withdrawal symptoms as well as preliminary evidence of increased long-term *(>6 months)* abstinence rates compared with lower doses.

For high levels of smokeless tobacco users *(≥3 cans/pouches of tobacco per week)*, clinicians can feel comfortable starting the patient on 42-to 63-mg patch dose daily *(two to three transdermal nicotine patches 21 mg/day)* for 4 to 6 weeks.

From intake, taper dose down as needed in 7-to 21-mg increments based on the patient's report of withdrawal symptoms, urges, and comfort. After abstinence is obtained, based on the same criteria, the clinician can discuss downward titration with the patient. Generally speaking, when in doubt, higher dosing for a longer period is preferable to lower dosing for shorter periods.

The clinician may also wish to determine (1) if the vaper or smokeless tobacco user is engaging in dual use or if they are only vaping or only using smokeless tobacco, and (2) if they formerly smoked, how many cigarettes per day they consumed. The treatment of tobacco patients who are dual users is a little more complicated.

If the patient did smoke traditional cigarettes in the past, the clinician may wish to determine (1) time to first cigarette, (2) how many cigarettes were smoked in the first 2 hours after awakening, and (3) if the patient engaged in nocturnal smoking and to what degree. *(i.e. how many nights per week does the patient awaken and smoke.)* These three items all highlight the degree of tobacco dependence.

If the patient did smoke traditional cigarettes in the past, the clinician should inquire if, after having switched to e-cigarettes or smokeless tobacco completely, whether they are experiencing withdrawal symptoms such as craving, irritability, anxiety, and hunger *(and/or weight gain)*. If they "feel" essentially the same vaping or using smokeless tobacco as they did while smoking traditional cigarettes and do not "miss" their cigarettes, consider starting the patient on the same treatment protocols used as if they were still smoking, aggressively titrating up and adding additional medications as needed. *(See treatment protocol and clinical pearls sections.)*

The clinical situation is more complicated when patients engage in dual use. The simplest approach is to treat empirically. *(eg, administer a 21mg nicotine patch and titrate from there based on therapeutic response.)*

As discussed in the section on diagnostics, expired (EtCO) and TNE *(nicotine and cotinine)* assays are powerful tools to assess levels of consumption, dependence, and therapeutic progress regarding all tobacco product use.

After baseline measurements of EtCO and TNE, adaptive treatment protocols can be implemented and modified based on changing clinical findings, patient preferences, and clinician input over the course of the treatment.

Generally, if the tobacco dependent patient is prescribed a non-nicotine medication *(eg varenicline)*, frequent EtCO and TNE measurements should both decrease over time, with corresponding decreases in combustible tobacco, smokeless tobacco, or vaping and related decreases nicotine consumption towards abstinence.

In contrast, successful administration of NRTs or successful combination pharmacotherapies *(NRT[s] plus varenicline and/or bupropion)* would result in a relatively rapid decrease in EtCO due to a reduction in combustible tobacco, while TNEs would remain relatively constant due to the additional nicotine from NRTs. After the patients attains tobacco abstinence, repeat TNE measurements over the course of weeks or months can be used to guide downward titration of medications.

- *Treating vapers or smokeless tobacco users empirically is clinically appropriate.*
- *With NRTs, after the initial high percentage replacement as treatment continues, TNE assays begin to decrease during downward titration of NRT towards abstinence.*
- *This reflects decreases in both combustible and non-combustible tobacco use.*
- *EtCO and TNEs enable personalized tobacco treatment and the titration of medications towards optimal efficacy.*
- *Under-dosing with tobacco treatment medications (using low sub-optimal dosing and discontinuing medications prematurely) is a much more common problem than overdosing.*

INSURANCE BILLING AND TELEHEALTH

Tobacco Treatment Toolkit Insurance and Billing

All clinicians should get reimbursed for their efforts. Clinicians should expect to be reimbursed for their interventions. This includes treating their tobacco-dependent patients.

Understanding the basic difference between a typical evaluation and management (E/M) visit and one focused only on health counseling is the first step in successfully integrating tobacco-dependence treatment into your practice. Only modest adjustments in style and content are necessary to document the level of service provided. Attention should be given to all of the most appropriate ICD-10 codes for the reimbursement problems physicians face, including those that relate to tobacco-dependence treatment. This Tool Kit will help physicians and their billing managers understand the reimbursement principles associated with tobacco-dependence treatment.

Correct Coding Principles For Tobacco-Dependence Treatment

Contrary to popular misconceptions, mechanisms for compensating clinicians for tobacco treatment services exist!

Introduction

The belief that “smoking cessation is not paid for” is true when referring to publicly provided lay counseling such as health associations, and community groups. "Smoking cessation" is defined as something the tobacco user does, whereas “tobacco treatment” is something the clinician does.

Cognitive services *(using clinical knowledge and experience to problem solve and treat)* are reimbursable, irrespective of the clinical problem. This of course includes patients who are tobacco dependent.

While the specifics of tobacco treatment reimbursement vary by both the specific insurer and contract, clinicians should expect to be fairly compensated for tobacco treatment services, in a manner similar to compensation for services delivered for other conditions.

This Tool Kit is intended only as a guide, and should not be interpreted as a guarantee of payment. When in doubt, contact payer representatives for specific plan details and definitive guidance.

Is it Counseling, Or Is it an (E&M) Visit?

There can be substantial confusion over whether what we do in the office or via telehealth to treat the tobacco-using patient should be considered counseling or management. There are distinctions between these two services within a clinical encounter that may be useful in deciding which coding and documentation requirements apply.

Evaluation refers to the clinician's cognitive processes applied while determining the significance or status of a problem or condition. This is typically accomplished through careful appraisal and study. As an example, the elements of evaluation in general medical practice might include a careful history, a review of systems, X-ray testing and review, and/or the physical exam.

Similarly, evaluation requirements for tobacco use often include a careful evaluation of factors such as severity of nicotine dependence, biochemical measurement of tobacco consumption, the toxic effects of prolonged tobacco exposure, severity of medical co-morbidities, the patient's insight into the problem and their confidence in abstinence, prior quitting experience and medications used previously, periods of abstinence or reduction in consumption, and/or the response to previously prescribed medications.

Management refers to the conduct or supervision of activities in pursuit of a pre specified end. This often implies that the plan be based on the results of the evaluation. As an example, the management plan for a severe asthmatic exacerbation might include the decision to begin systemic steroids and the advice to avoid environmental triggers. These decisions might be based on information garnered through historical, physical, spirometric, and radiographic evaluations.

Management decisions in the tobacco dependent patient might include the prescribing of medication(s) and reviewing appropriate medication use, environmental modification recommendations (avoiding alcohol for a time, avoiding other smokers), and are typically based on information obtained through biochemical assessment, historical, physical, and/or standardized instrument evaluations *(eg, screening for depression, Fagerström Test for Nicotine Dependence [FTND], Heaviness of Smoking Index).*

Counseling refers to the professional guidance provided to an individual or group. Though the typical connotation of counseling implies the utilization of psychological methods, counseling often happens in medical practice but is rebranded as patient education. With an asthmatic patient, instruction on proper inhaler technique and use of a metered-dose inhaler spacer chamber could be considered counseling or patient management. In tobacco use treatment, similar examples might include a discussion of potential smoking triggers and coping techniques or suggestions on stress management techniques.

Documentation Requirements

The documentation in the medical record must support the billing of the tobacco treatment services. The documentation needs to record what was discussed during counseling and should show a significant and separately identifiable service.

Items to document may include to following elements:

- *The patient's tobacco use (eg, cigarettes per day, vaping pods per day, smokeless tobacco pouches per day)*
- *Biochemical measurement of tobacco consumption (total nicotine equivalents assays and expired breath EtCO assessment)*
- *Advised to quit and impact of smoking related to patient's health*
- *Assessed willingness to attempt to quit or reduce consumption*
- *Providing tobacco treatment methods*
- *Medication management of tobacco treatment (eg, review of proper varenicline dosing and possible adverse events/side effects)*
- *Resources provided (eg, national quit-line, **1-800-QUIT-NOW**)*

- *Setting a quit date*
- *Follow-up care arranged*
- *Amount of time spent addressing and managing the patient's tobacco use and tobacco-related comorbidities (eg, review of chest X-ray with patient highlighting peri-bronchial cuffing, bilateral hyper-inflated lung fields secondary to airway obstruction, vertebral wedging, and ruling out osteoporosis possibly related to smoking)*

An entry in to the patient's health record simply stating that the doctor spent >11 minutes counseling the patient on tobacco use is inadequate and will not meet the standard for medical necessity or enable third-party reimbursement.

For more information and example of a clinical documentation notes form, please visit https://capturebilling.com/how-bill-smoking-cessation-counseling-99406-99407/#ixzz6WhnCf93o

Case Example 1:
Tobacco Dependence E/M Visit

Mrs. Smith presents to your office on referral from a colleague. She is referred for help with her current tobacco use, totaling approximately 25 cigarettes per day for over 30 years. She reports smoking more during the weekend. Your history focuses on details of her tobacco use patterns to date, including a fuller understanding of previous quit attempts, triggers to smoking, and the nature of her reluctance to quit. The review of systems reveals that Mrs. Smith often feels short of breath with one flight of steps that she attributes to "getting older," and your exam reveals coarse rhonchi in bilateral lung fields. Office evaluation procedures are performed, including administration of (FTND), administration of a depression screening instrument, and evaluation of spirometry before and after bronchodilator administration. At intake, her in-office urinary total nicotine equivalents was 95.2 nmol/mL, while her expired breath carboxyhemoglobin (COHb%) was 5.6%, which is consistent with moderately severe nicotine dependence. She also has a diagnosis of a major depressive disorder in the recent past, while her pre- and post-bronchodilation spirometry reveals moderate irreversible airflow obstruction.

Based on these insights, you determine the most appropriate pharmacologic and non-pharmacologic interventions, and begin developing a plan with the patient. After some discussion, the final plan is agreed upon and you confirm the patient's level of understanding and concurrence with the plan. You set a return visit appointment for 3 weeks in order to check response to medications, barriers to adherence, withdrawal symptoms, and any potential adverse events/side effects.

While some patient education and counseling occurs during the visit, the evaluative nature of the encounter is manifest in several ways. The results of this evaluation were used to formulate a plan that included an iterative reassessment of the effectiveness of the recommendations.

What Is the Level of Service?

E/M Services

For most E/M visits, clinicians will refer to the American Medical Association's Current Procedural Terminology to identify the correct level of service through the algorithms that relate elements of history, physical exam, and complexity of clinical decision making. The clinician may actively choose to forgo evaluating several systems on physical exam in favor of gaining more insight into tobacco use patterns and obstacles to treatment. Non-contributory details of the family history may be omitted in favor of evaluating concurrent substance abuse potential.

Case Example 2: Tobacco Dependence E/M Visit

If the primary goals of the visit relate directly to the diagnosis and management of tobacco use and related complications, clinicians may elect to code the visit using the appropriate E/M service codes that relate to the type and duration of the visit, as long as the time dedicated to tobacco treatment E/M services *(including patient education)* exceeds 50% of the total visit time. For example, the medical record should include reference to the subjective and/or objective evaluation of nicotine dependence, evaluation of potential concurrent comorbidities, and their relationship to the patient's tobacco use *(eg, depression, cardio-pulmonary health status, use of other drugs of abuse, treatment contraindications)*, as well as their potential impact on management decisions. Education efforts regarding the nature of tobacco use, treatment strategies, and possible side effects should be documented, as should the patient's response to the discussion.

The plan for treatment should be outlined, including any contingency planning discussed with the patient. These details help to establish the evaluative nature of the visit, as well as the more complex and iterative nature of longitudinal management.

The level of service can be determined using time thresholds *(Table 1)* as long as the note clearly documents (1) the time dedicated to patient education/ counseling, (2) that the total time of the visit exceeded the threshold, (3) that tobacco treatment activities *(E/M, patient education/ counseling)* occupied more than 50% of the total visit time, and (4) clinically relevant details.

It is acceptable for clinicians to use clear and concise notation to document these facts instead of long or cumbersome prose, *"Total 25 min tobacco treatment E/M 15 min."*

Table 1 - Time thresholds *(min)* that define levels of service per visit category.

Visit Category	Code Range	Level 1	Level 2	Level 3	Level 4	Level 5
New Patient	**99202-99205**	Deleted	15-29 mins	30-44 mins	45-59 mins	60-74 mins
Established Patient	**99212-99215**	N/A	10-19 mins	20-29 mins	30-39 mins	40-54 mins

Beginning with CPT 2021 and except for 99211, time alone may be used to select the appropriate code level for the office or other outpatient E/M services codes (99202, 99203, 99204, 99205, 99212, 99213, 99214, 99215). Time may be used to select a code level in office or other outpatient services whether or not counseling and/or coordination of care dominates the service. For office or other outpatient services, if the physician's or other qualified health care professional's time is spent in the supervision of clinical staff who perform the face- to-face services of the encounter, use 99211.

Physician/other qualified health care professional time includes the following activities, when performed:

- *Preparing to see the patient (eg, review of tests CXR, Chest CT, EKG, etc performed previously)*
- *Obtaining and/or reviewing separately obtained history*
- *Performing a medically appropriate examination and/or evaluation (eg, Nicotine assays, Expired breath carbon monoxide monitoring, Review of daily smoking logs, etc.)***
- *Counseling and educating the patient/family/caregiver*
- *Ordering medications, tests, or procedures*
- *Referring and communicating with other health care professionals (when not separately reported)*
- *Documenting clinical information in the electronic or other health record*
- *Independently interpreting results (not separately reported)** and communicating results to the patient/family/caregiver*
- *Care coordination (not separately reported)*

**Any specifically identifiable procedure or service *(i.e. identified with a specific CPT code)* performed on the date of E/M services may be reported separately. The actual performance and/or interpretation of diagnostic tests/studies during a patient encounter are not included in determining the levels of E/M services when reported separately. Physician performance of diagnostic tests/studies for which specific CPT codes are available may be reported separately, in addition to the appropriate E/M code. The physician's interpretation of the results of diagnostic tests/ studies *(i.e. professional component)* with preparation of a separate distinctly identifiable signed written report may also be reported separately, using the appropriate CPT code and, if required, with modifier 26 appended. If a test/study is independently interpreted in order to manage the patient as part of the E/M service, but is not separately reported, it is part of medical decision making.

https://www.ama-assn.org/system/files/2019-06/cpt-office-prolonged-svs-code-changes.pdf

Combined E/M and Tobacco Dependence Visit

Frequently, clinicians are faced with a visit that starts off focused on a different problem, but comes to include a discrete focus on tobacco. In this case, two options are available for coding the level of service. For visits in which the overall tobacco treatment E/M and education/counseling time exceeds 50% of the total time dedicated to the visit, the level of E/M service may be calculated based on the time thresholds listed in Table 1. In this case, all elements of patient education/counseling, including the time spent educating the patient on the relationship to tobacco use and the presenting problem/complaint, including diagnostic considerations, should be included when calculating the proportion of patient education/ counseling time for the visit. Conversely, if the time spent in patient education/counseling does not exceed 50% of the total visit time, the clinician may elect to code for the two component services separately.

That is to say that the level of E/M services may be based on the standard CPT rubric, with the additional counseling service coded using the Behavior Change Intervention codes listed on the next page.

There is a caveat to the above. In many practices, the E/M of cough, shortness of breath, and COPD may prompt a "referral" to the nurse practitioner at the conclusion of the visit for more complete counseling services. If the physician or other qualified health care professional's time is spent in the supervision of clinical staff who perform the face- to-face services of the encounter, use 99211. Remember that smoking cessation counseling services can be provided on the same day as E/M services, either directly by the physician or by other qualified health-care professionals. Chart and report the E/M visit separately from the behavioral health intervention, if guidelines for each service are met. When an office visit *(eg, 99213)* and tobacco treatment counseling *(eg, 99407)* are reported on the same day, append modifier 25 to the E/M *(eg, 99213-25)*. The CPT modifier 25 is used to report an E/M service on a day when another service was provided to the patient by the same physician.

Counseling Services: Behavior Change Interventions

Medicare, Medicaid, and some private insurance carriers deem tobacco treatment counseling to be reasonable and necessary for individuals who have evidence of conditions linked to tobacco. Clinicians should consider using the counseling codes when tobacco use treatment can be viewed as a portion of, or adjunct to, the primary purpose of the visit. For example, in a patient who presents for E/M of COPD, counseling would be considered a core component of their care, but may not be the main focus of the interaction.

Cessation counseling that lasts less than 3 minutes is considered to be part of the standard E/M service for the underlying condition. For patients who require additional counseling, the clinician may also report intermediate *(3-10 minutes)* or intensive *(> 10 minutes)* of service. Effective January 1, 2008, Medicare implemented two new CPT codes to reflect these services: 99406 for intermediate counseling, and 99407 for intensive counseling.

Tobacco Dependence Counseling Visit

Medicare requires that the medical record include some documentation of the necessity of this service, which may include reference to a condition or therapeutic agent that is being adversely affected by tobacco use. Comments in the record should document both the time spent in counseling as well as pertinent details of the cessation strategies discussed. Medicare has assigned intermediate counseling *(99406)*, and intensive counseling *(99407)*. The code 99406 cannot be reported in conjunction with 99407. Medicare will cover two attempts at smoking cessation each year, with each attempt consisting of a maximum of four sessions *(any combination of intermediate and/or intensive for a total of eight sessions per year)*. However, tobacco treatment can and should be addressed and billed at every appropriate clinical encounter.

Clinicians are advised to remember that Medicare covers and reimburses this service, while other payers may not. Private insurers may place Behavior Change Interventions codes within their behavioral health services carve out, in which case reimbursement for these services is not available to other clinicians. When the insurer denies payment for smoking cessation counseling, the financial responsibility for the charges may fall to the patient.

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Which Diagnosis Is Which?

Readers are referred to the ICD-10-CM for complete descriptions of diagnostic codes relevant to tobacco use treatment.

Selection of Primary Diagnosis

Health-care providers are expected to determine the primary diagnosis based on the condition most related to the current plan of care. The diagnosis may or may not be related to the patient's chief complaint or reason for presentation. The primary diagnosis must relate to the services rendered, and to the documentation of the visit details.

Selection of Secondary Diagnosis

Secondary diagnoses remain defined as "all conditions that coexisted at the time the plan of care was established, or which developed subsequently, or affect the treatment or care." Secondary diagnoses may include conditions actively addressed in the patient's plan of care as well as any comorbidities that affect treatment decisions. Avoid listing diagnoses that are of mere historical interest, those without impact on patient progress or outcome, or for which the physician does not mention a course of action. Depending on the clinical encounter, tobacco use disorder(s) can be appropriate for either the primary or secondary diagnosis.

IS THE VISIT ABOUT TOBACCO?				
	Yes		No	
	Is the service evaluative in nature?		Did counseling account for >50% of the total visit time?	
	Yes	No	Yes	No
Service type	E/M service	Counseling Service	E/M service	E/M service for the primary visit, PLUS Counseling service for tobacco portion
Notes	√ Use time thresholds?	Level based on time	Level based on time	√ Separate providers?
Example of primary diagnosis	Toxic effects of tobacco (ICD-10) T65.294A	Nicotine dependence (ICD-10) F17.200	Asthma (ICD-10) J45.20 COPD (ICD-10) J44.9 Cough (ICD-10) R05	COPD (ICD-10) J44.9 Cough (ICD-10) R05 Fever (ICD-10) R50.9
Example of secondary diagnosis	Shortness of breath (ICD-10) R06.02 Angina (ICD-10) I20.8	Toxic effects of tobacco (ICD-10) T65.294A Cough (ICD-10) R05	Toxic effects of tobacco (ICD-10) T65.294A	Toxic effects of tobacco (ICD-10) T65.294A
Additional counseling code	N/A	N/A	N/A	Nicotine dependence (ICD-10) F17.200

Correct Coding Principles For Tobacco-Dependence Treatment

As of August 2020, the ICD-10 listed 20 specific diagnoses and codes related to nicotine dependence F17.200 and more than 50 codes with the keyword "tobacco."

The code T65.2 "Toxic effect of tobacco and nicotine" is recommended unless directed otherwise from an insurance carrier or insurance billing staff. Multiple diagnoses are often appropriate.

Some other commonly used ICD-10 diagnosis codes used, if appropriate, given your patient's situation, may include:

F17.200 Nicotine dependence, unspecified, uncomplicated

F17.201 Nicotine dependence, unspecified, in remission

F17.210 Nicotine dependence, cigarettes, uncomplicated

F17.211 Nicotine dependence, cigarettes, in remission

F17.220 Nicotine dependence, chewing tobacco, uncomplicated

F17.221 Nicotine dependence, chewing tobacco, in remission

F17.290 Nicotine dependence, other tobacco product, uncomplicated

F17.291 Nicotine dependence, other tobacco product, in remission

Z87.891 Personal history of nicotine dependence

There is a caveat to the information provided. There are coding differences between nicotine dependence *(F17.200)* and toxic effects of tobacco harmful use *(T65.2)*. Nicotine dependence refers to the addictive nature of tobacco use. Be advised that insurance claims processors may view the E/M of addiction the purview of behavioral health professionals, and may be subject to behavioral health contractual restrictions when used as the primary justification for the E/M visit. Toxic effects of tobacco *(T65.2)* refers broadly to the set of untoward downstream consequences of tobacco use, within which dependence may be included. Within medical E/M encounters that relate primarily to tobacco, it may be most appropriate to list toxic effects of tobacco *(T65.2)* as the primary justification for the visit, and include the relevant related diagnoses and symptoms, *(eg, nicotine dependence [F17.200], COPD [J44.9], cough [R05])*, as the secondary diagnosis codes. It is best to note the related condition(s) as "resulting from" or "the toxic effect" of tobacco use.

Other relevant tobacco codes can be found here:

https://icd10cmtool.cdc.gov/?fy=FY2020&q=tobacco

https://icd10cmtool.cdc.gov/?fy=FY2020&q=nicotine

https://icd10cmtool.cdc.gov/?fy=FY2020&q=cigarettes

There is a caveat to the information listed above. Medicare guidelines allow nicotine dependence *(F17.200)* to be used as the primary diagnosis code when reporting Behavioral Health Interventions, as both intermediate *(99406)* and intensive *(99407)* services. Secondary diagnoses that reflect the related disorders or symptoms being affected by tobacco use should also be included to reflect the health concerns that prompted the counseling service. Regulations may prohibit nicotine dependence *(F17.200)* from being used as the primary diagnosis for inpatient services.

ICD-10-CM Official Coding Guidelines - Supplement Coding Encounters Related to E-cigarette, or Vaping, Product Use

Post Date: October 17, 2019

The purpose of this document is to provide official diagnosis coding guidance for healthcare encounters related to the 2019 health care encounters and deaths related to e-cigarette, or vaping, product use associated lung injury (EVALI). This guidance is consistent with current clinical knowledge about e-cigarette, or vaping, related disorders.

As necessary, this guidance will be updated as new clinical information becomes available. The clinical scenarios described below are not exhaustive and may not represent all possible reasons for health care encounters that may be related to e-cigarette, or vaping, product use. Proposals for new codes that are intended to address additional detail regarding use of e-cigarette, or vaping, products will be presented at the March 2020 ICD-10 Coordination and Maintenance Committee Meeting.

This guidance is intended to be used in conjunction with current ICD-10-CM classification and the ICD-10-CM Official Guidelines for Coding and Reporting (*effective October 1, 2019*). *https://www.cdc.gov/nchs/data/icd/10cmguidelines-FY2020_final.pdf*. The ICD-10-CM codes provided in the clinical scenarios below are intended to provide e-cigarette, or vaping, product use coding guidance only. Other codes for conditions unrelated to e-cigarette, or vaping products may be required to fully code these scenarios in accordance with the ICD-10-CM Official Guidelines for Coding and Reporting. A hyphen is used at the end of a code to indicate that additional characters are required.

General Guidance

Lung-Related Complications

For patients documented with EVALI, assign the code for the specific condition, such as:

J68.0, Bronchitis and pneumonitis due to chemicals, gases, fumes and vapors; includes chemical pneumonitis

J69.1, Pneumonitis due to inhalation of oils and essences; includes lipoid pneumonia

J80, Acute respiratory distress syndrome

J82, Pulmonary eosinophilia, not elsewhere classified

J84.114, Acute interstitial pneumonitis

J84.89, Other specified interstitial pulmonary disease

For patients with acute lung injury but without further documentation identifying a specific condition (pneumonitis, bronchitis), assign code:

J68.9, Unspecified respiratory condition due to chemicals, gases, fumes, and vapors

ICD-10-CM Coding Guidance

Vaping Related Disorders *(October 17, 2019)*

Poisoning and toxicity

Acute nicotine exposure can be toxic. Children and adults have been poisoned by swallowing, breathing, or absorbing e-cigarette liquid through their skin or eyes. For these patients assign code:

- T65.291-, Toxic effect of other nicotine and tobacco, accidental *(unintentional)*; includes toxic effect of other tobacco and nicotine NOS.

For a patient with acute THC toxicity, assign code:

- T40.7X1- Poisoning by cannabis *(derivatives)*, accidental *(unintentional)*.

Substance use, abuse, and dependence

For patients with documented substance use/abuse/dependence, additional codes identifying the substance(s) used should be assigned.

When the provider documentation refers to use, abuse and dependence of the same substance *(eg, nicotine, cannabis)*, only one code should be assigned to identify the pattern of use based on the following hierarchy:

- *If both use and abuse are documented, assign only the code for abuse*
- *If both abuse and dependence are documented, assign only the code for dependence*
- *If use, abuse and dependence are all documented, assign only the code for dependence*
- *If both use and dependence are documented, assign only the code for dependence*

Assign as many codes, as appropriate. Examples: Cannabis related disorders: F12.--- Nicotine related disorders: F17.----

Specifically, for vaping of nicotine, assign code:

- § F17.29-, Nicotine dependence, other tobacco products. Electronic Nicotine Delivery Systems are non combustible tobacco products.

Signs and Symptoms

For patients presenting with any signs/symptoms *(eg, such as fever)* and where a definitive diagnosis has not been established, assign the appropriate code(s) for each of the presenting signs and symptoms such as:

- M79.10 Myalgia, unspecified site
- R06.00 Dyspnea, unspecified
- R06.02 Shortness of breath
- R06.2 Wheezing
- R06.82 Tachypnea, not elsewhere classified
- R07.9 Chest pain, unspecified

ICD-10-CM Coding Guidance

Vaping-Related Disorders *(October 17, 2019)*

- **R09.02 Hypoxemia**
- **R09.89 Other specified symptoms and signs involving the circulatory and respiratory systems *(includes chest congestion)***
- **R10.84 Generalized abdominal pain**
- **R10.9 Unspecified abdominal pain**
- **R11.10 Vomiting, unspecified**
- **R11.11 Vomiting without nausea**
- **R11.2 Nausea with vomiting, unspecified**
- **R19.7 Diarrhea, unspecified**
- **R50.- Fever of other and unknown origin**
- **R53.83 Other fatigue**
- **R61 Generalized hyperhidrosis *(night sweats)***
- **R63.4 Abnormal weight loss**
- **R68.83 Chills *(without fever)***

This coding guidance regarding vaping related disorders *(October 17, 2019)* has been approved by the four organizations that make up the Cooperating Parties: the National Center for Health Statistics, the American Health Information Management Association, the American Hospital Association, and the Centers for Medicare & Medicaid Services.

CPT and Healthcare Common Procedure Coding may be appropriate for either or both of in-office point of care and/or telehealth procedures for tobacco treatment, evaluation, and management. Short descriptions and average national reimbursements are found below:

Medicare Fees for Service National averages (facility, non-facility, & limiting fees)

G0480 - In-office point of care nicotine metabolite assay - $114 per patient assay

G0659 - In-office point of care nicotine metabolite assay performed without drug-specific calibration - $62.14 per patient assay

80307 - In-office point of care nicotine metabolite assay performed without drug-specific calibration - $62.14

99453 - Device set-up and patient on-boarding - $20.95 per patient per device one time

99454 - Remote monitoring of physiological parameters - $64.85 per patient per month

99091 - Clinician Interpretation of Remotely Generated Data - $63.10 per patient per month

99457 - Remote monitoring & treatment management *(first 20 minutes)* - $45.18 per patient per month

99458 - Remote monitoring & treatment management *(plus 20 minutes increments)* - $40.23 per patient per month

G0513 - Prolonged preventive service(s) *(beyond the typical service time of the primary procedure),* in the office or other outpatient setting requiring direct patient contact beyond the usual service; first 30 minutes - $69.07

G0514 - Prolonged preventive service(s) (beyond the typical service time of the primary procedure), in the office or other outpatient setting requiring direct patient contact beyond the usual service; each additional 30 minutes *(list separately in addition to code G0513 for additional 30 minutes of preventive service)* - $68.93

99446 – 99449 Overview - Interprofessional internet consultation. CMS also finalized its proposal to pay separately for four existing and two new CPT codes describing consultations between physicians or other qualified health-care professionals when they are for the benefit of a specific patient. These consultations occur when a treating physician seeks the opinion and/or treatment advice of a consulting physician or other health-care professional with specific expertise, and CMS noted that the current lack of reimbursement for these interactions often leads to the scheduling of an office visit for the patient even though the patient's presence is not necessary and a telephone or internet consultation between health-care professionals would be sufficient. CMS views its recognition of these services as part of the movement away from a strictly fee-for-service-based system and toward a more care management-based approach to providing quality care to beneficiaries with multiple complex conditions. CMS is requiring documentation of beneficiary consent to receive these services.

Clinical Case Study

Ellen P. , a 60 y.o. female, arrives at your office for the first time. She is an office manager for a law firm. During the health and physical exam, she reports increasing SOB with a productive cough. During the health and physical exam, On auscultation you appreciate rhonchi and a midsystolic click consistent with mitral valve prolapse. Family history is significant. Her mother died from lung cancer at 61 y.o. She reports smoking an average of 25 to 30 cigarettes per day, having started smoking when she was 14 y.o. For one month, she has also been vaping 2 to 3 Juul pods per day in an attempt to quit and has reduced her smoking by approximately 5 to 10 cigarettes per day.

Anteroposterior and lateral chest X-ray reveal increased interstitial markings, and bilateral hyperinflated lung fields with peri-bronchial cuffing. Her lateral film shows vertebral wedging and CPFT demonstrates significantly reduced FEV1, FVC, FEF 25%-75%, and DLCO consistent with COPD and reversible airway obstruction and emphysemous changes. With a smoking history of 69 pack-years and no symptoms of lung cancer, Ellen was referred by her primary care provider for low-dose chest CT. The scan showed a small lung nodule of concern. The radiologist recommended PET or watchful waiting if clinically indicated.

After reviewing these findings in detail with her, you inquire about her motivation to quit tobacco products. She expresses significant cessation anxiety, dysphoria during previous attempts, and fear of failure. You inform her that her feelings are not unusual and that she does not have to quit today or all at once. You also inform Ellen that your therapeutic goal for her is to "feel normal" throughout the quitting process and that there are many medications and combinations of medications that can help her and that she is not in this alone. You and she determine that starting with varenicline is the best medication. To establish baselines at intake, you perform expired breath CO/carboxyhemoglobin and a TNE revealing a COhb% of 6.3% with a urinary TNE testing of 109.5 nmol/mL. The patient agrees to "take a mark" and record each time she smokes or vapes to both establish an accurate self-report and to increase her awareness or mindfulness of her tobacco use. Ellen leaves your office with prescriptions for varenicline, a bronchodilator, an inhaled corticosteroid, take-at-home nicotine metabolites test strips, the phone number for her state quit line **1-800-QUITNOW,** and a scheduled telehealth video follow-up within 2 to 3 weeks.

During the first follow-up telehealth consult, Ellen reports to you and your staff that she is taking varenicline, the bronchodilator, and corticosteroid as prescribed. She reports improvement in her SOB and cough and has been able to reduce her tobacco consumption to eight to twelve cigarettes a day with vaping in sessions of once or twice per day, but never exceeding 1 Juul pod per day. Her TNEs measured remotely have also reduced to 48.7 nm/mL, a reduction of 55%. Ellen reports few withdrawal symptoms with these reductions, few cravings, and no negative moods. In fact, she reports an improved sense of control over her tobacco use. You and she agree to continue her varenicline prescription for 2 months. She feels she may be ready to attempt a quit date within 2 or 3 weeks. You and your staff schedule a follow-up office visit within 5 to 6 weeks.

During her third visit *(second in office)* Ellen presents much improved. Exertional dyspnea *(climbing 1 to 2 flights of stairs)* has diminished, and she reports no SOB at rest. She has completely eliminated her Juul vaping but is experiencing some difficulty eliminating two to three cigarettes per day, which includes a first cigarette within 30 minutes of awakening, after dinner, and occasionally when drinking alcohol. Her COHb% and TNE have both continued to decrease consistent with her self-report. You and Ellen discuss the problem and together conclude that the Nicotrol nicotine inhaler is a good medication to use for these break through cravings. She reports and digital monitoring demonstrates that her sleep quality and total sleep time is significantly improved.

Three weeks later, the patient calls your office and reports she has stopped all tobacco products and is using her nicotine inhaler "sparingly", usually one to two cartridges per week. Ellen reports she is very proud of herself. Her TNE telehealth assessment confirms her self-report. You and she agree that completing the full course of varenicline is advisable; in fact, she would like to continue the medication through a fourth month while using the nicotine inhaler as a back-up for any breakthrough cravings. Your staff schedules Ellen for follow-up as they would for any COPD patient.

The chart below details the incidence of each procedure and the associated 2021 Medicare fees expected for the above clinical case study. Fees are based on new patient and established patient Level 3.

CPT/HCPCS codes	Procedure Description	Clinical Occurences	Total Fees
99203	Outpatient office visit-new patient 30-45 mins	1	$99.64
99213	Outpatient office visit-established patient 20-29 mins	1	$68.68
99407	Behavior change smoking > 10 min	4	$119.80
G0480	Nicotine metabolite assay	1	$114.43
80307	Nicotine metabolite assay without calibration	3	$186.42
99453	Device set-up and patient onboarding *(one-time)*	1	$20.95
99454	Remote monitoring of physiological parameters *(per patient per month)*	3	$194.55
99091	Clinician Interpretation of Remotely Generated Data *(per patient per month)*	3	$189.30

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