OBJECTIVE
The objective of this Clinical Practice Guideline (CPG) is to provide evidence-based practice recommendations for tobacco cessation. The CPG discusses the implications of tobacco use as well as ways to cease usage, including pharmacology interventions. Objectives and measurable health outcomes with respect to Care Management are included. In addition, the CPG outlines the organizations that WellCare aligns with regarding tobacco cessation and relevant Measurements of Compliance and Measureable Health Outcomes.

OVERVIEW
The most common cause of chemical dependence in the United States is nicotine (e.g., cigarettes, smokeless tobacco), and can be as addictive as heroin, cocaine, or alcohol. The Centers for Disease Control and Prevention (CDC) estimates that 1 in 5 deaths (approximately 480,000) occur annually in the United States due to smoking and tobacco use. Smoking causes more deaths each year than the following causes combined: Human immunodeficiency virus (HIV), illegal drug use, alcohol use, motor vehicle injuries, and firearm-related incidents. Nearly 90% of all deaths due to lung cancer are related to smoking; more women die from lung cancer annually than from breast cancer. Smoking related cancer is not limited to the lung; other common sites include: bladder, blood (acute myeloid leukemia), cervix, colon and rectum (colorectal), esophagus, kidney and ureter, larynx, liver, oropharynx (includes parts of the throat, tongue, soft palate, and the tonsils), pancreas, stomach, trachea, and bronchus.

Smokers are at a higher risk of developing cardiovascular disease and coronary heart disease. Smoking damages blood vessels and can cause them to thicken and narrow causing the heart to beat faster and cause blood pressure to rise. Clots can also form and may cause a stroke.

Smoking can damage your airways and the small air sacs (alveoli) found in the lungs. Lung cancer, COPD, emphysema, and chronic bronchitis are main respiratory related diagnoses; smoking can also trigger asthma attacks or make one worse. Smokers are 12 to 13 times more likely to die from COPD than nonsmokers. Approximately 80% of all deaths from chronic obstructive pulmonary disease (COPD) are caused by smoking.

Other health conditions impacted by smoking include:
- Bone health – risk of fractures, broken bones
- Dental health (teeth, gums)
- Cataracts and age-related macular degeneration
- Type 2 diabetes mellitus
- Decreased immune function
- Rheumatoid arthritis

In addition, smoking can make it harder for a woman to become pregnant and can affect her baby's health before and after birth. Smoking also increases risks for preterm delivery, stillbirth, low birth weight, sudden infant death syndrome (SIDS), ectopic pregnancy, and orofacial clefts in infants. Smoking can also affect men's sperm, which can reduce fertility and also increase risks for birth defects and miscarriage.
Hierarchy of Support

GUIDELINE HIERARCHY

CPGs are updated annually or as necessary due to updates made to the United States Preventive Services Task Force (USPSTF) and the United States Department of Health and Human Services (DHHS). When there are differing opinions noted by national organizations, WellCare will default to the member’s benefit structure as deemed by state contracts and Medicaid / Medicare regulations. If there is no specific language pertaining to tobacco use and smoking cessation, WellCare will default (in order) to the following:

- National Committee for Quality Assurance (NCQA);
- USPSTF, National Quality Strategy (NQS), Agency for Healthcare Research and Quality (AHRQ);
- Specialty associations, colleges, societies, etc. (e.g., American Academy of Family Physicians, American Congress of Obstetricians and Gynecologists, American Cancer Society, etc.).

Links to websites within the CPGs are provided for the convenience of Providers. Listings do not imply endorsement by WellCare of the information contained on these websites. NOTE: All links are current and accessible at the time of MPC approval.

WellCare aligns with the USPSTF and DHHS regarding tobacco cessation. Highlights from their publications are below.

UNITED STATES PREVENTIVE SERVICES TASK FORCE (USPSTF)

Adults. The USPSTF recommends that clinicians ask all adults (including pregnant women) about tobacco use, advise them to stop using tobacco, and provide behavioral interventions and U.S. Food and Drug Administration (FDA)–approved pharmacotherapy for cessation to adults who use tobacco. (Grade A).²

The USPSTF concludes that the current evidence is insufficient to assess the balance of benefits and harms of pharmacotherapy interventions for tobacco cessation in pregnant women. (Grade I).²

The USPSTF guideline for adults can be accessed here.

School-Aged Children and Adolescents. The USPSTF recommends that primary care clinicians provide interventions, including education or brief counseling, to prevent initiation of tobacco use among school-aged children and adolescents. (Grade B).³ The USPSTF guideline for children and adolescents can be accessed here.

UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES

The United States Department of Health and Human Services published Treating Tobacco Use and Dependence – a guideline with strategies and recommendations designed to assist Providers treating Members with nicotine dependence. The aim is for Providers to strongly recommend the use of effective tobacco dependence counseling and medication treatments to Members. The guideline contains sections on methods; information on the assessment of tobacco use; clinical interventions, both for patients willing and unwilling to make a quit attempt at this time; intensive interventions; systems interventions for health care administrators, insurers, and purchasers; scientific evidence supporting the guideline recommendations; and information relevant to specific populations and other topics. The full guideline can be accessed here.⁴

CENTERS FOR DISEASE CONTROL AND PREVENTION

The Centers for Disease Control and Prevention published Best Practices for Comprehensive Tobacco Control Programs – an evidence-based guide to help states plan and establish comprehensive tobacco control programs. Sections include: state and community interventions, mass-reach health communication interventions; cessation interventions; surveillance and education; and infrastructure administration and management. The mission of comprehensive tobacco control programs is to reduce disease, disability, and death related to tobacco use. A comprehensive approach that optimizes synergy from applying a mix of educational, clinical, regulatory, economic, and social strategies is the guiding principle for eliminating the health and economic burden of tobacco use. To access the entire document, click here.⁵
Evidence Based Practice

MEASURES OF COMPLIANCE

NCQA has published the following standard metrics related to smoking cessation:

Medical Assistance with Smoking and Tobacco Use Cessation

- Advising Smokers and Tobacco Users to Quit. A rolling average represents the percentage of members 18 years of age and older who are current smokers or tobacco users and who received advice to quit during the measurement year.
- Discussing Cessation Medications. A rolling average represents the percentage of members 18 years of age and older who are current smokers or tobacco users and who discussed or were recommended cessation medications during the measurement year.
- Discussing Cessation Strategies. A rolling average represents the percentage of members 18 years of age and older who are current smokers or tobacco users and who discussed or were provided cessation methods or strategies during the measurement year.

Care Management

WellCare Health Plans, Inc. enrolls members from Medicaid and Medicare with a high rate of smoking and the chronic conditions associated with cigarette use (e.g. COPD, Hypertension, Asthma, and Coronary Artery Disease). In addition, smoking is a prominent cause of obstetrical complications seen in our Medicaid population of pregnant women. Based on this information and desire to improve health outcomes in our members, WellCare has developed a specific program to address smoking cessation for our beneficiaries and embraces goals outlined in the CDC Best Practices for Comprehensive Tobacco Control Programs:

- Prevent initiation among youth and young adults
- Promote quitting among adults and youth
- Eliminate exposure to second-hand smoke
- Identify and eliminate tobacco-related disparities among population groups

Smokers improve their odds of successfully quitting when they use evidence-based treatments. Essential steps in the Smoking Cessation Program include:

- Motivational interviewing to assess readiness to change in the member;
- Provide positive reinforcement with each successful step
- Member education regarding treatment options for smoking cessation;
- Provider education regarding smoking cessation strategies; and
- Connection to state and national programs offering counseling, support for members desiring to quit smoking

MEASURABLE HEALTH OUTCOMES

Targeted Health Outcomes (Extended Program Goals) result from successful member self-management (see Case Management Objectives).

1. A decrease in smoking can be noted by fewer admissions or emergency room visits related to cardiovascular or respiratory diagnosis. Compare pre and post claims and service authorizations related to cardiovascular or respiratory diagnosis. In absence of claims data, the case manager may use Provider and/or Member narrative.
2. The member has an increase in exercise endurance blood flow to the heart, decreased blood pressure and fewer respiratory symptoms. Compare pre and post documentation of member’s heart rate, blood pressure, and respiratory vitals in electronic medical records. In absence of documentation, the case manager may use Provider and/or Member narrative.

CASE GOALS

Case Goals should target specific care gaps and/or adherence issues, and measure the member’s progress towards self-management and adherence which will lead to the targeted health outcomes above. Examples:

1. Member monitors and records blood pressure and heart rate. A decrease should be noted after 20 minutes of
quitting smoking
2. Member experiences an increase in taste and smell. The sense of smell and taste begin to return to normal after 48 hours of quitting, related to regrowth of nerve endings.
3. Member experiences a decrease in tiredness, coughing and shortness of breath. Within 2 weeks to 9 months of quitting, the member will experience a decrease in tiredness, coughing and shortness of breath.
4. Specific for Members requiring hospitalization: The Member participates in provider follow-up visit within 7 days of hospital discharge.

CASE MANAGEMENT OBJECTIVES

Case Management Objectives should focus on improving the Member’s self-management skills up including:

- Taking maintenance medications as prescribed
- Assessing the member’s level of motivation and confidence
- Assess for depression
- Reviewing daily routine and identify where smoking fits in
- Identifying pros and cons to smoking / smoking cessation
- Understanding risks of smoking, and ask member’s thoughts on potential impact to the member’s life plans
- Identifying member’s specific reasons for change
- Identifying people who can support with the changes
- Utilizing resources that can support the change (e.g., QuitLine, local support groups)
- Developing realistic cessation goals with dates
- Identifying personal barriers to quitting tobacco and making healthier choices

Care team should also review the member’s healthcare benefits to determine for tobacco cessation support options and discuss with member.

MEMBER EDUCATIONAL RESOURCES

WellCare contracts with Krames/StayWell for Member educational materials utilized by Case Managers. Items are available to review with Members to address knowledge gaps. Case Managers verbally educate Members on the topics below related to pneumonia. (Titles may also be sent to the member).

NOTE: Links are internal for WellCare Care Management staff.

- Why Do You Smoke
- How to Quit Smoking
- Health Effects of Smoking
- Smoking and Peripheral Arterial Disease (PAD)
- The Benefits of Living Smoke Free
- Kicking the Smoking Habit
- Coping with Smoking Withdrawal
- Staying Smoke Free
- Exercise Fitting It into Your Life - Smoking
- The Benefits of Living Smoke Free

Providers may wish to research the titles above related to tobacco cessation that Case Managers utilize with Members.

ADDITIONAL RESOURCES

- American Cancer Society
  http://www.cancer.org/Healthy/StayAwayfromTobacco/GuidetoQuittingSmoking/index
- American Heart Association
  http://www.heart.org/HEARTORG/GettingHealthy/QuitSmoking/Quit-Smoking_UCM_001085_SubHomePage.jsp
- American Lung Association
  http://www.lung.org/stop-smoking
- CDC State Tobacco Activities Tracking & Evaluation (STATE) System – www.cdc.gov/statesystem (an interactive application that displays current and historical state-level data on tobacco use prevention and control)
- National Tobacco Control Program – http://www.cdc.gov/tobacco/tobacco_control_programs/ntcp/
- FDA 101: Smoking Cessation Products
  http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm198176.htm
• Pathways to Freedom: Winning the Fight Against Tobacco
  http://www.cdc.gov/tobacco/quit_smoking/how_to_quit/pathways/index.htm

Smoking Quit and Information Lines
• (800) LUNG-USA : helpline and education for those wishing to stop smoking
• (800) QUIT-NOW : educational materials and coaches that can help you quit smoking or chewing tobacco
• (877) 44U–QUIT: individualized counseling, printed information, and referrals to other sources

PHARMA}COLOGY

Pharmacologic Intervention During Pregnancy. Pregnant patients should try to quit smoking without using pharmacologic agents. The 5 A’s approach has been shown to be an effective behavioral strategy for smoking cessation. Pharmacologic aids such as nicotine replacement therapy (NRT), bupropion, and varenicline have not been sufficiently tested for efficacy and safety in pregnant patients and should not be used as first-line smoking cessation strategies for these patients. Evidence is inconclusive that smoking cessation medications boost abstinence rates in pregnant smokers. In addition, U.S. clinical trials with sufficient power to determine statistical significance have been pulled or ended due to data or safety monitoring issues. If pharmacotherapy is considered for pregnant smokers who are unable to quit smoking by other means, it is important the woman demonstrate a resolve to quit smoking and to understand the benefits and risks of the use of the medication to herself and her fetus. Clinicians should carefully review patient information, drug side effect profiles, and current information in medical literature when recommending pharmacologic aids. Antidepressants marketed for smoking cessation, such as bupropion, carry risks of adverse effects which may include increased risk for suicide, insomnia and rhinitis. Pregnant patients who choose to use smoking cessation medications should be closely supervised.

Related WellCare Guidelines

Please reference the following CPGs: Asthma-HS 1001, Cardiovascular: HS-1002, Congestive Heart Failure: HS-1003, COPD: HS-1007, and Hypertension: HS-1010.

NOTE: Clinical Policies can be accessed by going to www.wellcare.com — select the Provider tab, then “Tools” and “Clinical Guidelines”.

References

8. Fu S et al. “Proactively engaging smokers leads to higher quit rates”. JAMA Intern Med. DOI:10.1001/jamainternmed.2014.177

Disclaimer

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MEMBER EDUCATION

Health Risks. The following benefits can be found in the days, weeks and months of smoking cessation:

- Heart rate and blood pressure begin to return to normal
- Levels of carbon monoxide in the blood declines
- Lung function and overall circulation improves - less phlegm is produced and coughing and wheezing decreases
- Sense of smell and taste increases

Long term benefits include reduced risk of cancer and diseases (e.g., heart disease, COPD) and premature death. In addition, studies show the following risk of premature death:

- Quitting at age 30 reduces a member’s risk by more than 90 percent
- Quitting at age 50 reduces a member’s risk by 50 percent
- Quitting at age 60 or above will still live longer than if they continue to smoke

For members diagnosed with cancer, smoking cessation will improve their body's ability to respond to surgery, chemotherapy, or other treatments and reduce the risk of pneumonia, respiratory failure, and reduce the chance of cancer recurrence or the development of a second cancer.

Health Benefits. Smoke caused by cigarettes contain a mixture of over 7,000 chemicals, many are toxic and at least 70 are linked to cancer. Smoking can cause health problems for smokers and those around them. Cessation of smoking and the use of tobacco products can lead to better health at any age and reduce risk of premature death. The following talking points can also be implemented:

1. **Get Ready!** Encourage members to a date and change their surroundings. Remove all cigarettes and ashtrays in the home, at work and in their car. Encourage them to tell others about their goal.

2. **Get Support and Encouragement.** The more support someone has, the more successful they will be at quitting.
   - Members can ask family, friends, and co-workers for support, including asking them not to smoke around them or leave cigarettes where they can see them.
   - Solicit advice from their health provider, psychologist, or enlist a smoking cessation counselor.
   - Find individual, group, or telephone counseling which can double the success rate.

3. **Learn New Skills and Behaviors.** Ask the member to identify what distracts them from their goal and substitute it with a different behavior (e.g. call someone, go for a walk, or focus on a task). A change in routine can also help – drive a different way to work, have breakfast in a different place, reduce stress (e.g., exercise, read a book).

4. **Get Medication and Use It Correctly.** Encourage adherence and questions. FDA-approved medications and/or individual, group or phone counseling may double their chance of success. Products may include:
   - Nicotine replacement products
   - Over-the-counter (e.g., nicotine patch, gum, lozenge)
   - Prescription (e.g., nicotine inhaler, nasal spray)
   - Prescription non-nicotine medications, such as bupropion SR (Zyban®)2 and varenicline tartrate (Chantix®)
5. **Be Prepared.** Let members know that relapse can occur within the first 3 months - many people try several times to quit smoking before finally doing so. Tell members they can avoid the following potential triggers:
   - *Drinking alcohol* can lower their chance of success.
   - *Being around other smokers* may make them want to smoke.
   - Follow a healthy diet and exercise regularly; do not let possible *weight gain* keep them from your goal.
   - Be prepared for *mood changes*. A referral to a counselor or smoking cessation counselor may be warranted.

**PROVIDER EDUCATION**

Provider education is given once the member has entered the preparation stage as determined by motivational interviewing. This education includes using “the 5 A’s” of (1) ask about tobacco use; (2) advise to quit; (3) assess willingness to make a quit attempt; (4) assist in the quit attempt and; (5) arrange follow-up.\(^2,3\) The intent of the provider education is to reinforce the evidence in favor of success in smoking cessation even in historically difficult populations such as long-term smokers, members with chronic mental illness and members in poor health status or with malignancy.

In addition, the provider education is geared to ensure a positive reception when the member initiates a smoking cessation strategy, and the provider will order the appropriate treatments to assist the member in their program. Provider education includes materials regarding the evidence-based treatments for smoking cessation in order to assist in selecting those treatments that are most appropriate to the member. Evidence-based treatments for smoking cessation include all of the following:\(^8\)

- Counseling for smoking cessation (including telephonic, group and individual)
- FDA approved medications (including Bupropion, Varenicline and Nicotine Replacement Therapies (NRT) such as patches, gums, lozenges, inhalers and nasal sprays.

Successful outcomes in smoking cessation attempts improve when these treatments are used as part of a comprehensive program that is tailored to the member’s individual needs and consistent with the medical treatment of any co-occurring medical conditions.

**ALGORITHM FOR TOBACCO CESSATION\(^8\)**

![Algorithm Diagram]

**MOTIVATIONAL INTERVIEWING**

Motivational interviewing (MI) refers to a counseling approach in part developed by William R. Miller, Ph.D., and Stephen Rollnick, Ph. D. from their experience in treating problem drinkers. The fundamental concepts and approaches work on facilitating and engaging intrinsic motivation within the client in order to change behavior. MI is a goal-oriented, client-centered counseling style for eliciting behavior change by helping clients to explore and resolve ambivalence. This technique has wide application to changing unhealthy behaviors, and is a core skill in WellCare’s Care Model. We emphasize the role of MI again as a primary step in the smoking cessation program. There are various ways of describing MI; however they all concern the steps in engaging a change in unhealthy behaviors.

- **Lay definition:** A collaborative conversation style to strengthening a one’s own motivation/commitment to change.
- **Clinical definition:** A person-centered counseling style for addressing ambivalence about change.
- **Technical definition:** A collaborative, goal-oriented style of communication with particular attention to the language of change, designed to strengthen personal motivation for and commitment to a specific goal by eliciting and exploring the person’s own reasons for change within an atmosphere of acceptance and compassion.

For additional information on MI, please reference *Motivational Interviewing and Health Behavior Change: HS 1042*. 