

**Initial Public Comment Period Smoking & Tobacco Use Cessation CAG-00241N  
June 23-July 23, 2004**

Comment #1:

Submitter: Rebecca Kleinschmidt

Organization:

Date: June 28, 2004

Comment:

I am in support of coverage for tobacco use cessation counseling and treatment. Tobacco use is the #1 cause of preventable death. In addition, almost 60,000 NON-SMOKING Americans die each year from tobacco related illnesses due to second hand smoke. Almost 30% of the population smokes, and many of them have made numerous attempts to quit. They need- and deserve affordable support with tobacco cessation.

Please support the movement for financial support of Tobacco Cessation Treatment through Medicare. Thank you.

Comment #2:

Submitter: Jill Quinn

Organization:

Date: June 28, 2004

Comment:

Please support Medicare coverage for tobacco cessation (FDA-approved medications) and counseling.

Comment #3:

Submitter: Alice Loper

Organization: Partnership for Prevention

Date: June 28, 2004

Comment:

I urgently ask you to please support Medicare coverage for tobacco cessation (FDA-approved medications) and counseling.

Comment #4:

Submitter: Rebecca Long

Organization:

Date: June 28, 2004

Comment:

Please support Medicare coverage for tobacco cessation, including meds, and counseling. It would save us tons of money in the long run.

Comment #5:

Submitter: Janie Heath

Organization: Georgetown University

Date: June 28, 2004

Comment:

Please support Medicare coverage for tobacco cessation with FDA approved medications and tobacco cessation

counseling. Too many individuals are tobacco dependent and need help with the costs of treatments that work.  
THANK YOU.

Comment #6:

Submitter: Loretta Forlaw, DNSc., RN, CHE

Organization: Wichita State University

Date: June 28, 2004

Comment:

Please support Medicare coverage for tobacco cessation (FDA-approved medications) and counseling.

Comment #7:

Submitter: Kathleen Wackerle

Organization: University of WI School of Nursing

Date: June 28, 2004

Comment:

Please support Medicare coverage for tobacco cessation (FDA-approved medications) and counseling

Comment #8:

Submitter: Marianne Cosentino

Organization: Loyola University Medical Center

Date: June 28, 2004

Comment:

Please support Medicare coverage for tobacco cessation FDA-approved medications and counseling, both group and individual. Quitting smoking is so important to improve one's health. Both medication and counseling have been shown to improve one's chance at quitting for good. Thank you.

Comment #9:

Submitter: Adele Young

Organization: George Mason University

Date: June 28, 2004

Comment:

Tobacco cessation can have a huge impact on health. Providers should be able to provide counseling and FDA approved medication support.

Comment #10:

Submitter: Donna Richardson

Organization: UMDNJ

Date: June 28, 2004

Comment:

I support the position of John M. Clymer, Partnership for Prevention, requesting Medicare coverage for tobacco dependence treatment. Please consider Medicare coverage of FDA-approved medications for tobacco dependence treatment as well.

Comment #11: Submitter: Laura Jannone Organization: Monmouth University Date: June 28, 2004 Comment: As a nurse I know it is very important counseling & smoking cessation treatment be covered!

Comment #12:

Submitter: Marvin Hinds

Organization: Snohomish Health District

Date: June 28, 2004

Comment:

I strongly support smoking and tobacco use cessation counseling as a covered activity under both Medicare and Medicaid. Tobacco use is the single most important cause of preventable premature death in our society. A number of clinical trials have demonstrated the effectiveness of clinician counseling, and although the reduction in smoking rates has been small, such counseling is very cost-effective compared to many other clinical interventions, because the positive benefits of cessation are so great. Clinician counseling for smoking cessation has been given an "A" recommendation by the U.S. Preventive Services Task Force.

Comment #13:

Submitter: Ann Marie Collins

Organization: Wayne State University

Date: June 28, 2004

Comment:

Please support Medicare coverage for tobacco cessation (FDA-approved medications) and counseling. Thankyou!

Comment #14:

Submitter: Mary Kollar

Organization:

Date: June 28, 2004

Comment:

Please support Medicare coverage for tobacco cessation (FDA-approved medications) and counseling.

Comment #15:

Submitter: Karin Luttman

Organization:

Date: June 28, 2004

Comment:

PLEASE support Medicare coverage for this very

Comment #16:

Submitter: Sheila Benz

Organization:

Date: June 28, 2004

Comment:

Please support Meidcare coverage for tobacco cessation (FDA approved medications) and counseling. Thank you.

Comment #17:

Submitter: Donna Garber

Organization:

Date: June 28, 2004

Comment:

I have just finished searching the literature on school-based interventions r/to youth and smoking. It would appear that focus groups and programs tailored to specific adolescent populations could have a greater impact on youth. Providers need to have the tools available for such tobacco cessation counseling and to have evidence-based research to apply to daily practice.

Comment #18:

Submitter: Kathleen O'Connell

Organization: Teachers College Columbia University

Date: June 28, 2004

Comment:

Please support reimbursement for tobacco cessation counseling. As the leading cause of death and disability in some populations, it is necessary to do what we can to get people to quit.

Comment #19:

Submitter: Jean Berry

Organization: University of Illinois at Chicago College of Nursing

Date: June 28, 2004

Comment:

Please support smoking cessation and counseling sessions to assist patients to smoke. COPD is the 4th leading cause of death in the USA and the #1 preventable cause of death. It is only by smoking cessation or prevention of smoking altogether that we can reduce tobacco-related deaths and disability in our country.

Comment #20:

Submitter: Laura R. Van Heest , RRT, NATAS

Organization:

Date: June 28, 2004

Comment:

I am a Registered Respiratory Therapist and a National Certified Tobacco Addiction Specialist. I have been working in Respiratory for over 26 years. It is impairative that counseling be reimbursed. It is recommend in the Clinical Practice Guidelines for Treating Tobacco Use and Dependence. It is also supported in the GOLD standards for the treatment of Chronic Obstructive Lung Disease. With the current Health care cost issues the hospital systems and physician can't continue to do justice to the issues of nicotine dependence in free programs. We need to step up to the plate and treat it as it is "an Addiction".

Thank You.

Comment #21:

Submitter: Gail Pohlman

Organization:

Date: June 29, 2004

Comment:

I am a registered nurse from Ohio and am employed as a school nurse in a rural tobacco raising Appalachian area. I work with our school district's Drug Prevention Programs in the school system and often meet with students and parents that are interested in assistance with tobacco cessation.

Deaths from Tobacco related illnesses are still the leading preventable cause of death in the US and I would think it would be cost effective to offer assistance to eligible clients that could/would benefit from cessation counseling or services. I would strongly support action in that direction. Thanks for your attention to my opinion.

Comment #22:

Submitter: Stephen Hansen,MD

Organization: AMA,CMA

Date: June 29, 2004

Comment:

This is the single most cost-effective preventive benefit of any of our interventions,and should be at the top of our list.(More than Pap tests,mammograms,beta- blockers or aspirin after MI, Rx for hypertension)

Comment #23:

Submitter: Debra Barowsky

Organization:

Date: June 29, 2004

Comment:

With the emphasis on preventative health care, I

Comment #24:

Submitter: Nancy Olson

Organization: Yale University School of Nursing

Date: June 29, 2004

Comment:

Nurses have been long aware of the difficulties that individuals encounter leading up to the decision to quit smoking, setting the date, sticking to it, dealing with slip ups, and getting back on the quit plan. These opportunities for counseling take extra time out of our busy clinic schedules. The ability to bill for this time, supports the success of these efforts by medical care providers. Smoking and Tobacco use cessation is one of the single most important activity toward prevention of many medical problems. Please support the reimbursement of this much needed counseling.

Comment #25:

Submitter: Carol Romback

Organization:

Date: June 29, 2004

Comment:

please support Medicare coverage for tobacco cessation (FDA-approved medications) and ounseling

Comment #26:

Submitter: Dr. Leslie A. Robinson

Organization: Society for Research on Nicotine and Tobacco

Date: June 29, 2004

Comment:

This letter is to support coverage of tobacco cessation counseling as well as pharmacotherapy. As a researcher on youth smoking prevention and cessation, I know that addiction develops early and that the odds of cessation

without assistance are still low. I have no doubt that the benefits of covering these services would far outweigh the costs of tobacco-related diseases.

Comment #27:

Submitter: Christine Gastelle

Organization: Poudre Valley Health System

Date: June 29, 2004

Comment:

Please support medicare coverage for tobacco cessation counseling and medication

Comment #28:

Submitter: Regina Torelli

Organization: Certified school nurse/LPN nursing Instructor

Date: June 29, 2004

Comment:

More funding for smoking cessation is needed for the youth of America. The word is still not getting through to teenagers. Working in the school system and living with 2 of them I can tell you 1st hand the message is not getting through.

Comment #29:

Submitter: Lisa Lewis

Organization:

Date: June 29, 2004

Comment:

"please support Medicare coverage for tobacco cessation (FDA-approved medications) and counseling"

Comment #30:

Submitter: Michael Steinberg, MD, MPH

Organization: UMDNJ-School of Public Health

Date: June 29, 2004

Comment:

As a physician who treats tobacco dependence as part of a treatment clinic, perhaps the single most important modality we use are medications for quitting smoking. We have seen thousands of smokers over the past 3 years and our success is largely dependent on the use of pharmacotherapy. The largest barrier to quitting success is payment for many smokers for these medications. Medicare NEEDS to cover tobacco treatment to prevent the immeasurable morbidity and mortality from smoking. Better to spend a little for effective prevention, than be spending millions upon millions on bypass surgery, cancer treatment, and long-term ventilator management. This is the clearest no-brainer in all of public health, and we owe it to ourselves and our children to do the right thing.

Comment #31:

Submitter: Douglas Marshall

Organization:

Date: June 29, 2004

Comment:

With most states having sold their rights to the Tobacco Settlement Monies for pennies on the dollar, many smokers have no or severely under funded resources to help them quit smoking. Tobacco Dependence is an

addiction, no different than any other drug. Medicare should reimburse for cessation counseling, as it does for any other addiction. Also by reimbursing, Medicare can help to set standards for the counseling, thus improving the field of Tobacco Dependence Treatment & Counseling. Thank you for reading

Comment #32:

Submitter: Chris Kotsen, Psy.D.

Organization: Somerset Medical Center, Tobacco Quitcenter

Date: June 29, 2004

Comment:

As the coordinator of a tobacco dependence treatment program, I am writing to formally request Medicare coverage for tobacco cessation counseling as detailed in the U.S. Department of Health and Human Services (PHS) guideline, treating tobacco use and dependence. We have helped many smokers quit tobacco

Research has shown that reducing cost as a barrier (setting insurance coverage), will lead to more people seeking help in overcoming this serious addiction. This reimbursement will also encourage health care providers to more aggressively treat tobacco dependence. Research also shows that people who seek counseling are more than 4X as successful in quitting, at a given quit attempt. Please implement the recommendations of Secretary Thompson's Steps to a Healthier U.S. Initiative and the report of the Interagency Committee on Smoking and Health, Subcommittee on Cessation.

Comment #33:

Submitter: Marc L. Steinberg, Ph.D.

Organization:

Date: June 29, 2004

Comment:

I am writing to strongly support the coverage of tobacco cessation counseling. The poor and mentally ill are over-represented among smokers and providing coverage for cessation services is the right thing to do - fiscally and morally.

As an example of the return on investment the government may experience from covering tobacco cessation counseling I would like to point out that smokers with schizophrenia were spending 27% of their public assistance monies on cigarette smoking (see citation below).

Steinberg, M. L., Williams, J. M., & Ziedonis, D. M. (2004). Financial Implications of Cigarette Smoking Among Individuals With Schizophrenia. *Tobacco Control*, 13(2), 206.

Comment #34:

Submitter: Deborah Kelly

Organization:

Date: June 29, 2004

Comment:

Please support Medicare coverage for tobacco cessation (FDA approved medications) and counseling.

Comment #35:

Submitter: Phil Konigsberg

Organization: Smokefree Educational Services

Date: June 29, 2004

Comment:

I support the formal request that tobacco use cessation coverage and counseling being covered for Medicare subscribers.

Our nation has a health epidemic because of tobacco use. We need to do everything possible to remedy this crisis. A comprehensive tobacco control program has proved to be extremely effective when implemented correctly. Such an example IS New York City. In New York, a smokefree workplace law was enacted, first in New York City, and then by state law, together with a significant increase in the tax on cigarettes AND A SMOKING CESSATION PROGRAM THAT PROVIDED 35,000 FREE SMOKING CESSATION KITS by the NYC Dept of Health. The combined comprehensive tobacco control program has reportedly resulted in 100,000 people quitting smoking or an 11% reduction in smokers. If it is working in New York City, then it should work throughout the entire country.

Comment #36:

Submitter: Melanie Kalman, RN PhD

Organization: Upstated Medical University

Date: June 29, 2004

Comment:

please support Medicare

Comment #37:

Submitter: Andrew Meyers

Organization:

Date: June 29, 2004

Comment:

Please support coverage for these valuable services.

Comment #38:

Submitter: Monica Scheibmeir

Organization: University of Kansas Medical Center

Date: June 29, 2004

Comment:

Please support Medicare coverage for tobacco cessation (FDA-approved medications) and counseling.

Comment #39:

Submitter: Susan Bruce

Organization: University at Buffalo; School of Nursing

Date: June 29, 2004

Comment:

Please support Medicare coverage for provider-ordered tobacco cessation products and counseling.

Comment #40:

Submitter: Adele Lash

Organization: Indiana State Medical Association

Date: June 30, 2004

Comment:

The Indiana State Medical Association (ISMA) supports Medicare coverage for tobacco cessation counseling, and would like to add that Medicare coverage of FDA-approved medications for tobacco cessation should also be considered.

The ISMA currently is conducting a campaign to encourage Indiana physicians to do tobacco cessation counseling in their offices. Indiana Medicaid already reimburses for tobacco cessation. Certainly Medicare recipients who smoke will benefit from increased delivery of tobacco cessation services. The costs of delivering cessation services will be minimal compared to the costs of caring for someone with a tobacco-related disease.

Comment #41: Submitter: Tom Houston, MD Organization: LSU School of Public Health Date: June 30, 2004  
Comment:

Solving the problem of disparities in health is one of the key missions of HHS, according to "Healthy People 2010." Persons served by Medicaid and Medicare have a higher prevalence of tobacco use, and suffer disproportionately from smoking-related illnesses. Tobacco use cessation has been identified as one of the most cost-effective interventions in medical practice. Medicare and Medicaid should offer coverage for all eligible recipients based on the evidence-based guidelines for smoking cessation.  
(See <http://www.surgeongeneral.gov/tobacco/>)

Comment #42: Submitter: Nancy Popp Organization: Date: June 30, 2004

Comment: Please provide coverage of FDA-approved medications for tobacco dependence/treatment as well as payment for smoking cessation counseling. It is essential to saving lives and billions of dollars spent on treating individuals with tobacco related illness. Thanks.

Comment #43: Submitter: Mary Brown Organization: UTK Date: June 30, 2004

Comment:

I am an assistant professor at UTK and also a critical care nurse in the cardiac ICUs at UT Medical Center. I see the effects of smoking every day.

Smoking is the number one risk factor for numerous cardiovascular and pulmonary diseases. If people quit smoking many of their present and future problems could be resolved or prevented. Smoking cessation for many people requires more than one try. Patients should be counseled at every opportunity. Many times patients do better in a support situation such as smoke cessation group. I support Smoke Cessation being covered by Medicare. Thank You.

Comment #44: Submitter: Nancy Knapp Organization: Date: June 30, 2004

Comment:

I am writing to support the use of Medicare funds to cover tobacco cessation treatment and counseling.

Health care organizations need to place tobacco cessation at the forefront of their efforts to prevent needless death and disability. Quit tobacco programs are among the most effective treatments that can be provided, in terms of prevention. Without reimbursement from Medicare and Medicaid, this will not happen. Medicare coverage of FDA-approved medications for tobacco cessation should be considered at the same time as

CMS reviews the matter of Medicare payment for cessation counseling. Please fund this extremely important measure.

Comment #45: Submitter: Phyllis du Mont Organization: Date: June 30, 2004

Comment:

Coverage of smoking cessation counseling should be an absolute "no brainer". Smoking is the single most pervasive PREVENTABLE health risk among my patients. There is plenty of evidence to show that smoking cessation efforts work (albeit the natural history is to have a few failed attempts before finally becoming a former-smoker). There is also an ample body of evidence showing that real benefits accrue to the person who quits even if it happens late in life.

Comment #46: Submitter: Frederic Grannis MD Organization: City of Hope National Medical Center Date: June 30, 2004

Comment:

The current strategy of management of lung cancer in the US is to do NOTHING until the patient presents with advanced stage lung cancer, and then try to treat the disease with chemotherapy. This strategy is not only almost completely ineffective, it is also ruinously expensive. Smoking cessation is an effective strategy to prevent lung cancer and other disease caused by tobacco products. It is also cost effective.

BUT It is not available to underserved populations, which coincidentally bear most of the burden of tobacco-caused disease. Medicare and Medicaid should pay for smoking cessation methods proven to be effective in prospective randomized trials, including counseling, nicotine replacement and bupropion.

Comment #47: Submitter: Lynda Koski Organization: Date: June 30, 2004

Comment:

I am very much in support for reimbursement for this type of counseling. As a nurse and one who does tobacco cessation counseling I am very much aware of its importance in the process of Quitting Smoking and the prevention of disease. Statistics show that nicotine replacement therapy alone is not as effective as when used in conjunction with tobacco cessation counseling.

Comment #48: Submitter: Michele Higbee Organization: Banning Unified School District Date: June 30, 2004

Comment:

Please support Medicare coverage for tobacco cessation and counseling. I believe prevention and intervention to decrease risk factors saves lives and money in the long run. Thank-you

Comment #49: Submitter: David Bibo, Sr. Organization: Date: June 30, 2004

Comment:

Funding for smoking cessation counselling has been cut irreverently over the past several years. We have made great strides in reducing the availability of public places where it is acceptable over that time period, however, the youth population is smoking as much now as ever before. WE are losing our future to this poor health choice and need to provide funding for counselling and other tobacco cessation techniques.

Comment #50: Submitter: Saro Helpinstill Organization: Date: June 30, 2004

Comment:

Medicare coverage of FDA-approved medications for tobacco cessation should be considered at the same time as CMS reviews the matter of Medicare payment for cessation counseling.

Comment #51: Submitter: Sally Helton, APRN,BC,SANE-A Organization: American Nurses Association/TN Nurses Assoc. Date: June 30, 2004

Comment:

Please support the Medicare approval for smoking cessation, FDA approved medication, and counseling. I see many patients each week whose health would be improved if they could stop smoking--and they want to. Thank you,

Comment #52: Submitter: Bette Idemoto Organization: Case Western Reserve University Date: June 30, 2004

Comment:

More Americans die each year from tobacco related illnesses than total soldiers who died in the whole WWII. Please support Medicare coverage for tobacco cessation (FDA-approved medications) and counseling

Comment #53: Submitter: Colleen Hughes Organization: President, Nevada Tobacco Prevention Coalition Date: July 1, 2004

Comment:

Smoking cessation at any age benefits the patient and his/her family (secondhand smoke effects)..Nurses do a fine job in this effort of cessation for the patient and should be reimbursed for this service.

Comment #54: Submitter: John Hughes Organization: Date: July 1, 2004

Comment:

As a physician and a former Chair of the VT Tobacco Evaluation and Review Board, I strongly support the inclusion of counseling because it is consistent with USPHS guidelines. I believe with appropriate duration and time limits this would not be expensive as in our state (VT) even when 80% of smokers know that free in person counseling is available at their local hospital through our tobacco control program, less than 1% use this resource each year. However, for some smokers this resource is vital to their ability to stop smoking.

Comment #55: Submitter: Ivy Pearlstein Organization: HiTOPS

Date: July 1, 2004

Comment:

I am a Nurse Practitioner who has been working in the field of tobacco dependence counseling for the past three years. I have seen first hand what the current research has shown- that tobacco use rapidly leads to a daily addiction with devastating financial and health implications. Research has shown that 1/3 of tobacco users are able to quit without assistance, and another 1/3 are willing to accept the choice they make to continue using tobacco but the remaining 1/3 of tobacco users are unable to quit unless they receive intensive counseling and help. Even when this help is available, many relapse and require several episodes of counseling or "Quit attempts" until they have the skills and support they need to remain abstinent from tobacco. For these people, tobacco use must be treated like any other chronic illness. The counseling requires more than a cursory warning during a health care visit for other reasons. I have seen the counseling process work for many clients when it involves tailoring the program to address the individual needs. These include addressing the physical component of tobacco dependence with Nicotine replacement, the psychological component with bupropion and training to learn coping skills to manage cravings, avoid smoking triggers and prevent relapse, stress management skills training, and nutritional counseling. If medicare pays for the costs of treating tobacco related illness such as heart and lung disease, it would seem prudent to pay for services which can prevent these illnesses from occurring and in many cases reverse the effects of illnesses such as hypertension, chronic bronchitis, circulatory problems, humanpapilloma virus(HPV)progressing to cervical cancer. the tobacco companies argue that people who use their product have to choice to use it or not. I currently work with adolescents and adults and have seen that by the time people are in their 40's the "choice" they made as teens has them in an addiction that is extremely difficult to break free from without assistance. We have the knowledge to help these people and our health care system must financially address their needs.

Comment #56: Submitter: Bonnie Ewing Organization: University Date: July 1, 2004

Comment:

please support Medicare coverage for tobacco cessation (FDA-approved medications) and counseling".

Comment #57: Submitter: Christopher Covert-Bowlds, MD Organization: COMMIT for a Tobacco Free Whatcom County Date: July 2, 2004

Comment:

As a family doctor working hard to help tobacco users break free of their deadly addiction and a leader of Washington state tobacco control efforts, I strongly urge CMS to begin covering treatment of smoking (tobacco use disorder), smoking cessation counseling, and the FDA approved medications that pertain.

Treating tobacco dependence is one of the most cost effective health improvement strategies known. As the Surgeon General has reported ([www.surgeongeneral.gov/tobacco](http://www.surgeongeneral.gov/tobacco)), all types of insurance should cover both tobacco dependence counseling as well as medications. Since most people use over the counter nicotine replacement therapy (patch, gum, lozenge), these should be covered as well as the prescription pill bupropion, the nicotine inhaler, and nasal spray.

I would appreciate hearing the outcome of this consideration. Thank you for your deliberation of this important health issue.

Comment #58: Submitter: Mary Ann Dale Organization: University of Texas at Austin School of Nursing Date:

July 2, 2004

Comment:

Please add my name to the petition for medicare and medicaid coverage of the smoking and tobacco use cessation and counseling program. We need to provide this for all people to assist them to quit this health hazardous practice. This will greatly help our society as a whole with both health maintenance and economic issues.

Comment #59: Submitter: Lorna Schumann Organization: Date: July 3, 2004

Comment:

Please support tobacco cessation legislation. We need to work for improving healthcare for smokers and those who are subjected to second hand smoke.

Comment #60: Submitter: Karen Schiavone Organization: Date: July 6, 2004

Comment:

Coverage for any health problem is vital, especially tobacco cessation. Tobacco use may lead to so many other health problems that stopping the use of tobacco can improve the quality of life overall and reduce medical costs in general.

Comment #61: Submitter: Cheryl Horn Organization: Student Tobacco Options Program Date: July 7, 2004

Comment:

I am a tobacco cessation counselor, and also a respiratory therapist that daily witnesses the devastating effects of tobacco use.

My patients definately need coverage for tobacco cessation treatment. At the same time, they also need coverage for nicotine replacement therapy, or other pharmacological aids. In the long run, Medicare will save money by promoting tobacco cessation.

Comment #62: Submitter: Barbara Krivda Organization: Date: July 8, 2004

Comment:

I endorse coverage for medicare or medicaid covered individuals for stop smoking programs.

Comment #63: Submitter: Kathleen McKool Organization: Massachusetts General Hospital Date: July 9, 2004

Comment:

Treating tobacco dependence is one of the most cost effective treatments available and should be provided to Medicare patients. I am currently running a quit smoking group. In the group is an 80 year old woman with chronic lung disease. She has been quit for 2 weeks now. Her quitting will save Medicare thousands of dollars in avoided emergency room visits and hospitalizations just for this one person. Please do not be short sighted. Many more seniors and Medicare patients would take advantage of such programs if subsidized.

Comment #64: Submitter: Sharon Czabafy Organization: Date: July 11, 2004

Comment:

Nicotine is a drug & needs to be treated as such with same coverage other drugs have plus coverage for NRT and other helpful cessation meds.

Comment #65: Submitter: Kim Astroth Organization: Mennonite Colleg of Nursing @ Il. State University Date: July 13, 2004

Comment:

Please support Medicare coverage for tobacco cessation (FDA-approved medications) and counseling. Thank-you.

Comment #66: Submitter: James H. Craggs Organization: Mayo Clinic Jacksonville Date: July 14, 2004

Comment:

Without question the greatest beneficial action an individual could take with regard to health status is to quit smoking. Nicotine addiction is the number one addiction facing Americans today. Almost one-half million people are dying every year from smoking-related behavior with 11,000 victims of Environmental Tobacco Smoke dying every year as well. We have the technology and procedures to effectively eliminate the majority of these deaths through therapeutic interventions involving pharmacotherapy and cognitive and behavioral counseling. Why in the world would the FDA pull products containing ephedra off the shelf and issue a statement saying "we believe as many as 150 people have died from products containing ephedra" and show reticence with regard to tobacco products? Refer to my previous statement - every year in the United States alone there are 430,000 deaths attributable to smoking.

I am the Director of the Nicotine Dependence Center at the Mayo Clinic in Jacksonville Florida. It is my passion and my pleasure to help patients stop smoking. Our program is marvously effective, affordable and in the context of health-related costs vs. benefits is paralled by few medical procedures. In other words there is hardly an intervention that can be more cost effective and provide the health benefits than that achieved through smoking cessation. Regardless of how old or how long a person has been smoking they can be sucessful at quitting and halt COPD progression and beneficially affect other disease processes. They can also experience a higher quality of life, save (or spend) money they are not spending on cigarettes etc.

Normally I am seeing patients for an initial evaluation, using nicotine replacement, sometimes Zyban, and then seeing the patient back for 4 to 6 15-30 minute sessions. The cost for all of this including prescriptions is a maximum of approx. \$900 but could be as low as \$600 and well worth the investment.

Comment #67: Submitter: Denise Wilson Organization: Date: July 15, 2004

Comment:

As a nurse practitioner who sees adult and geriatric patients, I see the results of long-term smoking on their health on a daily basis. Many want to stop smoking but don't have the financial resources to pay for the medications and counseling which can make cessation attempts successful. Therefore, I am asking you to please support Medicare coverage for tobacco cessation (FDA-approved medications) and counseling.

Comment #68: Submitter: Brenda Jeffers Organization: Date:

July 16, 2004

Comment:

Please support Medicare coverage for tobacco cessation (FDA-approved medications) and counseling.

Comment #69: Submitter: Richard Martielli, M.S. Organization: Date: July 19, 2004

Comment:

Medicare coverage of FDA-approved medications for tobacco cessation should be considered at the same time as CMS reviews the matter of Medicare payment for cessation counseling.

Comment #70: Submitter: Randall D. Ehrbar, Psy.D. Organization: Date: July 19, 2004

Comment:

Smoking and Tobacco use Cessation Counseling should be a covered service. As a psychotherapist, I see several clients, who among other issues, are having difficulties with smoking cessation. Quitting smoking would vastly improve their quality of life as well as reducing their risk for a variety of health problems down the line. Some of these clients are especially at risk from smoking due to interaction effects with medications they are taking. As you are probably aware, nicotine is a very addictive substance, and quitting smoking and tobacco use is very difficult. Therapeutic approaches to this problem (often in addition to medical support, such as Welbutrin or nicotine replacement therapy) substantially improve the odds of success (x4).

As more and more of the health problems Americans tend to suffer have behavioral components, it becomes more and more important to cover those behaviors in treatment. Psychologists and other mental health professionals are best able to address these issues due to our training in helping people with addictions and problematic behavior patterns. Furthermore, the behavior component of so many health problems makes prevention especially important. Therefore it is especially important to insure that Americans have access to these services through providing coverage.

Thank you,

Comment #71: Submitter: Richard Hurt Organization: Mayo Clinic Date: July 22, 2004

Comment:

We appreciate the opportunity to comment on coverage for tobacco cessation counseling and strongly recommend CMS issue a National Coverage Decision to establish coverage for tobacco cessation treatment.

There are many reasons that Medicare should cover tobacco dependence treatment services provided by clinicians, i.e. physicians and other qualified healthcare providers. First of all, older smokers can stop smoking at the same, if not better rate than younger smokers(1). Further, stopping smoking at any time in life improves quality of life and longevity. It has been well described in the literature that ex-smokers or non-smokers experience compressed morbidity compared to their smoking counterparts(2). That is, people who stop smoking live longer and die shorter avoiding a protracted, costly death often seen with tobacco-caused diseases. Cigarette smokers live shorter lives but spend much more time in nursing homes, intensive care units, etc. due to the morbidity of tobacco-related diseases at the end of their life. The 2000 U.S. Public Health Service Guideline, "Treating Tobacco Use and Dependence" states that behavioral counseling and pharmacotherapy are effective and there is a dose response(3). That is, the more intensive the treatment, the more often treatment is provided

and greater the variety of providers delivering the service the better the ultimate outcome. It is also widely understood that lack of reimbursement to providers for tobacco dependence treatment services is a barrier to clinicians and health care systems, for provision of these services. In addition, non-coverage has been clearly demonstrated to be a barrier for patients to even seek out treatment services. More comprehensive coverage leads more patients to avail themselves of treatment services(4). This comes at a time when more medical centers throughout the country are now providing treatment services because of the compelling need to do the right thing.

In 1988, we initiated a treatment program at Mayo Clinic Rochester, which is based on the philosophical underpinnings of behavioral treatment, addictions treatment, pharmacotherapy and relapse prevention(5). We have provided treatment to over 29,000 patients with a range of services including face-to-face individual counseling both at the hospital bedside and in the outpatient practice. We have group programs, and we have a residential treatment program for patients with more severe tobacco dependence(6). Treatment outcomes range from 23% tobacco abstinence at one year for those receiving an initial counseling session lasting 45 to 60 minutes to one year tobacco abstinence rates of 45% for patients attending the Residential Treatment Program. These outcomes have been fairly consistent over the 16 years of providing this service(7). Further, we provide services to patients with a range of co-morbid conditions including lung cancer and have demonstrated that the tobacco abstinence outcomes were actually better in lung cancer survivors than it was in matched controls without lung cancer, all treated in our program(8).

For our outpatient and bedside behavioral counseling, our counselors estimate that after the initial 45 to 60 minute counseling session an additional 3 or 4 additional follow-up sessions (15 to 30 minutes each) are optimal to increase the likelihood of successful tobacco abstinence.

Pharmacotherapy is provided to practically every patient and is individualized to the patient's tobacco use history, their degree of tobacco dependence and previous experience with medications. This means that on occasion we will use more than one nicotine patch at a time(9). In addition, combination treatments with multiple nicotine replacement therapy products (gum, lozenge, inhaler, nasal spray) as well as in combination with bupropion are the rule rather than the exception. Thus, just as with the treatment of hypertension, clinicians should be given the latitude to use multiple different types of medications in order to successfully treat patients with tobacco dependence. Because the efficacy of residential treatment is much higher than individual or group programs, we also would recommend coverage (at least partial if not complete coverage) for residential treatment, which gives the best efficacy of any type of treatment that we have developed. While the cost of residential treatment averages around \$5000 per stay, the cost effectiveness has been demonstrated to be exceptional(10).

The U.S. Public Service Guidelines state that there is an unwritten contract between healthcare providers and their patients to provide services that are effective once they have been shown to be effective(3). It is time for Medicare to provide coverage for treatment services in order to reduce a long-standing barrier for the patient and provider. Compared to other commonly covered treatments, providing treatment for tobacco dependence is amongst the most cost-effective treatment in medicine today(10). In the long run it will save Medicare money by assisting elderly patients in stopping smoking and allow the phenomenon of "compressed morbidity" for ex-smokers and non-smokers to be realized. This will reduce the burden on the extremes of the health care system such as intensive care units and nursing homes. The more we can reduce the morbidity from tobacco-caused diseases by financially supporting effective treatments of tobacco use and dependence the less resources will be expended on the costly, long-term treatment of those diseases.

## Minimal Recommended Coverage Criteria

Consistent and ongoing tobacco cessation treatment is a key factor to long-term success.

¶ The physician/patient team should be responsible for deciding the best mechanism for tobacco cessation counseling (individual, group, or combination). We would not want to see CMS limit cessation counseling to a group environment which may hinder beneficiary access.

¶ We concur that two cessation attempts per year is reasonable. The beneficiary should not have a lifetime limit to the number of cessation attempts as research demonstrates that stopping at any time is associated with improved health. It is desired to have the attitude of never giving up.

¶ The number of counseling hours per cessation attempt may vary by beneficiary. We believe it is reasonable to have up to a 60 minute initial counseling session for tobacco cessation and approximately 2 ½ to 3 hours for follow up visits per cessation attempt. This would equate to seven to eight hours per year.

### References:

1. LC Dale, DA Olsen, CA Patten, DR Schroeder, IT Croghan, RD Hurt, KP Offord, TD Wolter. Predictors of Smoking Cessation Among Elderly Smokers Treated for Nicotine Dependence. *Tobacco Control* 1997; 6:181-187.
2. WJ Nusselder, CWN Looman, PJ Marang-van de Mheen, H van de Mheen, JP Mackenbach. Smoking and the Compression of Morbidity. *Journal of Epidemiology and Community Health* 2000; 54:566-574.
3. MC Fiore, WC Bailey, SJ Cohen. Treating Tobacco Use and Dependence. Clinical Practice Guideline. Rockville, MD: U.S. Department of Health and Human Services. Public Health Service June 2000.
4. SJ Curry, LC Grothaus, T McAfee, C Pabiniak. Use and Cost Effectiveness of Smoking Cessation Services Under Four Insurance Plans in a Health Maintenance Organization. *New England Journal of Medicine* 1998; 339(10):673-678.
5. RD Hurt, GG Lauger, KP Offord, BK Bruce, LC Dale, FL McClain, KM Eberman. An Integrated Approach to the Treatment of Nicotine Dependence in a Medical Center Setting: Description of the Initial Experience. *Journal of General Internal Medicine* 1992; 7(1):114-116.
6. JT Hays, TD Wolter, KM Eberman, IT Croghan, KP Offord, RD Hurt. Residential (Inpatient) Treatment Compared With Outpatient Treatment for Nicotine Dependence. *Mayo Clinic Proceedings* 2001; 76:124-133.
7. JA Ferguson, CA Patten, DR Schroeder, KP Offord, KM Eberman, RD Hurt. Predictors of 6- Month Tobacco Abstinence Among 1224 Cigarette Smokers Treated for Nicotine Dependence. *Addictive Behaviors* 2003; 28:1203-1218.
8. LS Cox, MM Clark, JR Jett, CA Patten, DR Schroeder, LM Nirelli, SJ Swenson, RD Hurt. Change in Smoking Status After Spiral Computed Tomography Scan Screening. *Journal of Clinical Oncology* 2003; 98:2495-2501.
9. LC Dale, JO Ebbert, JT Hays, RD Hurt. Treatment of Nicotine Dependence. *Mayo Clinic Proceedings* 2000; 75(12):1311-1316.
10. IT Croghan, KP Offord, RW Evans, S Schmidt, LC Gomez-Dahl, DR Schroeder, CA Patten, RD Hurt. Cost-Effectiveness of Treating Nicotine Dependence: The Mayo Clinic Experience. *Mayo Clinic Proceedings* 1997; 72:917-924.

Comment #72: Submitter: Nancy Schlichting, Chief Executive Officer Organization: Henry Ford Health System Date: July 22, 2004

Comment: Henry Ford Health System strongly supports the recommendation by Partnership for Prevention that Medicare issue a national coverage determination on smoking cessation counseling for individuals with smoking-related diseases or symptoms (NCA # CAG-00241N). Smoking cessation counseling represents a critical intervention for patients who smoke and goes to the heart of their disease process.

Older adults, who represent the bulk of Medicare beneficiaries, benefit tremendously from smoking cessation. More than 94% of deaths due to smoking occur in people aged 50 and older, and over 70% in those aged 65 and older. More than 10% of people aged 65 and older smoke, as do over 23% of those aged 50 to 64, accounting for about 4 million seniors who smoke and are covered by Medicare. Smoking contributes to all of the major causes of death among the elderly—cancer, cardiovascular disease, and stroke—each of which can cause long periods of disability and suffering among its victims. Quitting smoking benefits health (both immediately and long-term) at any age, including those 65 and older. Quitting helps patients reduce their use of pharmaceuticals and medical services, providing cost savings and improved quality of care.

Even brief intervention by providers can be effective in increasing quit rates. The more intensive the intervention, the likelier a patient will quit. However, some studies suggest that Medicare beneficiaries frequently are not advised to quit smoking. Whenever providers are asked why they are unable to regularly intervene with patients about smoking, many see the lack of reimbursement for such services as a major barrier. As with any medical intervention, providers must be compensated for their services. Should Medicare choose to cover smoking cessation counseling, not only would such services become available to current beneficiaries, but many other health plans and providers would be encouraged to provide similar benefits for their clients.

Finally, we understand that under the new Medicare prescription drug benefit, prescription nicotine replacement therapies (NRTs) and bupropion for smoking cessation will be covered explicitly. We urge Medicare to cover over-the-counter NRTs in addition to counseling, as they are used much more commonly than prescription medications by patients making assisted quit-smoking attempts. Although Medicare coverage for OTC medications would be unusual or unprecedented, it could be justified for NRTs on the basis that these products were originally available only by prescription. Health Alliance Plan, our 550,000-member HMO, covers both prescription and OTC smoking cessation medications in order to maximize its members' access to these life-saving agents.

Thank you for your consideration.

Comment #73: Submitter: Janis Dauer Organization: Alliance Prevention/Treatment Nicotine Addiction Date: July 23, 2004

Comment:

Medicaid and Medicare coverage for the counseling interventions and medication recommendations in the US PHS clinical practice guideline when assessed and provided appropriately by qualified service providers and for services provided by licensed clinicians qualified to treat mental disorders when a patient is diagnosed with nicotine dependence in accordance with DSM-IV criteria is vital to continued progress in reducing the morbidity and mortality related to tobacco use.

Comment #74: Submitter: Richard S. Irwin, MD, FCCP Organization: American College of Chest Physicians  
Date: July 23, 2004 Comment:

We are writing to express our strong support for the request for a National Coverage Determination (NCD) for tobacco cessation counseling under Medicare submitted by Partnership for Prevention. The American College of Chest Physicians (ACCP) membership is comprised of over 15,700 physicians and allied health professionals, whose everyday practice involves diseases of the chest in the specialties of pulmonology, cardiology, thoracic and cardiovascular surgery, critical care medicine, and anesthesiology. These health care professionals practice in virtually every hospital in this country, and many of the physicians head major departments in these hospitals. As a multidisciplinary society, the ACCP offers broad viewpoints on matters of public health and clinical policy in cardiopulmonary medicine and surgery.

The request by the Partnership for Prevention is a comprehensive, thorough, and highly credible assessment of the clinical merits and cost-related benefits of providing tobacco cessation counseling services under the Medicare program. This request is consistent with the recommendations of other key programs and advisory bodies within the Department of Health and Human Services, including Secretary Thompson's Steps to a Healthier U.S. Initiative, and the report of the Interagency Committee on Smoking and Health, Subcommittee on Cessation.

It has been documented that tobacco cessation counseling services target those individuals who are suffering most, and have a strong potential for improved health should they receive these services. This is significant because of the health risks of using tobacco products over long periods of time. In fact, according to Surgeon General Richard Carmona, in his May 27, 2004 remarks releasing his office's most recent report on tobacco use in the United States, he states "smoking causes disease in nearly every organ in the body, at every stage of life" (emphasis added). ACCP members care for patients with chronic obstructive pulmonary disease (COPD), which is consistently among the top 10 most common chronic health conditions and among the top 10 conditions that limit daily activities. Prevalence of COPD is highest in men and women 65 years of age and older (16.7% among men and 12.6% among women). We also care for patients with lung cancer, chronic bronchitis, and other lung diseases associated with tobacco use. Because of this front line knowledge of the effects that smoking has on the human body, we have been deeply committed to promoting smoking cessation and have been on the cutting edge as it pertains to aiding our members in this endeavor. The risks of tobacco are compounded by the addictive nature of tobacco products and nicotine and the difficulty in quitting that this generates for users. Drug addictions or dependencies are widely recognized to be chronic relapsing disorders for which there is wide variation across individuals in their ability to achieve and sustain abstinence. Tobacco is no different from other addicting substances in this regard. The majority of tobacco users are daily users and exhibit the classic signs of addiction. Accordingly, ACCP has developed a comprehensive Tobacco Cessation Tool Kit that instructs physicians about how to counsel patients and provides the necessary written tools to reinforce this counseling. The materials are based upon guidelines detailed in the U.S. Department of Health and Human Services Treating Tobacco Use and Dependence: Clinical Practice Guideline released in June 2000. In addition, ACCP's Chest Foundation has developed and distributed a multi-ethnic tobacco education speaker's kit that stresses the importance of smoking cessation. We would appreciate the opportunity to share these materials with CMS staff to use when establishing and maintaining smoking cessation programs. Tobacco use cessation counseling is appropriate for coverage as a Medicare benefit because it is reasonable and necessary for the treatment of an illness or injury, specifically a tobacco-related illness or injury. Further, tobacco use cessation counseling has been scientifically proven through clinical trials to be both a clinically effective and cost effective service. For example, in a July 2001 study published in the American Journal of Preventive Medicine (AJPM), the authors found, using a one to ten scale with ten being the highest possible score, that of the thirty preventive services evaluated, tobacco cessation counseling ranked second in its degree of effectiveness, scoring a nine out of 10 (the highest ranking was for childhood vaccines which scored a 10). The AJPM study examined the burden of disease prevented by each service and cost effectiveness. Of particular interest in relation to this request was the authors' finding that among other preventive services currently covered by Medicare, colorectal cancer screening received a score of eight and mammography screening scored a six.

The evidence used in support of the Partnership for Prevention request is current and authoritative and represents the best science available on the subject. We know that cessation works and we know that older age is not a barrier to successfully quitting because seniors who do try to quit are 50 percent more likely to be successful than all other age groups when they try. Approval of this request will give all seniors who use tobacco, and want to quit, a greater opportunity to succeed and to live a healthier, longer and higher quality of life.

The recently enacted legislation to provide prescription drug coverage under Medicare also made available FDA-approved prescription cessation aids (e.g., nicotine nasal spray, nicotine inhaler, bupropion SR, legend drug, nicotine patches). The availability of pharmacotherapy to health care providers will complement and reinforce the effectiveness of counseling. In fact, when combined, counseling and medications nearly double each respective intervention's quit rates.

Please be aware that we are also very concerned that the Center for Medicare and Medicaid Services (CMS) will argue that smoking cessation interventions are currently included as part of the "counseling and coordination of care" element of every level of Evaluation and Management services rendered by a physician or a physician's employee as an "incident to" service. ACCP does not believe this is correct, as this counseling entails more than just telling the patient to stop smoking and handing them literature. The patient usually has a longstanding addiction which requires stringent intervention. Therefore, specific guidelines and codes are needed for this complex, time-consuming, important behavior modification.

Finally, we would like to emphasize that if CMS determines that Medicare will cover smoking cessation counseling, the Medicare expenditures for these new services should be included as an allowance in the law and regulatory changes component of the Sustainable Growth Rate target.

If any CMS staff has any questions or wishes further information, please feel free to contact me or Lynne Marcus at lmarcus@chestnet.org or at (847) 498-8331.

Comment #75: Submitter: L. Kristen Welker-Hood, MSN, RN Organization: University of Texas Medical Branch Date: July 23, 2004 Comment:

Please support Medicare coverage for tobacco cessation (FDA-approved medications) and counseling

Comment #76: Submitter: Matthew L. Myers Organization: Campaign for Tobacco Free Kids Date: July 23, 2004 Comment:

Marcel Salive, MD, MPH Director, Division of Medical & Surgical Services Coverage and Analysis Group 7500 Security Boulevard - C1-09-28 Baltimore, Maryland 21244

RE: National Coverage Determination Request for Smoking and Tobacco Use Cessation Counseling (CAG-00241N)

Dear Dr. Salive:

This letter is being submitted by several interested parties, including: Partners for Effective Tobacco Policy, a coalition of more than 60 national organizations - including the American Medical Association, the American Cancer Society, American Heart Association, and the American Lung Association - committed to reducing death and disability caused by tobacco use; and the Society for Research on Nicotine and Tobacco, the leading scientific society in the world devoted exclusively to the generation of new knowledge concerning nicotine and tobacco. We are writing to express our strong support for the request for a National Coverage Determination for tobacco cessation counseling under Medicare submitted by Partnership for Prevention on June 23, 2004.

The request by the Partnership for Prevention is a comprehensive, thorough, and highly credible assessment of the clinical merits and cost-related benefits of providing tobacco cessation counseling services under the Medicare program. The evidence used in support of their request is current and authoritative and represents the best science available on the subject. Further, the evidence upon which the request has been made represents the collective expertise of some of the nation's most prestigious scientific and medical organizations, including the Agency for Health Care Research and Quality, the National Cancer Institute, the National Heart, Lung, and Blood Institute, the National Institute on Drug Abuse, the Centers for Disease Control and Prevention, and the University of Wisconsin Medical School's Center for Tobacco Research and Intervention. In addition, this request is consistent with the recommendations of other key programs and advisory bodies within the Department of Health and Human Services, including Secretary Thompson's Steps to a Healthier U.S. Initiative and the report of the Interagency Committee on Smoking and Health, Subcommittee on Cessation. (1)

In our view, it is important to note that tobacco cessation counseling services target those individuals who are suffering most and have a strong potential for improved health should they receive these services. This is significant for several reasons. First, the evidence is overwhelming concerning the health risks of using tobacco products, particularly for long periods of time (e.g., decades). In fact, according to Surgeon General Richard Carmona in his May 27, 2004 remarks releasing his office's most recent report on tobacco use in the United States, "smoking causes disease in nearly every organ in the body, at every stage of life" (emphasis added). (2) The Surgeon General's report specifically found, with respect to tobacco use among seniors in the United States, that: "Smoking reduces bone density among postmenopausal women." "Smoking is causally related to an increased risk for hip fractures in men and women and that of the 850,000 fractures occurring in individuals over age 65, 300,000 are hip fractures. Persons with a hip fracture are 12% to 20% more likely to die than those without a hip fracture." "Smoking is related to nuclear cataracts of the lens of the eye, the most common type of cataract in the United States. Cataracts are the leading cause of blindness worldwide and a leading cause of visual loss in the United States. Smokers have two to three times the risk of developing cataracts as nonsmokers." "Chronic obstructive pulmonary disease (COPD) is consistently among the top 10 most common chronic health conditions and among the top 10 conditions that limit daily activities. Prevalence of COPD is highest in men and women 65 years of age and older (16.7% among men and 12.6% among women). (3)

Second, if the risks of tobacco use weren't bad enough, they are compounded by the addictive nature of tobacco products and nicotine and the difficulty in quitting that this generates for users. Drug addictions or dependencies are widely recognized to be chronic relapsing disorders for which there is wide variation across individuals in their ability to achieve and sustain abstinence. (4) Tobacco is no different from other addicting substances in this regard except that most patients who take drugs that can be addictive are not actually addicted, whereas the majority of tobacco users are daily users and do show signs of addiction. (5) Tobacco dependence is recognized by health professionals worldwide through its classification and coding in the International Classification of Diseases (ICD-9-CM) and the Diagnostic and Statistical Manual of Mental Disorders - Fourth Edition (DSM- IV). In recognition of this fact, as of December 2002, 36 State Medicaid programs covered some tobacco-dependence counseling or medication for all their Medicaid recipients. (6)

While all of our organizations are interested in preventing the initiation of tobacco use, this request is not about preventing initiation. Rather, this request is solely focused on tobacco cessation. Tobacco use cessation counseling is appropriate for coverage as a Medicare benefit because it is reasonable and necessary for the treatment of an illness or injury, specifically a tobacco-related illness or injury. Further, tobacco use cessation counseling has been scientifically proven through clinical trials to be both a clinically effective and cost effective service. For example, in a July 2001 study published in the American Journal of Preventive Medicine (AJPM), the authors found, using a one to ten scale with ten being the highest possible score, (7) that of the thirty preventive services evaluated, tobacco cessation counseling ranked second in its degree of effectiveness, scoring a nine out of 10 (the highest ranking was for childhood vaccines which scored a 10). The AJPM study examined the burden of disease prevented by each service and cost effectiveness. Of particular interest in relation to this request was the authors' finding that among other preventive services currently covered by Medicare, colorectal cancer screening received a score of eight and mammography screening scored a six.

In addition to the AJPM study, we also know that in individuals 65 and older who smoke, that those who quit can achieve cardiovascular mortality rates similar to those of nonsmokers.(8) Further, a person who smokes more than 20 cigarettes per day but quits at age 65 will still, on average, increase his or her life expectancy by two to three years.(9) And, smoking cessation in older smokers can reduce the risk of myocardial infarction, death from coronary heart disease, and lung cancer, while abstinence can promote more rapid recovery from illnesses that are exacerbated by smoking and can improve cerebral circulation.

Again, the evidence provided in support of this request is overwhelming and highly credible. We know that cessation works and we know that older age is not a barrier to successfully quitting since seniors who do try to quit are 50 percent more likely to be successful than all other age groups when they try.(10,11) Approval of this request will give all seniors who use tobacco and want to quit a greater opportunity to succeed and to live a healthier, longer and higher quality of life.

Finally, the recently enacted legislation to provide prescription drug coverage under Medicare also made available FDA-approved prescription cessation aids (e.g., nicotine nasal spray, nicotine inhaler, bupropion SR, legend drug, nicotine patches). The availability of pharmacotherapy to health care providers will complement and reinforce the effectiveness of counseling. In fact, when combined, counseling and medications nearly doubles each respective intervention's quit rates.(12)

Our organizations fully support this request for a National Coverage Determination for tobacco cessation counseling services under Medicare. Thank you for the opportunity to provide comments on this request.

Sincerely,

Action on Smoking or Health American Academy of Family Physicians American Association for Respiratory Care American Cancer Society American College of Chest Physicians American College of Occupational and Environmental Medicine American College of Physicians American College of Preventive Medicine American Heart Association American Lung Association American Medical Association

American Medical Women's Association American Psychological Association American Public Health Association American Thoracic Society Association of Maternal and Child Health Programs Campaign for Tobacco-Free Kids Center for Tobacco Cessation General Board of Church and Society of the United Methodist Church Hadassah, the Women's Zionist Organization of America Maine Coalition on Smoking or Health Medical Society of the State of New York National Association of County and City Health Officials National Association of School Nurses National Center for Policy Research for Women & Families National Women's Law Center Oncology Nursing Society Oral Health America Society for Public Health Education Society for Research on Nicotine and Tobacco University of Wisconsin Medical School/Center for Tobacco Research and Intervention

1. Fiore MC, Croyle RT, Curry SJ, Cutler CM, Davis RM, Gordon C, Heaton C, Koh HK, Orleans CT, Richling D, Satcher D, Seffrin J, Williams C, Williams LN, Keller PA, Baker TB. Preventing 3 million premature deaths and helping 5 million smokers quit: a national action plan for tobacco cessation. *Am J Pub Hlth* 2004;94(2):205-10.
2. U.S. Department of Health and Human Services. *The Health Consequences of Smoking: A Report of the Surgeon General*. U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health, 2004.
3. U.S. Department of Health and Human Services. *The Health Consequences of Smoking: A Report of the Surgeon General*. U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health, 2004.
4. McLellan AT, Lewis DC, O'Brien CP, Kleber HD, "Drug dependence, a chronic medical illness: implications for treatment, insurance, and outcomes evaluation," *Journal of the American Medical Association*, October 4, 2000; 284: 1689- 1695.
5. Department of Health and Human Services, Food and Drug Administration, "Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents," Final Rule, 21 CFR Parts 801, 803, 804, 807, 820, and 897, Docket Number 95N-0253, Federal Register, Volume 61, No. 168, August 28, 1996.
6. Halpin, HL et al, "State Medicaid Coverage for Tobacco-Dependence Treatments --- United States, 1994-2002," *Morbidity and Mortality Weekly Report*, January 30, 2004 / 53(03);54-57, January 30, 2004.
7. Coffield, A, et al. "Priorities Among Recommended Clinical Preventive Services," *American Journal of Preventive Medicine*, July 2001, 21(1), [www.meddevel.com/site.mash?left=/library.exe&m1=1&m2=1&right=/library.exe&action=home&site=AJPM&jcode=AMEPRE](http://www.meddevel.com/site.mash?left=/library.exe&m1=1&m2=1&right=/library.exe&action=home&site=AJPM&jcode=AMEPRE).
8. Lacroix, AZ, "Thiazide diuretic agents and prevention of hip fracture," *Comprehensive Therapy* 1991, 17(8)30-9 [published erratum in *Comprehensive Therapy* 1992 February, 18(2):42]; RAND, 2000.
9. Sachs, DPL, "Cigarette Smoking: Health Effects and Cessation Strategies," *Clinical Geriatric Medicine* 1986; 2:337-362; RAND 2000.
10. CDC. Smoking cessation during previous year among adults—United States, 1990 and 1991. *MMWR*.1993;42(26):504-7.
11. Clark MA, Rakowski W, Kviz FJ, Hogan JW. Age and stage of readiness for smoking cessation. *J Gerontol B Psychol Sci Soc Sci*. 1997;52(4):S212- 21.
12. Fiore MC, Bailey WC, Cohen SJ, et al. *Treating Tobacco Use and Dependence. Clinical Practice Guideline*. Rockville, MD: U.S. Department of Health and Human Services. Public Health Service. June 2000.

Comment #77: Submitter: Sharon I.S. Rounds, MD, President Organization: American Thoracic Society Date: July 23, 2004

Comment:

On behalf of the 14,000 members of the American Thoracic Society (ATS), I would like to offer our strong support Partnership for Prevention's petition for issuing a national coverage determination on smoking cessation under Medicare. The ATS believes that developing Medicare NCD that explicitly covers smoking cessation will bring significant health benefits to Medicare beneficiaries.

ATS physicians, researchers and allied health professionals are actively engaged in diagnosis, treatment, training, and research of tobacco-related diseases. The ATS recently published, with our international partner the European Respiratory Society, a revised version of the statement: Standards for the Diagnosis and Management of Patients with COPD. The statement represents the combined scientific knowledge and expert opinion on the optimum care of patients with COPD - a disease most commonly caused by tobacco use.

While the ATS strongly supports the Partnership for Prevention's request for a Medicare NCD on smoking cessation, we would like to add the following clarifying points:

**Smoking Cessation Benefits Should Be for All Medicare Beneficiaries** The ATS is concerned that any Medicare smoking cessation benefit not be limited to Medicare beneficiaries who have tobacco-related disease. The CMS tracking sheet states that:

“The Centers for Medicare & Medicaid Services (CMS) received a formal request from Partnership for Prevention, asking that we issue a national coverage determination (NCD) on tobacco cessation counseling for the treatment of individuals who use tobacco and have been diagnosed with a recognized tobacco-related disease or who exhibit symptoms consistent with tobacco-related disease.”

While we support the PFP request, we would strongly urge that coverage for smoking cessation not be limited to individuals who “have been diagnosed with a recognized tobacco-related disease or who exhibit symptoms consistent with tobacco-related disease.” Tobacco use is bad for your health whether you are currently exhibiting tobacco-related symptoms or not. More than half of long-term smokers will eventually develop serious smoking related diseases. The goal of smoking cessation is to stop disease before it starts or prevent disease from progressing further. A Medicare NCD that required patients to exhibit tobacco related-disease before they could receive Medicare covered tobacco cessation services would limit the benefits of smoking cessation. We strongly recommend that a NCD on smoking cessation apply to all Medicare beneficiaries who use tobacco products.

**Cost of Smoking Cessation Should be Captured in SGR** The ATS recommends that the cost of providing smoking cessation benefits be included in the law and regulation component of the Medicare sustainable growth rate (SGR) formula. This way, tobacco cessation coverage isn't funded at the expense (literally) of payments for all the other necessary and reasonable services Medicare covers.

Again, the ATS appreciates the opportunity to comment on this important issue. We strongly support the Partnership for Prevention's petition for a NCD that provides Medicare coverage for smoking cessation services.

Comment #78: Submitter: George A. Mensah, M.D., FACP, FACC Organization: National Center for Chronic Disease Prevention and Health Promotion, Centers for Disease Control Date: July 23, 2004

Comment:

The National Center for Chronic Disease Prevention and Health Promotion, at the Centers for Disease Control and Prevention, would like to offer its support for the proposal put forward by the Partnership for Prevention to cover tobacco cessation counseling for eligible smokers diagnosed with or demonstrating symptoms of tobacco-related disease.

Tobacco use remains the leading preventable cause of death in the United States, resulting in approximately 440,000 preventable deaths each year. Of these deaths, nearly 300,000 (68%) occur among those aged 65 years or older. For those in this age group, the total years of potential life lost due to smoking is 880,000 annually and the average years of potential life lost due to smoking is 9.7 years. In fact, cigarette smoking is responsible for doubling premature mortality rates for America's seniors aged 65 and over. In addition, for every smoking-related death, there are at least another 20 people living with a serious illness caused by smoking, primarily emphysema, chronic bronchitis, and heart disease. Smoking harms nearly every organ in the body, causing many diseases and reduces the health of smokers in general. A study which followed non-disabled seniors aged  $\geq 65$  for six years found that nonsmokers survived 1.6 to 3.9 years longer than smokers, and when smokers were disabled and close to death, most nonsmokers were still non-disabled. As a result, smoking-attributable illness is a major contributor to the \$75 billion per year in direct medical costs from smoking.

Quitting smoking, however, has immediate as well as long-term benefits, reducing risks for diseases caused by smoking and improving health in general. This is also true for older smokers. After 10-15 years of abstinence, the risk of all-cause mortality returns to that of persons who never smoked. Within a year of quitting smoking, former smokers reduce their risk of coronary heart disease by half which then continues to decline gradually thereafter. Over 5 years, cessation also reduces the risk of lung cancer by half. Smoking cessation also yields important health benefits to those who already suffer from smoking-related illness. Among persons with diagnosed coronary heart disease, smoking cessation markedly reduces the risk of recurrent heart attack and cardiovascular death. Smoking cessation is also the most important intervention in the management of peripheral artery occlusive disease, as quitting smoking improves exercise tolerance, reduces the risk of amputation, and increases overall survival. As a result, smoking cessation treatments are cost-effective; in fact, it has been referred to as the "gold standard" of preventive interventions

The U.S. Public Health Service cessation guideline, using meta-analysis, showed that counseling services are an important component to the successful treatment of tobacco addiction. Less intensive interventions, such as physicians advising their patients to quit smoking, can produce cessation rates of 5% to 10% per year. More intensive counseling interventions can produce 20% to 25% quit rates in one year.

CMS coverage for brief physician counseling, cessation-specific visits, and intensive counseling will greatly contribute to the health of our nation. It will also be a vital key in reaching the nation's Healthy People 2010 goals of reducing the rate of cigarette smoking by adults to 12%, increasing smoking cessation attempts by adult smokers to 75%, and increasing insurance coverage of evidence-based treatment for nicotine dependency.

To further support the cessation efforts of current smokers, CMS might also consider coverage of other evidence-based treatments such as FDA-approved pharmacotherapy, including bupropion SR, nicotine gum, nicotine inhaler, nicotine nasal spray, and the nicotine patch. Another proven intervention is proactive telephone counseling, and we would encourage CMS to consider covering this counseling modality as well. Thank you for this opportunity to comment.

174

**SAINT BARNABAS**  
**HEALTH CARE SYSTEM**  
*Saint Barnabas Medical Center*

RONALD J. DEL MAURO  
 Chairman  
 Board of Trustees

July 2, 2004

Steve E. Phurrough, MD, MPA  
 Director, Coverage and Analysis Group  
 Office of Clinical Standards and Quality  
 Centers for Medicare and Medicaid Services  
 7500 Security Boulevard, Mailstop C1-09-06  
 Baltimore, MD 21244

Dear Mr. Phurrough,

On behalf of the Tobacco Treatment Program at Saint Barnabas Medical Center, I am writing to request Medicare coverage for tobacco cessation counseling.

A hospital setting can offer a unique and effective environment in which to offer brief treatments for tobacco dependence. Tobacco dependence and its multitude of related health problems create one of the most pressing public health epidemics facing America today. If you don't believe me, visit the cardiac, pulmonary, oncology and neonatal intensive care units at Saint Barnabas Medical Center. Too often, we treat the asthmatic patient, but don't address the smoking that may trigger attacks. Physicians treat the expectant mother for pre-term labor, but fail to suggest removing smoking from the household, or educate the mother on the risk of Sudden Infant Death Syndrome. We medicate the problem, but disregard the core issue of nicotine addiction.

For smoking cessation intervention to impact a large number of tobacco users, it is essential that clinicians and health care delivery systems institutionalize the consistent identification, documentation, and treatment of every tobacco user seen in a health care setting.

Standards set by hospital accreditation and review organizations suggests that smoking advice/counseling should be offered to individuals who are admitted to the hospital. In an effort to comply with this requirement reimbursement for such services should be considered by Medicare. Coverage of cessation treatment under all forms of insurance, including Medicare, has been recommended by Secretary Thompson's *Steps to a Healthier U.S. Initiative* and the report of the Interagency Committee on Smoking and Health, Subcommittee on Cessation.

I appreciate your review and decision on this request.

Sincerely,  
  
 Roland Romano, RRT  
 Tobacco Treatment Coordinator



**2004-2005 BOARD**

**PRESIDENT**

David H. Johnson, MD

**PRESIDENT-ELECT**

Sandra J. Horning, MD

**IMMEDIATE PAST PRESIDENT**

Margaret A. Tempero, MD

**SECRETARY/TREASURER**

David R. Gandara, MD

**EXECUTIVE VICE PRESIDENT  
AND CHIEF EXECUTIVE OFFICER**

Charles M. Balch, MD

**DIRECTORS**

Jose Baselga, MD

Joseph DiBenedetto, Jr., MD

S. Gail Eckhardt, MD

Peter D. Eisenberg, MD

Patricia A. Ganz, MD

Lee J. Helman, MD

Gabriel N. Hortobagyi, MD

Bruce D. Minsky, MD

Hyman B. Muss, MD

Michael C. Perry, MD

John M. Rainey, MD

Valerie W. Rusch, MD

Nagahiro Saijo, MD, PhD

Richard L. Schilsky, MD

2005 Annual Meeting  
May 14-May 17, 2005  
Orlando, Florida

For more information  
about ASCO Meetings  
Phone: (703) 631-6200  
Fax: (703) 818-6425  
Website: www.asco.org

VIA FACSIMILE & FED EX

July 23, 2004

Steve E. Phurrough, M.D., MPA  
Director, Coverage and Analysis Group  
Office of Clinical Standards and Quality  
Centers for Medicare and Medicaid Services  
7500 Security Boulevard, Mailstop C1-09-06  
Baltimore, MD 21244

Re: Smoking & Tobacco Use Cessation Counseling (CAG-00241N)

Dear Dr. Phurrough:

The American Society of Clinical Oncology (ASCO), representing cancer researchers and clinicians, is writing to endorse the petition of the Partnership for Prevention for a national coverage determination for tobacco cessation counseling. A consistent national Medicare reimbursement policy will improve access to tobacco cessation services.

ASCO has long been committed to policies that will reduce tobacco use in the United States and throughout the world. In 2003, ASCO convened a taskforce that recommended reforms in both domestic and international tobacco policy.<sup>1</sup> The resulting Policy Statement outlined a comprehensive strategy that includes enhanced efforts to discourage tobacco use and additional research into addiction and prevention strategies.<sup>2</sup> Tobacco cessation counseling is a critical component of this strategy, and as we noted in our 2003 Policy Statement, Medicare coverage of tobacco cessation counseling is essential to ensure that individuals have access to these valuable services.<sup>3</sup>

Then, as now, we base our support for Medicare coverage on numerous scientific studies demonstrating that counseling greatly improves the rate of cessation. Counseling sessions with nurses, psychologists, and physicians have proven especially effective in helping smokers quit.<sup>4</sup> Tailored, individualized treatment like that recommended by the Public Health Service promises to be more effective than any treatment currently accessible to individuals on Medicare.<sup>5</sup>

<sup>1</sup> *American Society of Clinical Oncology Policy Statement Update: Tobacco Control – Reducing Cancer Incidence and Saving Lives*, 21 J. of Clinical Oncology 1,2 (2003).

<sup>2</sup> *Id.*

<sup>3</sup> *Id.* at 6.

<sup>4</sup> Walter A. Mojica et al., *Smoking-Cessation Interventions by Type of Provider: A Meta-Analysis*, 26 Am. J. of Preventive Med. 391, 394 (2004).

<sup>5</sup> See S. Shiffman et al., *The Efficacy of Computer-Tailored Smoking Cessation Material as a Supplement to Nicotine Patch Therapy*, 64 Drug & Alcohol Dependence 35, 43 (2001).



AMERICAN SOCIETY OF CLINICAL ONCOLOGY

**2004-2005 BOARD**

**PRESIDENT**

David H. Johnson, MD

**PRESIDENT-ELECT**

Sandra J. Horning, MD

**IMMEDIATE PAST PRESIDENT**

Margaret A. Tempero, MD

**SECRETARY/TREASURER**

David R. Gandara, MD

**EXECUTIVE VICE PRESIDENT  
AND CHIEF EXECUTIVE OFFICER**

Charles M. Balch, MD

**DIRECTORS**

Jose Baselga, MD

Joseph DiBenedetto, Jr., MD

S. Gail Eckhardt, MD

Peter D. Eisenberg, MD

Patricia A. Ganz, MD

Lee J. Helman, MD

Gabriel N. Hortobagyi, MD

Bruce D. Minsky, MD

Hyman B. Muss, MD

Michael C. Perry, MD

John M. Rainey, MD

Valerie W. Rusch, MD

Nagahiro Saijo, MD, PhD

Richard L. Schilsky, MD

We encourage CMS, in evaluating this request, to recognize tobacco dependency as a tobacco-related disease for purposes of coverage. The letter from Partnership for Prevention requests a national coverage determination on tobacco cessation counseling for individuals who use tobacco and who have been diagnosed with a recognized tobacco-related disease or who exhibit symptoms consistent with a tobacco-related disease. In order for this program to be most effective at reducing smoking rates, CMS should acknowledge that tobacco dependency itself is a precursor to many health problems and should be considered a treatable disease.<sup>6</sup> The Department of Health and Human Services recently acknowledged the importance of early disease prevention and the health risks associated with obesity when it deleted the phrase "obesity itself cannot be considered an illness" from the Medicare Coverage Issues Manual.<sup>7</sup> Similar to obese individuals, tobacco dependent individuals may in some cases require treatment not just for any diseases resulting from dependency, but rather for dependency itself.

We urge CMS to embrace this important opportunity and adopt a national position regarding the benefits of cessation services. Tobacco cessation counseling has proven both cost-effective and clinically effective, especially when compared to other methods.<sup>8</sup> A decision by CMS establishing uniform national coverage for smoking cessation services would send a strong message that the federal government is truly committed to reducing smoking rates in the United States and would serve as a "powerful lever" for reducing tobacco use nationwide.<sup>9</sup>

We appreciate the willingness of CMS to review this request. ASCO looks forward to working with CMS in the future to ensure that patients can benefit from the most effective programs for smoking cessation.

Sincerely,

David H. Johnson, M.D.  
President

Cc: Joseph Chin, M.D., Lead Medical Officer  
William Larson, Lead Analyst

2005 Annual Meeting  
May 14-May 17, 2005  
Orlando, Florida

For more information  
about ASCO Meetings  
Phone: (703) 631-6200  
Fax: (703) 818-6425  
Website: www.asco.org

<sup>6</sup> Indeed, tobacco use disorder is a recognized diagnosis with its own ICD-9 code, 305.1.

<sup>7</sup> Mark Glassman, *Deletion Opens Medicare to Coverage for Obesity*, N.Y. Times, July 16, 2004, available at [www.nytimes.com/2004/07/16/politics/16obesity.html](http://www.nytimes.com/2004/07/16/politics/16obesity.html).

<sup>8</sup> U.S. Dept. of Health and Human Services, Public Health Service, *Clinical Practice Guideline: Treating Tobacco Use and Dependence 42* (2000).

<sup>9</sup> Mojica, *supra* note 3, at 394.