Decision Summary

The Centers for Medicare and Medicaid Services (CMS) proposes the following:

The evidence is adequate to conclude that intensive behavioral therapy for cardiovascular disease (CVD) is reasonable and necessary for the prevention or early detection of illness or disability, is appropriate for individuals entitled to benefits under Part A or enrolled under Part B and is comprised of components that are recommended with a grade of A or B by the U.S. Preventive Services Task Force (USPSTF).

Intensive behavioral therapy consists of the following three components:

- encouraging aspirin use for the primary prevention of cardiovascular disease when the benefits outweigh the risks for men age 45-79 years and women 55-79 years;
- screening for high blood pressure in adults age 18 years and older; and
- intensive behavioral counseling to promote a healthy diet for adults with hyperlipidemia, hypertension, advancing age and other known risk factors for cardiovascular and diet-related chronic disease.

We note that only a small proportion (about 4%) of the Medicare population is under 45 years (men) or 55 years (women), therefore the vast majority of beneficiaries should receive all three components. Intensive behavioral counseling to promote a healthy diet is broadly recommended to cover close to 100% of the population due to the prevalence of known risk factors.

Therefore, CMS proposes to cover one face-to-face CVD risk reduction visit every two years for Medicare beneficiaries:

- who are competent and alert at the time that counseling is provided; and whose counseling is furnished by a qualified primary care physician or other primary care practitioner and in a primary care setting.

The behavioral counseling intervention for aspirin use and healthy diet should be consistent with the Five As approach that has been adopted by the USPSTF to describe such services:

- **Assess**: Ask about/assess behavioral health risk(s) and factors affecting choice of behavior change goals/methods.
- **Advise**: Give clear, specific, and personalized behavior change advice, including information about personal health harms and benefits.
- **Agree**: Collaboratively select appropriate treatment goals and methods based on the patient's interest in and willingness to change the behavior.
- **Assist**: Using behavior change techniques (self-help and/or counseling), aid the patient in achieving agreed-upon goals by acquiring the skills, confidence, and social/environmental supports for behavior change, supplemented with adjunctive medical treatments when appropriate.
- **Arrange**: Schedule follow-up contacts (in person or by telephone) to provide ongoing assistance/support and to adjust the treatment plan as needed, including referral to more intensive or specialized treatment.

For the purposes of this proposed decision memorandum, a primary care setting is defined as one in which there is provision of integrated, accessible health care services by clinicians who are accountable for addressing a large majority of personal health care needs, developing a sustained partnership with patients, and practicing in the context of family and community. Emergency departments, inpatient hospital settings, outpatient hospital settings, ambulatory surgical centers, independent diagnostic testing facilities, skilled nursing facilities, inpatient rehabilitation facilities and hospices are not considered primary care settings under this definition.

For the purposes of this proposed decision memorandum a “primary care physician” and “primary care practitioner” will be defined consistent with existing sections of the Social Security Act (§1833(u)(6), §1833(x)(2)(A)(i)(I) and §1833(x)(2)(A)(i)(II)).

§1833(u)
(6) Physician Defined.—For purposes of this paragraph, the term “physician” means a physician described in section 1861(r)(1) and the term “primary care physician” means a physician who is identified in the available data as a general practitioner, family practice practitioner, general internist, or obstetrician or gynecologist.

§1833(x)(2)(A)
Primary care practitioner—The term “primary care practitioner” means an individual—
(i) who—
(I) is a physician (as described in section 1861(r)(1)) who has a primary specialty designation of family medicine, internal medicine, geriatric medicine, or pediatric medicine; or
(II) is a nurse practitioner, clinical nurse specialist, or physician assistant (as those terms are defined in section 1861(aa)(5)).

We are requesting public comments on this proposed determination pursuant to section 1862(l) of the Social Security Act. After considering the public comments, we will make a final determination and issue a final decision memorandum.

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Proposed Decision Memo

TO: Administrative File: (CAG-00424N)
FROM:

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SUBJECT: Proposed Coverage Decision Memorandum for Intensive Behavioral Therapy for Cardiovascular Disease.
DATE: August 10, 2011

I.
Proposed Decision

The Centers for Medicare and Medicaid Services (CMS) proposes the following:

The evidence is adequate to conclude that intensive behavioral therapy for cardiovascular disease (CVD) is reasonable and necessary for the prevention or early detection of illness or disability, is appropriate for individuals entitled to benefits under Part A or enrolled under Part B and is comprised of components that are recommended with a grade of A or B by the U.S. Preventive Services Task Force (USPSTF).

Intensive behavioral therapy consists of the following three components:

- encouraging aspirin use for the primary prevention of cardiovascular disease when the benefits outweigh the risks for men age 45-79 years and women 55-79 years;
- screening for high blood pressure in adults age 18 years and older; and
- intensive behavioral counseling to promote a healthy diet for adults with hyperlipidemia, hypertension, advancing age and other known risk factors for cardiovascular and diet-related chronic disease.

We note that only a small proportion (about 4%) of the Medicare population is under 45 years (men) or 55 years (women), therefore the vast majority of beneficiaries should receive all three components. Intensive behavioral counseling to promote a healthy diet is broadly recommended to cover close to 100% of the population due to the prevalence of known risk factors.

Therefore, CMS proposes to cover one face-to-face CVD risk reduction visit every two years for Medicare beneficiaries:

- who are competent and alert at the time that counseling is provided; and whose counseling is furnished by a qualified primary care physician or other primary care practitioner and in a primary care setting.

The behavioral counseling intervention for aspirin use and healthy diet should be consistent with the Five As approach that has been adopted by the USPSTF to describe such services:

- **Assess**: Ask about/assess behavioral health risk(s) and factors affecting choice of behavior change goals/methods.
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For the purposes of this proposed decision memorandum, a primary care setting is defined as one in which there is provision of integrated, accessible health care services by clinicians who are accountable for addressing a large majority of personal health care needs, developing a sustained partnership with patients, and practicing in the context of family and community. Emergency departments, inpatient hospital settings, outpatient hospital settings, ambulatory surgical centers, independent diagnostic testing facilities, skilled nursing facilities, inpatient rehabilitation facilities and hospices are not considered primary care settings under this definition.

For the purposes of this proposed decision memorandum a "primary care physician" and "primary care practitioner" will be defined consistent with existing sections of the Social Security Act (§1833(u)(6), §1833(x)(2)(A)(i)(I) and §1833(x)(2)(A)(i)(II)).

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(II) is a nurse practitioner, clinical nurse specialist, or physician assistant (as those terms are defined in section 1861(aa)(5)).

We are requesting public comments on this proposed determination pursuant to section 1862(l) of the Social Security Act. After considering the public comments, we will make a final determination and issue a final decision memorandum.

II. Background

The USPSTF Recommendation Statements on aspirin for the primary prevention of cardiovascular disease (March 2009), blood pressure screening in adults (hypertension) (December 2007), and behavioral counseling in primary care to promote a healthy diet (January 2003) state the following:

- The USPSTF recommends the use of aspirin for men age 45 to 79 years when the potential benefit due to a reduction in myocardial infarctions outweighs the potential harm due to an increase in gastrointestinal hemorrhage. **Grade: A recommendation.**
- The USPSTF recommends the use of aspirin for women age 55 to 79 years when the potential benefit of a reduction in ischemic strokes outweighs the potential harm of an increase in gastrointestinal hemorrhage. **Grade: A recommendation.**
- The USPSTF recommends screening for high blood pressure in adults aged 18 and older. **Grade: A recommendation.**
- The USPSTF recommends intensive behavioral dietary counseling for adult patients with hyperlipidemia[1] and other known risk factors for cardiovascular and diet-related chronic disease. Intensive counseling can be delivered by primary care clinicians or by referral to other specialists, such as nutritionists or dietitians. **Grade: B recommendation.**

CVD is the leading cause of mortality in the United States and has been for the past 100 years. CVD, which is comprised of hypertension, coronary heart disease (such as myocardial infarction and angina pectoris), heart failure and stroke, is also the leading cause of hospitalizations. Although the overall adjusted mortality rate from heart disease has declined over the past decade, opportunities for improvement still exist. While much current research has focused on new novel biomarkers as risk factors and predictors, the “most prominent contributors to mortality in the United States” include poor diet, physical inactivity and smoking and have not changed considerably since the initial report by McGinnis and Foege in 1993. Franco and colleagues noted that research on “novel risk factors” and “rapid advances in the technology to treat established disease tend to divert attention from the basic processes driving the epidemic of heart disease and stroke.” (Franco, 2011) This is acutely evident in the rapid proliferation of costly tests and treatments that have unproven health benefits for the general population.

Risk factors for CVD include being overweight, obesity, physical inactivity, diabetes, cigarette smoking, high blood pressure, high blood cholesterol, family history of myocardial infarction, and older age. In addition, coronary mortality from heart disease and stroke are concerns for African Americans, as noted by Keenan and Shaw (2011). The National Heart, Lung, and Blood Institute (NHLBI) reported in the 2009 Chart Book on Cardiovascular, Lung, and Blood Diseases that heart disease was the leading cause of death for whites, African Americans, and Native Americans; and the second leading cause of death for Asian Americans in 2006. Coronary artery disease and its risk factors affect all Americans, although disparities exist for racial and ethnic minorities. “Compared with non-Hispanic whites, African Americans are 1.5 times more likely to have high blood pressure…American Indians/Alaska Natives are 1.3 times more likely than whites to have high blood pressure.” (Wallace et al., 2008)

Specifically for heart disease, the USPSTF has made several recommendations to decrease modifiable risk of cardiovascular events including myocardial infarction. On October 29, 2010, the Centers for Medicare and Medicaid Services (CMS) received a formal request from Partnership for Prevention asking that CMS initiate a national coverage determination (NCD) for aspirin counseling for primary prevention of cardiovascular disease, which is recommended with a grade A by the USPSTF.

After reviewing the request, we decided to more broadly address modifiable cardiovascular risk reduction and, in this analysis, we focus on these particular recommendations:

1. Aspirin Use for Primary Prevention of Cardiovascular Disease.

   Since the large randomized trials of the 1990s (such as the Thrombosis Prevention Trial, MRC, 1998), aspirin has been considered for primary prevention of cardiovascular events. The USPSTF initially recommended aspirin use in 2002 and reiterated the recommendation in 2009.

2. Screening for High Blood Pressure in Adults (Hypertension).

   The Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure, which is comprised of experts from academic institutions, professional societies and federal agencies led by the National Heart, Lung, and Blood Institute, noted: “the relationship between BP [blood pressure] and risk of CVD events is continuous, consistent, and independent of other risk factors. The higher the BP, the greater the chance of heart attack, HF [heart failure], stroke, and kidney diseases.” Screening for high blood pressure is widely recommended. They further noted: “Individuals over age 60 represent the most rapidly growing segment of the U.S. population, and even in those who remain normotensive between 55 and 65 years of age, there remains a lifetime risk of developing hypertension that exceeds 90 percent. At the same time, there is a three- to four- fold increase in CVD risk in older compared to younger individuals.” The USPSTF in 2003 recommended screening and reconfirmed the recommendation in 2007. The prior assessment found “strong indirect evidence supports screening adults for hypertension. Hypertension is an important contributor to CVD morbidity and mortality. It is predictive of CHD events and is reliably detected through screening blood pressure measurements using a standard arm blood pressure cuff and sphygmomanometer.” (Sheridan, 2003)

3. Behavioral Counseling in Primary Care to Promote a Healthy Diet (intensive behavioral dietary counseling for adult patients with hyperlipidemia and other known risk factors for cardiovascular and diet-related chronic disease).

   As McGinnis and Foege noted in 1993 and Mokdad and colleagues reaffirmed in 2004, diet and physical inactivity are among the “most prominent contributors to mortality.” Diet and physical inactivity are directly or indirectly associated with developing CVD. While these have long been accepted as modifiable risk factors, changing behavior in practice remains challenging, but necessary if long term benefits are to be gained. Thus a key intermediate outcome of behavioral interventions is documented, long term, behavioral change. While the USPSTF noted the clinical importance of physical activity, they concluded that “the evidence is insufficient to recommend for or against behavioral counseling in primary care settings to promote physical activity. I statement” For diet, they concluded similarly that “the evidence is insufficient to recommend for or against routine behavioral counseling to promote a healthy diet in unselected patients in primary care settings. I statement” However the USPSTF recommended “intensive behavioral dietary counseling for adult patients with hyperlipidemia and other known risk factors for cardiovascular and diet-related chronic disease” with a grade B. They further noted: “Adherence to these intensive interventions and the dietary changes they require may be dependent on patients' heightened perceived risk and motivation for change.”

III. History of Medicare Coverage

Pursuant to §1861(ddd) of the Social Security Act, CMS may add coverage of "additional preventive services" if certain statutory requirements are met. Our regulations provide:

§410.64 Additional preventive services

(a) Medicare Part B pays for additional preventive services not described in paragraph (1) or (3) of the definition of “preventive services” under §410.2, that identify medical conditions or risk factors for individuals if the Secretary determines through the national coverage determination process (as defined in section 1869(f)(1)(B) of the Act) that these services are all of the following:

(1) Reasonable and necessary for the prevention or early detection of illness or disability.
(2) Recommended with a grade of A or B by the United States Preventive Services Task Force.
(3) Appropriate for individuals entitled to benefits under part A or enrolled under Part B.

(b) In making determinations under paragraph (a) of this section regarding the coverage of a new preventive service, the Secretary may conduct an assessment of the relation between predicted outcomes and the expenditures for such services and may take into account the results of such an assessment in making such national coverage determinations (42 CFR 410.64).

We do not believe that aspirin itself, which is usually self-administered, falls within the scope of Medicare Part B benefits.

IV. Timeline of Recent Activities

February 11, 2011	CMS initiates this national coverage analysis for Intensive Behavioral Therapy for Cardiovascular Disease, and the initial 30-day public comment period begins.
March 13, 2011	The initial 30-day public comment period closes.

V. FDA Status

Counseling services do not generally fall under the purview of the FDA.

VI. General Methodological Principles

When making national coverage determinations concerning additional preventive services, CMS applies the statutory criteria in §1861(ddd)(1) of the Social Security Act and evaluates relevant clinical evidence to determine whether or not the service is reasonable and necessary for the prevention or early detection of illness or disability, is recommended with a grade of A or B by the USPSTF, and is appropriate for individuals entitled to benefits under part A or enrolled under Part B of the Medicare program.

Public comment sometimes cites the published clinical evidence and gives CMS useful information. Public comments that give information on unpublished evidence such as the results of individual practitioners or patients are less rigorous and therefore less useful for making a coverage determination. CMS uses the initial public comments to inform its proposed decision. CMS responds in detail to the public comments on a proposed decision when issuing the final decision memorandum.

VII. Evidence

A. Introduction

Consistent with §1861(ddd)(1)(A) and 42 CFR 410.64(a)(1), additional preventive services must be reasonable and necessary for the prevention or early detection of illness or disability. With respect to evaluating whether screening tests conducted on asymptomatic individuals are reasonable and necessary, the analytic framework involves consideration of different factors compared to either diagnostic tests or therapeutic interventions. Evaluation of screening tests has been largely standardized in the medical and scientific communities, and the "value of a screening test may be assessed according to the following criteria:

i. *Simplicity*. In many screening programmes more than one test is used to detect one disease, and in a multiphasic programme the individual will be subjected to a number of tests within a short space of time. It is therefore essential that the tests used should be easy to administer and should be capable of use by para-medical and other personnel.
ii. *Acceptability*. As screening is in most instances voluntary and a high rate of co-operation is necessary in an efficient screening programme, it is important that tests should be acceptable to the subjects.
iii. *Accuracy*. The test should give a true measurement of the attribute under investigation.
iv. *Cost*. The expense of screening should be considered in relation to the benefits resulting from the early detection of disease, i.e., the severity of the disease, the advantages of treatment at an early stage and the probability of cure.
v. *Precision (sometimes called repeatability)*. The test should give consistent results in repeated trials.
vi. *Sensitivity*. This may be defined as the ability of the test to give a positive finding when the individual screened has the disease or abnormality under investigation.
vii. *Specificity*. This may be defined as the ability of the test to give a negative finding when the individual screened does not have the disease or abnormality under investigation (Cochran and Holland 1971)."

As Cochrane and Holland further noted, evidence on health outcomes, i.e., "evidence that screening can alter the natural history of disease in a significant proportion of those screened," is important in the consideration of screening tests since individuals are asymptomatic and "the practitioner initiates screening procedures."

B. United States Preventive Services Task Force (USPSTF)

The USPSTF Recommendation Statements on aspirin for the primary prevention of cardiovascular disease (March 2009), blood pressure screening in adults (hypertension) (December 2007), and behavioral counseling in primary care to promote a healthy diet (January 2003) state the following:

- The USPSTF recommends the use of aspirin for men age 45 to 79 years when the potential benefit due to a reduction in myocardial infarctions outweighs the potential harm due to an increase in gastrointestinal hemorrhage. **Grade: A recommendation.**
- The USPSTF recommends the use of aspirin for women age 55 to 79 years when the potential benefit of a reduction in ischemic strokes outweighs the potential harm of an increase in gastrointestinal hemorrhage. **Grade: A recommendation.**
- The USPSTF recommends screening for high blood pressure in adults aged 18 and older. **Grade: A recommendation.**
- The USPSTF recommends intensive behavioral dietary counseling for adult patients with hyperlipidemia and other known risk factors for cardiovascular and diet-related chronic disease. Intensive counseling can be delivered by primary care clinicians or by referral to other specialists, such as nutritionists or dietitians. **Grade: B recommendation.**

USPSTF Grade Definitions Prior to May 2007

The definitions below (of USPSTF grades and quality of evidence ratings were in use prior to the update and apply to recommendations voted on by the USPSTF prior to May 2007.

A – Strongly Recommended: The USPSTF strongly recommends that clinicians provide [the service] to eligible patients. The USPSTF found good evidence that [the service] improves important health outcomes and concludes that benefits substantially outweigh harms.

B – Recommended: The USPSTF recommends that clinicians provide [the service] to eligible patients. The USPSTF found at least fair evidence that [the service] improves important health outcomes and concludes that benefits outweigh harms.

C – No Recommendation: The USPSTF makes no recommendation for or against routine provision of [the service]. The USPSTF found at least fair evidence that [the service] can improve health outcomes but concludes that the balance of benefits and harms is too close to justify a general recommendation.

D – Not Recommended: The USPSTF recommends against routinely providing [the service] to asymptomatic patients. The USPSTF found at least fair evidence that [the service] is ineffective or that harms outweigh benefits.

I – Insufficient Evidence to Make a Recommendation: The USPSTF concludes that the evidence is insufficient to recommend for or against routinely providing [the service]. Evidence that the [service] is effective is lacking, of poor quality, or conflicting and the balance of benefits and harms cannot be determined."

Quality of Evidence

The USPSTF [prior to May 2007] graded the quality of the overall evidence for a service on a 3-point scale (good, fair, poor):

Good: Evidence includes consistent results from well-designed, well-conducted studies in representative populations that directly assess effects on health outcomes.

Fair: Evidence is sufficient to determine effects on health outcomes, but the strength of the evidence is limited by the number, quality, or consistency of the individual studies, generalizability to routine practice, or indirect nature of the evidence on health outcomes.

Poor: Evidence is insufficient to assess the effects on health outcomes because of limited number or power of studies, important flaws in their design or conduct, gaps in the chain of evidence, or lack of information on important health outcomes.

USPSTF Grade Definitions after May 2007

"The U.S. Preventive Services Task Force (USPSTF) assigns one of five letter grades to each of its recommendations (A, B, C, D, I). The USPSTF changed its grade definitions based on a change in methods in May 2007."

"The USPSTF updated its definitions of the grades it assigns to recommendations and now includes "suggestions for practice" associated with each grade. The USPSTF has also defined levels of certainty regarding net benefit. These definitions apply to USPSTF recommendations voted on after May 2007.

Grade	Definition	Suggestions for Practice
A	The USPSTF recommends the service. There is high certainty that the net benefit is substantial.	Offer or provide this service.
B	The USPSTF recommends the service. There is high certainty that the net benefit is moderate or there is moderate certainty that the net benefit is moderate to substantial.	Offer or provide this service.
C	The USPSTF recommends against routinely providing the service. There may be considerations that support providing the service in an individual patient. There is at least moderate certainty that the net benefit is small.	Offer or provide this service only if other considerations support the offering or providing the service in an individual patient.

Grade	Definition	Suggestions for Practice
D	The USPSTF recommends against the service. There is moderate or high certainty that the service has no net benefit or that the harms outweigh the benefits.	Discourage the use of this service.
I Statement	The USPSTF concludes that the current evidence is insufficient to assess the balance of benefits and harms of the service. Evidence is lacking, of poor quality, or conflicting, and the balance of benefits and harms cannot be determined.	Read the clinical considerations section of USPSTF Recommendation Statement. If the service is offered, patients should understand the uncertainty about the balance of benefits and harms.

Levels of Certainty Regarding Net Benefit

Level of Certainty*	Description
High	The available evidence usually includes consistent results from well-designed, well-conducted studies in representative primary care populations. These studies assess the effects of the preventive service on health outcomes. This conclusion is therefore unlikely to be strongly affected by the results of future studies.
Moderate	The available evidence is sufficient to determine the effects of the preventive service on health outcomes, but confidence in the estimate is constrained by such factors as: • The number, size, or quality of individual studies. • Inconsistency of findings across individual studies. • Limited generalizability of findings to routine primary care practice. • Lack of coherence in the chain of evidence. As more information becomes available, the magnitude or direction of the observed effect could change, and this change may be large enough to alter the conclusion.
Low	The available evidence is insufficient to assess effects on health outcomes. Evidence is insufficient because of: • The limited number or size of studies. • Important flaws in study design or methods.

Level of Certainty*	Description
	• Inconsistency of findings across individual studies. • Gaps in the chain of evidence. • Findings not generalizable to routine primary care practice. • Lack of information on important health outcomes. More information may allow estimation of effects on health outcomes.

* The USPSTF defines certainty as "likelihood that the USPSTF assessment of the net benefit of a preventive service is correct." The net benefit is defined as benefit minus harm of the preventive service as implemented in a general, primary care population. The USPSTF assigns a certainty level based on the nature of the overall evidence available to assess the net benefit of a preventive service."

C. Literature Search

In addition to the prerequisite USPSTF recommendations, CMS must consider not only whether an additional preventive service is reasonable and necessary for the prevention or early detection of illness or disability, but whether the service is appropriate for individuals entitled to benefits under Part A or enrolled under Part B of the Medicare program.

To facilitate these determinations, we searched PubMed from the year of the most recent evidence review and USPSTF recommendation to March 2011 using key words: (1) aspirin and prevention limited to cardiovascular disease, myocardial infarction; (2) counseling and hypertension, high blood pressure; and (3) counseling and diet, nutrition for hyperlipidemia, and lipid disorder. Given the extensive literature base for each of these topics, studies were limited to randomized trials published in peer reviewed journals and available in the English language.

D. Discussion of Evidence Reviewed

Aspirin Use for Primary Prevention of CVD
1. Questions:

Our discussion focuses upon the adequacy of the evidence to draw conclusions about the risks and benefits of aspirin use for primary prevention of CVD in Medicare patients. CMS analyzed the following questions:

- *Is the evidence sufficient to determine that aspirin use for primary prevention of CVD is recommended with a grade of A or B by the USPSTF for any indications?*

- Is the evidence sufficient to determine that aspirin use for primary prevention of CVD is reasonable and necessary for the prevention or early detection of illness or disability?

- Is the evidence sufficient to determine that aspirin use for primary prevention of CVD is appropriate for Medicare beneficiaries?

2. External technology assessment (TA)

Wolff T, Miller T, Ko S. Aspirin for the Primary Prevention of Cardiovascular Events: An Update of the Evidence for the U.S. Preventive Services Task Force. Ann Intern Med. 2009;150:405-410.

Wolff and colleagues reported the results of an evidence review “to determine the benefits and harms of taking aspirin for the primary prevention of myocardial infarctions, strokes, and death.” The authors addressed the following key questions: (1) “Does aspirin use in men and women without known cardiovascular disease decrease coronary heart events, strokes, death from coronary heart events or strokes, or all-cause mortality?” (2) “Does aspirin use in women and men increase gastrointestinal bleeding or hemorrhagic strokes?” Studies were included if they “evaluated aspirin versus control for the primary prevention of cardiovascular disease events in adults, had a study population of patients without a history of CVD or who were not at very high risk for CVD (such as patients with atrial fibrillation) and was generalizable to the U.S. primary care population, and calculated risk estimates for 1 of the following outcomes: myocardial infarction, stroke, death from myocardial infarction or stroke, or all-cause mortality for benefits and gastrointestinal bleeding, serious bleeding episodes, hemorrhagic stroke, or cerebral hemorrhage for harms.”

Of the 726 articles identified since 2002, four studies (two randomized controlled trials, one other randomized trial and one meta-analysis) were included in the analysis. The authors reported: (1) “This evidence demonstrates that aspirin use reduces the number of CVD events in both men and women without known CVD. Men in these studies experienced fewer myocardial infarctions, and women experienced fewer ischemic strokes. Aspirin does not seem to affect CVD mortality or all-cause mortality in either men or women. Aspirin use for the primary prevention of CVD events probably provides more benefits than harms to men at increased risk for myocardial infarction and women at increased risk for ischemic stroke. The reason for the differences by sex is unknown.” (2) “The use of aspirin in primary prevention increases the risk for major bleeding events, primarily gastrointestinal bleeding events, in both men and women. Men have an increased risk for hemorrhagic strokes with aspirin use, whereas a new RCT and meta-analysis suggest that the risk for hemorrhagic strokes in women is not significantly increased.” They concluded: “In summary, consistent evidence from randomized clinical trials indicates that aspirin use reduces the risk for CVD events in adults without a history of CVD. Men have a reduced risk for myocardial infarctions, and women have a reduced risk for ischemic strokes. Consistent evidence shows that aspirin use increases the risk for gastrointestinal bleeding events, and limited evidence shows that aspirin use increases the risk for hemorrhagic strokes. The overall benefit in the reduction of CVD events with aspirin use depends on baseline CVD risk and risk for gastrointestinal bleeding.”

3. Internal technology assessment

Antithrombotic Trialists' (ATT) Collaboration. Aspirin in the primary and secondary prevention of vascular disease: collaborative meta-analysis of individual participant data from randomised trials. Lancet 2009;373:1849–60.

The ATT collaborative group conducted a meta-analysis to assess the benefits and risks of low dose aspirin in primary prevention of "serious vascular events (myocardial infarction, stroke, or vascular death) and major bleeds in six primary prevention trials (95 000 individuals at low average risk, 660 000 person-years, 3554 serious vascular events) and 16 secondary prevention trials (17 000 individuals at high average risk, 43000 person-years, 3306 serious vascular events) that compared long-term aspirin versus control." Trials were included if included studies "evaluated aspirin versus control for the primary prevention of cardiovascular disease events in adults, had a study population of patients without a history of CVD or who were not at very high risk for CVD (such as patients with atrial fibrillation) and was generalizable to the U.S. primary care population, and calculated risk estimates for 1 of the following outcomes: myocardial infarction, stroke, death from myocardial infarction or stroke, or all-cause mortality for benefits and gastrointestinal bleeding, serious bleeding episodes, hemorrhagic stroke, or cerebral hemorrhage for harms." Trials with less than 1000 non-diabetic patients were excluded. Trials included in the analysis were: British Doctors' Study, US Physicians' Health Study, Thrombosis Prevention Trial, Hypertension Optimal Treatment Trial, Primary Prevention Project, and Women's Health Study.

The authors reported: "In the primary prevention trials, aspirin allocation yielded a 12% proportional reduction in serious vascular events (0.51% aspirin vs 0.57% control per year, p = 0.0001), due mainly to a reduction of about a fifth in non-fatal myocardial infarction (0.18% vs 0.23% per year, p < 0.0001). The net effect on stroke was not significant (0.20% vs 0.21% per year, p = .04: haemorrhagic stroke 0.04% vs 0.03%, p = 0.05; other stroke 0.16% vs 0.18% per year, p = 0.08). Vascular mortality did not differ significantly (0.19% vs 0.19% per year, p = 0.7). Aspirin allocation increased major gastrointestinal and extracranial bleeds (0.10% vs 0.07% per year, p < 0.0001), and the main risk factors for coronary disease were also risk factors for bleeding." They concluded: "In primary prevention without previous disease, aspirin is of uncertain net value as the reduction in occlusive events needs to be weighed against any increase in major bleeds. Further trials are in progress." While the overall results were inconclusive, the risk benefit analysis may be influenced by older age and gender. The USPSTF considered the ATT Collaboration and believed "the analysis supports USPSTF's gender-specific recommendations." They further noted that "there is not a simple message for aspirin prophylaxis as a primary preventive strategy, and we need to consider gender, age, and the associated balance of potential risks and benefits to provide the best advice and preventive care for our patients."

Screening for High Blood Pressure

1. Questions:

Our discussion focuses upon the adequacy of the evidence to draw conclusions about screening for high blood pressure in Medicare patients. CMS analyzed the following questions:

- *Is the evidence sufficient to determine that screening for high blood pressure to reduce cardiovascular risk is recommended with a grade of A or B by the USPSTF for any indications?*

- Is the evidence sufficient to determine that screening for high blood pressure to reduce cardiovascular risk is reasonable and necessary for the prevention or early detection of illness or disability?

- Is the evidence sufficient to determine that screening for high blood pressure to reduce cardiovascular risk is appropriate for Medicare beneficiaries?

2. External technology assessment (TA)

Wolff T, Miller T. Evidence for the Reaffirmation of the U.S. Preventive Services Task Force Recommendation on Screening for High Blood Pressure. Ann Intern Med. 2007;147:787-791.

Wolff and Miller reported the results of an evidence review of screening for high blood pressure. The authors addressed the following key questions: (1) "What are the benefits of screening for high blood pressure in adults?" (2) "What are the harms of screening and/or early treatment of high blood pressure?" Studies on benefits and harms of screening and treatment of early hypertension [defined as "prehypertension (systolic blood pressure of 120 to 139 mm Hg or diastolic blood pressure of 80 to 89 mm Hg), hypertension detected through screening, or untreated or newly diagnosed mild to moderate hypertension (systolic blood pressure of 140 to 180 mm Hg or diastolic blood pressure of 90 to 110 mm Hg, when information was not given about how hypertension was detected)"] were included. Of the 378 articles initially found, there were "no new studies on the benefits or harms of screening for high blood pressure" that met inclusion criteria. Five studies on the harms of early treatment were evaluated. They concluded: "No new evidence was found on the benefits of screening. Pharmacotherapy for early hypertension is associated with common side effects." In 2003, the USPSTF concluded that "substantial indirect evidence supports the effectiveness of screening adults to detect hypertension and treating them to reduce cardiovascular disease." Given the risk of CVD, older adults were a specific focus. The USPSTF noted that "recent treatment trials have confirmed large potential benefit in detecting and treating isolated systolic hypertension in the elderly, highlighting the importance of screening and treating older adults."

3. Internal technology assessment

Given the extensive research background on high blood pressure, studies were limited to randomized trials. Much of the past evidence was summarized in the JNC7 report by NIH and included in the discussion of evidence-based clinical guidelines below. There were no published randomized controlled trials since the evidence review by Wolff and Miller in 2007.

Intensive Behavioral Counseling in Primary Care to Promote a Healthy Diet for Beneficiaries with Hyperlipidemia and Other Known Risk Factors for Cardiovascular and Diet-related Chronic Disease.

1. Questions:

Our discussion focuses upon the adequacy of the evidence to draw conclusions about the risks and benefits of intensive behavioral dietary counseling for Medicare beneficiaries with hyperlipidemia and other known risk factors for cardiovascular and diet-related chronic disease. Other known risk factors include older age, hypertension, and smoking. CMS analyzed the following questions:

- *Is the evidence sufficient to determine that intensive behavioral dietary counseling for adult patients with hyperlipidemia and other known risk factors for cardiovascular and diet-related chronic disease is recommended with a grade of A or B by the USPSTF for any indications?*

- Is the evidence sufficient to determine that intensive behavioral dietary counseling for adult patients with hyperlipidemia and other known risk factors for cardiovascular and diet-related chronic disease is reasonable and necessary for the prevention or early detection of illness or disability?

- Is the evidence sufficient to determine that intensive behavioral dietary counseling for adult patients with hyperlipidemia and other known risk factors for cardiovascular and diet-related chronic disease is appropriate for Medicare beneficiaries?

2. External technology assessment (TA)

Lin JS, O'Connor E, Whitlock EP, Beil TL. Behavioral Counseling to Promote Physical Activity and a Healthful Diet to Prevent Cardiovascular Disease in Adults: A Systematic Review for the U.S. Preventive Services Task Force. Ann Intern Med 2010;153:736-750.

Lin and colleagues reported the results of a systematic evidence review to "assist the U.S. Preventive Services Task Force in updating its previous recommendations by systematically reviewing trials of physical activity or dietary counseling to prevent cardiovascular disease." They addressed the following key questions: (1) "Do primary care-relevant behavioral counseling interventions for physical activity or healthful diet improve cardiovascular disease health outcomes (prevent morbidity and mortality) in adults?" (2) "Do primary care-relevant behavioral counseling interventions for physical activity or healthful diet improve intermediate outcomes associated with cardiovascular disease (such as lipid levels, blood pressure, glucose tolerance, weight, or body mass index) in adults (including older adults)?" (3) "Do primary care-relevant behavioral counseling interventions for physical activity or healthful diet change associated health behaviors in adults?" (4) "What are the adverse effects of primary care-relevant behavioral counseling interventions for physical activity or healthful diet in adults?"

Trials on primary care–relevant counseling on physical activity or healthful diet interventions were included. Studies with “interventions primarily aimed at weight loss or those that provided controlled diets or supervised physical activity” were excluded. Of the 481 studies reviewed, 66 were included in the analysis. Of these, 13 were considered good quality trials. Men accounted for approximately 17% of all trial participants. Eleven trials included only women. Weighted mean age was 59 years. There were nine trials in older adults. The authors reported: “Long-term observational follow-up of intensive sodium reduction counseling showed a decrease in the incidence of cardiovascular disease; however, other direct evidence for reduction in disease morbidity is lacking. High-intensity dietary counseling, with or without physical activity counseling, resulted in changes of -0.3 to -0.7 kg/m2 in body mass index (adiposity), -1.5 mm Hg (95% CI, -0.9 to -2.1 mm Hg) in systolic blood pressure, -0.7 mm Hg (CI, -0.6 to -0.9 mm Hg) in diastolic pressure, -0.17 mmol/L (CI, -0.09 to -0.25 mmol/L) (-6.56 mg/dL [CI, -3.47 to -9.65 mg/dL]) in total cholesterol level, and -0.13 mmol/L (CI, -0.06 to -0.21 mmol/L) (-5.02 mg/dL [CI, -2.32 to -8.11 mg/dL]) in low-density lipoprotein cholesterol level. Medium- and high-intensity counseling resulted in moderate to large changes in self-reported dietary and physical activity behaviors.” They concluded: “Counseling to improve diet or increase physical activity changed health behaviors and was associated with small improvements in adiposity, blood pressure, and lipid levels.”

3. Internal technology assessment

Given the extensive research background on healthy diet and behavioral counseling, studies were limited to randomized trials. There were no published randomized controlled trials since the evidence review by Lin and colleagues in 2010.

4. Medicare Evidence Development and Coverage Advisory Committee (MEDCAC) Meeting.

CMS did not hold a MEDCAC meeting on this topic.

5. Evidence-based Clinical Guidelines

Aspirin Use for the Prevention of Cardiovascular Disease

U.S. Preventive Services Task Force. Aspirin for the Prevention of Cardiovascular Disease: U.S. Preventive Services Task Force Recommendation Statement. Ann Intern Med. 2009;150:396-404.

In 2009, the USPSTF updated their 2002 recommendations as follows:

- “Encourage men age 45 to 79 years to use aspirin when the potential benefit of a reduction in myocardial infarctions outweighs the potential harm of an increase in gastrointestinal hemorrhage. (A recommendation)
- Encourage women age 55 to 79 years to use aspirin when the potential benefit of a reduction in ischemic strokes outweighs the potential harm of an increase in gastrointestinal hemorrhage. (A recommendation)
- Evidence is insufficient to assess the balance of benefits and harms of aspirin for cardiovascular disease prevention in men and women 80 years or older. (I statement)
- Do not encourage aspirin use for cardiovascular disease prevention in women younger than 55 years and in men younger than 45 years. (D recommendation)”

The USPSTF noted the following considerations:

Patient Population Under Consideration: “These recommendations apply to adult men and women without a history of coronary heart disease or stroke.”

Assessment of Risk for Cardiovascular Disease

- Men: “The net benefit of aspirin depends on the initial risk for coronary heart disease events and gastrointestinal bleeding. Thus, decisions about aspirin therapy should consider the overall risks for coronary heart disease and gastrointestinal bleeding. Risk assessment for coronary heart disease should include ascertainment of risk factors: age, diabetes, total cholesterol levels, high-density lipoprotein cholesterol levels, blood pressure, and smoking. Available tools provide estimations of coronary heart disease risk (such as the calculator available at http://healthlink.mcw.edu/article/923521437.html).”
- Women: “The net benefit of aspirin depends on the initial risks for stroke and gastrointestinal bleeding. Thus, decisions about aspirin therapy should consider the overall risk for stroke and gastrointestinal bleeding. Risk factors for stroke include age, high blood pressure, diabetes, smoking, a history of cardiovascular disease, atrial fibrillation, and left ventricular hypertrophy. Tools for estimation of stroke risk are available (such as the calculator available at www.westernstroke.org/PersonalStrokeRisk1.xls).”

Goldstein LB, Bushnell CD, Adams RJ, Appel LJ, Braun LT, Chaturvedi S, Creager MA, Culebras A, Eckel RH, Hart RG, Hinchey JA, Howard VJ, Jauch EC, Levine SR, Meschia JF, Moore WS, Nixon JV, Pearson TA; on behalf of the American Heart Association Stroke Council, Council on Cardiovascular Nursing, Council on Epidemiology and Prevention, Council for High Blood Pressure Research, Council on Peripheral Vascular Disease, and Interdisciplinary Council on Quality of Care and Outcomes Research. Guidelines for the primary prevention of stroke: a guideline for healthcare professionals from the American Heart Association/American Stroke Association. Stroke 2011;42:517–584.

Goldstein and colleagues “used systematic literature reviews (covering the time since the last review was published in 2006 up to April 2009), reference to previously published guidelines, personal files, and expert opinion to summarize existing evidence indicate gaps in current knowledge, and when appropriate, formulate recommendations using standard AHA [American Heart Association] criteria.”

The authors reported: “Previous guidelines endorse the use of aspirin (dose as low as 75 mg/d as reflected in the US Preventive Services Task Force recommendation) for cardiovascular prophylaxis among men whose risk is sufficiently high for the benefits to outweigh the risks associated with treatment (a 10-year risk of 6% to 10%). These recommendations are based on a reduction of cardiovascular events, not stroke. Since these recommendations, JPAD (Japanese Primary Prevention of Atherosclerosis With Aspirin for Diabetes) found no primary prevention benefit of aspirin among persons with diabetes, and POPADAD (Prevention of Progression of Arterial Disease and Diabetes) found no benefit among persons with diabetes and peripheral arterial disease. The WHS (Women’s Health Study) found a reduction in the risk of a first stroke in women (including those with diabetes), but not cardiac events or death from cardiovascular causes with aspirin. The overall stroke prevention benefit of aspirin is most consistent among women > 65 years of age; however, there was not an overall reduction of stroke in this group. The reasons for the differences between men and women remain uncertain.

The authors made the following evidence-based recommendations:

1. "The use of aspirin for cardiovascular (including but not specific to stroke) prophylaxis is recommended for persons whose risk is sufficiently high for the benefits to outweigh the risks associated with treatment (a 10-year risk of cardiovascular events of 6% to 10%) (Class I; Level of Evidence A).
2. Aspirin (81 mg daily or 100 mg every other day) can be useful for prevention of a first stroke among women whose risk is sufficiently high for the benefits to outweigh the risks associated with treatment (Class IIa; Level of Evidence B).
3. Aspirin is not useful for preventing a first stroke in persons at low risk (Class III; Level of Evidence A).
4. Aspirin is not useful for preventing a first stroke in persons with diabetes or diabetes plus asymptomatic peripheral artery disease (defined as an ankle brachial pressure index <0.99) in the absence of other established CVD (Class III; Level of Evidence B)."

Screening for High Blood Pressure

U.S. Preventive Services Task Force. Screening for High Blood Pressure: U.S. Preventive Services Task Force Reaffirmation Recommendation Statement. Ann Intern Med. 2007;147:783-786.

In 2007 the USPSTF reaffirmed their 2003 recommendation: "Screen for high blood pressure in adults age 18 years or older. (Grade A recommendation)." They noted the following considerations:

- Patient Population: "This recommendation applies to adults without known hypertension."
- Screening Tests: "Office measurement of blood pressure is most commonly done with a sphygmomanometer. High blood pressure (hypertension) is usually defined in adults as a systolic blood pressure of 140 mm Hg or higher or a diastolic blood pressure of 90 mm Hg or higher. Because of the variability in individual blood pressure measurements, it is recommended that hypertension be diagnosed only after 2 or more elevated readings are obtained on at least 2 visits over 1 to several weeks."
- Risk Assessment: "The relationship between systolic blood pressure and diastolic blood pressure and cardiovascular risk is continuous and graded. The actual level of blood pressure elevation should not be the sole factor in determining treatment. Clinicians should consider the patient's overall cardiovascular risk profile, including smoking, diabetes, abnormal blood lipid values, age, sex, sedentary lifestyle, and obesity, when making treatment decisions."
- Screening Interval: "Evidence is lacking to recommend an optimal interval for screening adults for hypertension. The seventh report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure (JNC 7) recommends screening every 2 years in persons with blood pressure less than 120/80 mm Hg and every year in persons with systolic blood pressure of 120 to 139 mm Hg or diastolic blood pressure of 80 to 90 mm Hg."

Goldstein LB, Bushnell CD, Adams RJ, Appel LJ, Braun LT, Chaturvedi S, Creager MA, Culebras A, Eckel RH, Hart RG, Hinchey JA, Howard VJ, Jauch EC, Levine SR, Meschia JF, Moore WS, Nixon JV, Pearson TA; on behalf of the American Heart Association Stroke Council, Council on Cardiovascular Nursing, Council on Epidemiology and Prevention, Council for High Blood Pressure Research, Council on Peripheral Vascular Disease, and Interdisciplinary Council on Quality of Care and Outcomes Research. Guidelines for the primary prevention of stroke: a guideline for healthcare professionals from the American Heart Association/American Stroke Association. Stroke 2011;42:517–584.

Goldstein and colleagues "used systematic literature reviews (covering the time since the last review was published in 2006 up to April 2009), reference to previously published guidelines, personal files, and expert opinion to summarize existing evidence, indicate gaps in current knowledge, and when appropriate, formulate recommendations using standard AHA criteria."

The council reported: "Hypertension remains the most important well-documented, modifiable risk factor for stroke, and treatment of hypertension is among the most effective strategies for preventing both ischemic and hemorrhagic stroke. Across the spectrum of age groups, including adults ≥ 80 years of age, the benefit of hypertension treatment in preventing stroke is clear. Reduction in BP is generally more important than the specific agents used to achieve this goal. Hypertension remains undertreated in the community, and additional programs to improve treatment compliance need to be developed, tested, and implemented.

They also reported the following recommendations:

1. In agreement with the JNC 7 report, regular BP screening and appropriate treatment, including both lifestyle modification and pharmacological therapy, are recommended (Class I; Level of Evidence A).
2. Systolic BP should be treated to a goal of <140 mm Hg and diastolic BP to < 90 mm Hg because these levels are associated with a lower risk of stroke and cardiovascular events (Class I; Level of Evidence A). In patients with hypertension with diabetes or renal disease, the BP goal is < 130/80 mm Hg (also see section on diabetes) (Class I; Level of Evidence A)."

U.S. DHHS, National Institutes of Health, National Heart, Lung, and Blood Institute National, High Blood Pressure Education Program. The Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure. NIH Publication No. 04-5230 August 2004.

The NIH noted the importance of accurate blood pressure measurements in the physician's office and stated: "the accurate measurement of BP is the sine qua non for successful management. The equipment — whether aneroid, mercury, or electronic —should be regularly inspected and validated. The operator should be trained and regularly retrained in the standardized technique, and the patient must be properly prepared and positioned. The auscultatory method of BP measurement should be used. Persons should be seated quietly for at least 5 minutes in a chair (rather than on an exam table), with feet on the floor, and arm supported at heart level. Caffeine, exercise, and smoking should be avoided for at least 30 minutes prior to measurement. Measurement of BP in the standing position is indicated periodically, especially in those at risk for postural hypotension, prior to necessary drug dose or adding a drug, and in those who report symptoms consistent with reduced BP upon standing. An appropriately sized cuff (cuff bladder encircling at least 80 percent of the arm) should be used to ensure accuracy. At least two measurements should be made and the average recorded. For manual determinations, palpated radial pulse obliteration pressure should be used to estimate SBP—the cuff should then be inflated 20–30 mmHg above this level for the auscultatory determinations; the cuff deflation rate for auscultatory readings should be 2 mmHg per second. SBP is the point at which the first of two or more Korotkoff sounds is heard (onset of phase 1), and the disappearance of Korotkoff sound (onset of phase 5) is used to define DBP. Clinicians should provide to patients, verbally and in writing, their specific BP numbers and the BP goal of their treatment."

Intensive Behavioral Counseling to Promote a Healthy Diet

U.S. Preventive Services Task Force. Behavioral Counseling in Primary Care to Promote a Healthy Diet Recommendations and Rationale. Am J Prev Med 2003;24:93-100.

In 2003, the USPSTF stated: "The USPSTF recommends intensive behavioral dietary counseling for adult patients with hyperlipidemia and other known risk factors for cardiovascular and diet-related chronic disease. Intensive counseling can be delivered by primary care clinicians or by referral to other specialists, such as nutritionists or dietitians. (B recommendation.)

The USPSTF found good evidence that medium- to high-intensity counseling interventions can produce medium to large changes in average daily intake of core components of a healthy diet (including saturated fat, fiber, and fruit and vegetables) among adult patients at increased risk of diet-related chronic disease. Intensive counseling interventions that have been examined in controlled trials among at-risk adult patients have combined nutrition education with behavioral dietary counseling provided by a nutritionist, dietitian, or specially trained primary care clinician (e.g., physician, nurse, or nurse practitioner). The USPSTF concluded that such counseling is likely to improve important health outcomes and that benefits outweigh potential harms. No controlled trials of intensive counseling in children or adolescents that measured diet were identified."

They also reported the following clinical considerations:

1. “Several brief dietary assessment questionnaires have been validated for use in the primary care setting. These instruments can identify dietary counseling needs, guide interventions, and monitor changes in patients’ dietary patterns. However, these instruments are susceptible to the bias of the respondent. Therefore, when used to evaluate the efficacy of counseling, efforts to verify self-reported information are recommended because patients receiving dietary interventions may be more likely to report positive changes in dietary behavior than control patients.”

2. “Effective interventions combine nutrition education with behaviorally oriented counseling to help patients acquire the skills, motivation, and support needed to alter their daily eating patterns and food preparation practices. Examples of behaviorally oriented counseling interventions include teaching self monitoring, training to overcome common barriers to selecting a healthy diet, helping patients to set their own goals, providing guidance in shopping and food preparation, role playing, and arranging for intratreatment social support. In general, these interventions can be described with reference to the 5-A behavioral counseling framework: Assess dietary practices and related risk factors, Advise to change dietary practices, Agree on individual diet change goals, Assist to change dietary practices or address motivational barriers, and Arrange regular follow-up and support or refer to more intensive behavioral nutritional counseling (e.g., medical nutrition therapy) if needed.”

3. “Two approaches appear promising for the general population of adult patients in primary care settings: (1) medium-intensity face-to-face dietary counseling (two to three group or individual sessions) delivered by a dietitian or nutritionist or by a specially trained primary care physician or nurse practitioner and (2) lower-intensity interventions that involve 5 minutes or less of primary care–provider counseling supplemented by patient self-help materials, telephone counseling, or other interactive health communications. However, more research is needed to assess the long-term efficacy of these treatments and the balance of benefits and harms.”

4. “The largest effect of dietary counseling in asymptomatic adults has been observed with more intensive interventions (multiple sessions lasting 30 minutes or longer) among patients with hyperlipidemia or hypertension and among others at increased risk of diet-related chronic disease. Effective interventions include individual or group counseling delivered by nutritionists, dietitians, or specially trained primary care practitioners or health educators in the primary care setting or in other clinical settings by referral. Most studies of these interventions have enrolled selected patients, many of whom had known diet related risk factors such as hyperlipidemia or hypertension. Similar approaches may be effective with unselected adult patients, but adherence to dietary advice may be lower, and health benefits smaller, than in patients who have been told they are at higher risk of diet-related chronic disease.”

5. “Office-level systems supports (prompts, reminders, and counseling algorithms) have been found to significantly improve the delivery of appropriate dietary counseling by primary care clinicians.”

6. “Possible harms of dietary counseling have not been well defined or measured. Some have raised concerns that if patients focus only on reducing total fat intake without attention to reducing caloric intake, an increase in carbohydrate intake (e.g., reduced-fat or low-fat food products) may lead to weight gain, elevated triglyceride levels, or insulin resistance. Nationally, obesity rates have increased despite declining fat consumption, but studies did not consistently examine effects of counseling on outcomes such as caloric intake and weight.”

Goldstein and colleagues “used systematic literature reviews (covering the time since the last review was published in 2006 up to April 2009), reference to previously published guidelines, personal files, and expert opinion to summarize existing evidence, indicate gaps in current knowledge, and when appropriate, formulate recommendations using standard AHA criteria.”

The council reported: “On the basis of evidence from epidemiological studies and randomized trials, it is likely that consumption of a diet with reduced sodium that is rich in fruits and vegetables, such as a DASH (Dietary Approaches to Stop Hypertension)-style diet, will reduce stroke risk. Few randomized trials with clinical outcomes have been conducted. The Dietary Guidelines for Americans report recommends a sodium intake of <2.3 g/d (100 mmol/d) for the general population. In blacks, persons with hypertension, and middle- and older-aged persons, a lower level of intake is recommended because these groups are especially sensitive to the BP-lowering effects of a reduced sodium diet. The Dietary Guidelines for Americans recommend a potassium intake of at least 4.7 g/d (120 mmol/d).” They recommended:

1. "Reduced intake of sodium and increased intake of potassium as indicated in the report Dietary Guidelines for Americans are recommended to lower BP (Class I; Level of Evidence A).
2. A DASH-style diet, which emphasizes consumption of fruits, vegetables, and low-fat dairy products and is reduced in saturated fat, also lowers BP and is recommended (Class I; Level of Evidence A).
3. A diet that is rich in fruits and vegetables and thereby high in potassium is beneficial and may lower risk of stroke (Class I; Level of Evidence B).”

U.S. DHHS, National Institutes of Health, National Heart, Lung, and Blood Institute National, High Blood Pressure Education Program. The Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure. NIH Publication No. 04-5230 August 2004.

The NIH highlighted the importance of diet: “Adoption of healthy lifestyles by all persons is critical for the prevention of high BP and is an indispensable part of the management of those with hypertension. Weight loss of as little as 10 lbs (4.5 kg) reduces BP and/or prevents hypertension in a large proportion of overweight persons, although the ideal is to maintain normal body weight. BP is also benefited by adoption of the Dietary Approaches to Stop Hypertension (DASH) eating plan which is a diet rich in fruits, vegetables, and low fat dairy products with a reduced content of dietary cholesterol as well as saturated and total fat (modification of whole diet). It is rich in potassium and calcium content. Dietary sodium should be reduced to no more than 100 mmol per day (2.4 g of sodium). Everyone who is able should engage in regular aerobic physical activity such as brisk walking at least 30 minutes per day most days of the week. Alcohol intake should be limited to no more than 1 oz (30 mL) of ethanol, the equivalent of two drinks per day in most men and no more than 0.5 oz of ethanol (one drink) per day in women and lighter weight persons. A drink is 12 oz of beer, 5 oz of wine, and 1.5 oz of 80-proof liquor. Lifestyle modifications reduce BP, prevent or delay the incidence of hypertension, enhance antihypertensive drug efficacy, and decrease cardiovascular risk. For example, in some individuals, a 1,600 mg sodium DASH eating plan has BP effects similar to single drug therapy. Combinations of two (or more) lifestyle modifications can achieve even better results. For overall cardiovascular risk reduction, patients should be strongly counseled to quit smoking.”

1. Professional Society Position Statements

Aspirin Use

Pignone M, Alberts MJ, Colwell JA, Cushman M, Inzucchi SE, Mukherjee D, Rosenson RS, Williams CD, Wilson PW, Kirkman MS. Aspirin for primary prevention of cardiovascular events in people with diabetes: a position statement of the American Diabetes Association, a scientific statement of the American Heart Association, and an expert consensus document of the American College of Cardiology Foundation. Circulation 2010;121:2694 –2701.

Pignone and colleagues reported the following evidence-based recommendation:

"Low-dose (75–162 mg/d) aspirin use for prevention is reasonable for adults with diabetes and no previous history of vascular disease who are at increased CVD risk (10 year risk of CVD events over 10%) and who are not at increased risk for bleeding (based on a history of previous gastrointestinal bleeding or peptic ulcer disease or concurrent use of other medications that increase bleeding risk, such as NSAIDs [non-steroidal anti-inflammatory drugs] or warfarin). Those adults with diabetes at increased CVD risk include most men over age 50 years and women over age 60 years who have 1 or more of the following additional major risk factors: smoking, hypertension, dyslipidemia, family history of premature CVD, and albuminuria. (ACCF/AHA Class IIa, Level of Evidence: B) (ADA Level of Evidence: C)"

The authors noted the following consideration:

Cardiovascular Risk Assessment: "These recommendations depend on the accurate assessment of cardiovascular risk as part of the decision-making process about aspirin use. All patients with diabetes do not have high cardiovascular risk, despite the assumptions of some previous guidelines. We have provided treatment guidance based on either a combination of age, sex, and other risk factors or on an estimate of absolute cardiovascular risk. An important consideration is that patients may acquire additional risk factors over time, which would necessitate a reassessment of their overall risk profile. The absolute risk-based recommendations require the use of a risk prediction tool. Tools that can be used in patients with diabetes are available from several sources, for example:

1. UKPDS Risk Engine: http://www.dtu.ox.ac.uk/riskengine/index.php
2. ARIC CHD Risk Calculator: http://www.aricnews.net/riskcalc/html/RC1.html
3. American Diabetes Association Risk Assessment Tool, Diabetes PHD: http://www.diabetes.org/phd"

Professional society position statements regarding screening for high blood pressure and intensive behavioral dietary counseling for adult patients with hyperlipidemia and other known risk factors for cardiovascular and diet-related chronic disease are discussed earlier in the section discussing the evidence reviewed.

7. Public Comments

During the initial 30-day public comment period (02/11/2011 – 03/13/2011), CMS received six timely comments. Five of the comments were generally supportive of CMS adding “Intensive Behavioral Therapy for Cardiovascular Disease” as a covered benefit under Medicare. Two of the commenters were hospital providers; two were from education/advocacy associations; one from a professional society; and one from a multi-national pharmaceutical manufacturer. Four commenters expressed support for expanding coverage to include counseling on lifestyle, diet, and regular exercise. One commenter had concerns about aspirin usage requiring intensive behavioral therapy. Commenters also queried about the inclusion of tobacco cessation and cognitive behavioral therapy methods. Another commenter urged coverage of digital health coaching programs. Two commenters asked how the preventive service will be defined as well as differentiated, including beneficiary eligibility, who can provide the services, frequency, and limitations on coverage.

The comments can be viewed in their entirety on our website at:
http://www.cms.gov/medicare-coverage-database/details/nca-view-public-comments.aspx?NCAId=248&ExpandComments=n&ver=2&NcaName=Intensive+Behavioral+Therapy+for+Cardiovascular+Disease&bc=BEAAAAAAEAAA&

VIII. CMS Analysis

National coverage determinations (NCDs) are determinations by the Secretary with respect to whether or not a particular item or service is covered nationally under title XVIII of the Social Security Act §1869(f)(1)(B). In order to be covered by Medicare, an item or service must fall within one or more benefit categories contained within Part A or Part B, and must not be otherwise excluded from coverage. Since January 1, 2009, CMS is authorized to cover "additional preventive services" (see Section III above) if certain statutory requirements are met as provided under §1861(ddd) of the Social Security Act. Our regulations at 42 CFR 410.64 provide:

(a) Medicare Part B pays for additional preventive services not described in paragraph (1) or (3) of the definition of “preventive services” under §410.2, that identify medical conditions or risk factors for individuals if the Secretary determines through the national coverage determination process (as defined in section 1869(f)(1)(B) of the Act) that these services are all of the following:

(1) Reasonable and necessary for the prevention or early detection of illness or disability.
(2) Recommended with a grade of A or B by the United States Preventive Services Task Force.
(3) Appropriate for individuals entitled to benefits under part A or enrolled under Part B.

(b) In making determinations under paragraph (a) of this section regarding the coverage of a new preventive service, the Secretary may conduct an assessment of the relation between predicted outcomes and the expenditures for such services and may take into account the results of such an assessment in making such national coverage determinations.

Is the evidence sufficient to determine that (1) aspirin use, (2) screening for high blood pressure, and (3) intensive behavioral dietary counseling for adult patients with hyperlipidemia and other known risk factors for cardiovascular and diet-related chronic disease is recommended with a grade of A or B by the USPSTF for any indications?

Aspirin Use

The USPSTF recommends “the use of aspirin for men age 45 to 79 years when the potential benefit due to a reduction in myocardial infarctions outweighs the potential harm due to an increase in gastrointestinal hemorrhage. Grade: A recommendation.”

The USPSTF recommends “the use of aspirin for women age 55 to 79 years when the potential benefit of a reduction in ischemic strokes outweighs the potential harm of an increase in gastrointestinal hemorrhage. Grade: A recommendation.”

Screening for High Blood Pressure in Adults Aged 18 and Older

The USPSTF recommends “screening for high blood pressure in adults aged 18 and older. Grade: A recommendation.”

Intensive Behavioral Dietary Counseling for Adult Patients with Hyperlipidemia and Other Known Risk Factors for Cardiovascular and Diet-related Chronic Disease

The USPSTF recommends “intensive behavioral dietary counseling for adult patients with hyperlipidemia and other known risk factors for cardiovascular and diet-related chronic disease. Intensive counseling can be delivered by primary care clinicians or by referral to other specialists, such as nutritionists or dietitians. Grade: B recommendation.”

We conclude that (1) aspirin use, (2) screening for high blood pressure, and (3) intensive behavioral dietary counseling for adult patients with hyperlipidemia and other known risk factors for cardiovascular and diet-related chronic disease are each recommended with a grade of A or B by the USPSTF.

Is the evidence sufficient to determine that (1) aspirin use, (2) screening for high blood pressure, and (3) intensive behavioral dietary counseling for adult patients with hyperlipidemia and other known risk factors for cardiovascular and diet-related chronic disease is reasonable and necessary for the prevention or early detection of illness or disability?

Aspirin Use

In 2009 Wolff and colleagues conducted a systematic evidence review that included past randomized controlled trials and concluded that “aspirin use reduces the number of CVD events in both men and women without known CVD.” The position statements by the AHA and the American Diabetes Association (ADA) are consistent, and state that:

- “aspirin for cardiovascular (including but not specific to stroke) prophylaxis is recommended for persons whose risk is sufficiently high for the benefits to outweigh the risks associated with treatment” (AHA).
- “aspirin use for prevention is reasonable for adults with diabetes and no previous history of vascular disease who are at increased CVD risk” (ADA).

The benefits of aspirin in prevention have been well established in past trials including the Thrombosis Prevention Trial (MRC, 1998) and the Hypertension Optimal Treatment Trial (Hansson, 1998). The USPSTF first recommended aspirin for prevention of cardiovascular disease in 2002 and revised and reaffirmed the recommendation in 2009. The USPSTF recommendations are age and gender specific and include an assessment of individual benefits and risks.

Screening for High Blood Pressure in Adults Aged 18 and Older

In 2003, the USPSTF reviewed the evidence and recommended screening for high blood pressure. This position was reaffirmed in 2007. The Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure (JNC7) summarized the evidence in support of screening in 2004 and provided information on how to accurately measure blood pressure. The benefits of screening for and treatment of hypertension have been well established in past randomized controlled trials like Hypertension Optimal Treatment Trial (Hansson, 1998). In 2004 the JNC7 summarized the past evidence and stated: “The relationship between BP and risk of CVD events is continuous, consistent, and independent of other risk factors. The higher the BP, the greater the chance of heart attack, HF, stroke, and kidney diseases.” The USPSTF recommended screening in 2003 and reconfirmed the recommendation in 2007.

Intensive Behavioral Dietary Counseling for Adult Patients with Hyperlipidemia and Other Known Risk Factors for Cardiovascular and Diet-related Chronic Disease

Lin and colleagues conducted a systematic evidence review and concluded: “Counseling to improve diet or increase physical activity changed health behaviors and was associated with small improvements in adiposity, blood pressure, and lipid levels.” The AHA/American Stroke Association (ASA) reported: “On the basis of evidence from epidemiological studies and randomized trials, it is likely that consumption of a diet with reduced sodium that is rich in fruits and vegetables, such as a DASH (Dietary Approaches to Stop Hypertension)-style diet, will reduce stroke risk.” The Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure (JNC7) summarized the evidence in support and presented the “Dietary Approaches to Stop Hypertension (DASH) eating plan which is a diet rich in fruits, vegetables, and low fat dairy products with a reduced content of dietary cholesterol as well as saturated and total fat (modification of whole diet).” The influence of diet on health has been well known for decades. McGinnis and Foege first quantified the impact of diet in 1993. The findings persisted as noted by Mokdad and colleagues in 2004. There is also public and private consensus as note the JNC7, AHA and the American College of Cardiology (ACC). The JNC7 stated: “Adoption of healthy lifestyles by all persons is critical for the prevention of high BP and is an indispensable part of the management of those with hypertension.” While the benefits of healthy diet and physical activity are widely accepted, the challenge lies in changing behaviors in a meaningful and sustainable manner.

We conclude that the evidence is sufficient to determine that (1) aspirin use, (2) screening for high blood pressure, and (3) intensive behavioral dietary counseling for adult patients with hyperlipidemia and other known risk factors for cardiovascular and diet-related chronic disease is reasonable and necessary for the prevention or early detection of illness or disability.

Is the evidence sufficient to determine that (1) aspirin use, (2) screening for high blood pressure and (3) intensive behavioral dietary counseling for adult patients with hyperlipidemia and other known risk factors for cardiovascular and diet-related chronic disease is appropriate for Medicare beneficiaries?

Aspirin Use

The ATT collaborative group conducted a meta-analysis and concluded that “aspirin is of uncertain net value as the reduction in occlusive events needs to be weighed against any increase in major bleeds.” They noted that the “most important predictor of risk was age.” A systematic review of the evidence by Wolff and colleagues in 2009 showed improved health outcomes with a careful review of benefits and harms for older adults.

Screening for High Blood Pressure in Adults Aged 18 and Older

The AHA/ASA stated: “Hypertension remains the most important well-documented, modifiable risk factor for stroke, and treatment of hypertension is among the most effective strategies for preventing both ischemic and hemorrhagic stroke. Across the spectrum of age groups, including adults ≥ 80 years of age, the benefit of hypertension treatment in preventing stroke is clear.”

Intensive Behavioral Dietary Counseling for Adult Patients with Hyperlipidemia and Other Known Risk Factors for Cardiovascular and Diet-related Chronic Disease

In their systematic review in 2010, Lin and colleagues found that “counseling to improve diet or increase physical activity changed health behaviors and was associated with small improvements in adiposity, blood pressure, and lipid levels.” The evidence review included trials in older adults. The weighted median age was 59 years. Nine trials were conducted in older adults. The USPSTF noted that “good evidence that medium- to high-intensity counseling interventions can produce medium-to-large changes in average daily intake of core components of a healthy diet (including saturated fat, fiber, fruit, and vegetables) among adult patients at increased risk for diet-related chronic disease. Intensive counseling interventions that have been examined in controlled trials among at-risk adult patients have combined nutrition education with behavioral dietary counseling provided by a nutritionist, dietitian, or specially trained primary care clinician (e.g., physician, nurse, or nurse practitioner).” They concluded that “such counseling is likely to improve important health outcomes and that benefits outweigh potential harms.”

We conclude that the evidence sufficient to determine that (1) aspirin use, (2) screening for high blood pressure, and (3) intensive behavioral dietary counseling for adult patients with hyperlipidemia and other known risk factors for cardiovascular and diet-related chronic disease is appropriate for Medicare beneficiaries.

Intensive Behavioral Counseling Interventions Model

Whitlock and colleagues presented a model for behavioral counseling interventions:
"The Four A's construct (ask, advise, assist, arrange) was originally developed by the National Cancer Institute to guide physician intervention in smoking cessation. Recently, the Canadian Task Force on Preventive Health Care proposed that clinicians use a Five A's construct (adding an agree step) to organize their general approach to assisting patients with behavioral counseling issues (W. Elford, Canadian Task Force on Preventive Health Care, personal communication, December 2000). The U.S. Public Health Service used the A's construct to report on high-quality, controlled clinical trials in tobacco cessation, many conducted in primary care settings to test brief, feasible, population level interventions. The A's construct has also been applied to brief primary care interventions for a variety of other behaviors. To be congruent with the U.S. Public Health Service and Canadian Task Force concepts of the A's construct, we adopted the following terminology to describe minimal contact interventions that are provided by a variety of clinical staff in primary care settings:

- Assess: Ask about/assess behavioral health risk(s) and factors affecting choice of behavior change goals/methods.
- Advise: Give clear, specific, and personalized behavior change advice, including information about personal health harms and benefits.
- Agree: Collaboratively select appropriate treatment goals and methods based on the patient's interest in and willingness to change the behavior.
- Assist: Using behavior change techniques (self-help and/or counseling), aid the patient in achieving agreed-upon goals by acquiring the skills, confidence, and social/environmental supports for behavior change, supplemented with adjunctive medical treatments when appropriate (e.g., pharmacotherapy for tobacco dependence, contraceptive drugs/devices).
- Arrange: Schedule follow-up contacts (in person or by telephone) to provide ongoing assistance/support and to adjust the treatment plan as needed, including referral to more intensive or specialized treatment."

Intensive Behavioral Therapy for Risk Factor Reduction

Given the prevalence of cardiovascular events in the Medicare population and the importance of prevention of such events, CMS assessed the addition of services recommended by the USPSTF to reduce as much risk as possible in a single visit. Separately, aspirin for prevention, screening for high blood pressure and behavioral intervention to promote healthy diet were determined to meet the standards in §1861 (ddd). These services were combined into a single visit to allow a physician an opportunity to assess specific risk factors, provide personalized recommendations and counseling services to reduce risks and subsequent events. Each component of the visit should be addressed as appropriate, specifically with the ultimate goal of short and long term behavioral changes.

It should be stressed that the reductions in risks and subsequent cardiovascular events are a direct result of the behavior changes such as adherence to medications and healthful diet. Documentation of the individual components and behavioral changes in the physician's records should be done at each subsequent visit to establish long term improvements. We note that counseling to prevent tobacco use is already a covered Part B benefit (Medicare National Coverage Determination Manual §210.4.1), and could also be provided to qualifying patients following this visit.

Aspirin Use Risk Assessment and Counseling

Risk assessment tools are important in determining benefits and risk and have been previously published. One example by the USPSTF is presented below and available at: http://www.uspreventiveservicestaskforce.org/uspstf09/aspirincvd/aspcvdsum.htm.

Shared decision making is strongly encouraged with individuals whose risk is close to (either above or below) the estimates of 10-year risk levels indicated below. As the potential CVD benefit increases above harms, the recommendation to take aspirin should become stronger.

Both 10-year CVD risk and age must be considered to determine whether the potential benefit of myocardial infarctions prevented (men) and strokes prevented (women) outweighs the potential harm of increased gastrointestinal (GI) hemorrhage.

Risk level at which CVD events prevented (benefit) exceeds GI harms

Men		**Women**	
10-year CVD risk		**10-year stroke risk**	
Age 45-59 years	≥4%	Age 55-59 years	≥3%
Age 60-69 years	≥9%	Age 60-69 years	≥8%
Age 70-79 years	≥12%	Age 70-79 years	≥11%

The table above applies to adults who are not taking NSAIDs and who do not have upper GI pain or a history of GI ulcers.

NSAID use and history of GI ulcers raise the risk of serious GI bleeding considerably and should be considered in determining the balance of benefits and harms. NSAID use combined with aspirin use approximately quadruples the risk of serious GI bleeding compared to the risk with aspirin use alone. The rate of serious bleeding in aspirin users is approximately 2-3 times higher in patients with a history of GI ulcers."

Additional risk assessment tools are available at:
•http://hp2010.nhlbihin.net/atpiii/calculator.asp (for men), and
•http://www.westernstroke.org/ (for women).

The requestor (Jason M. Spangler, MD, Chief Medical Officer, Partnership for Prevention) provided a list of components that should be conducted for aspirin use:

1. "Initiation of discussion of aspirin's use in cardiovascular disease prevention.
2. Assessment of coronary artery disease/cerebrovascular disease risk and estimated benefits of aspirin use.
3. Assessment of the risk of adverse events, including gastrointestinal bleeding and hemorrhagic stroke.
4. Assessment of aspirin contraindications.
5. Discussion of risks, benefits, clinical alternatives, uncertainties surrounding treatment, and patient values through shared patient-provider decision-making.
6. Provision of specific advice, including aspirin formulation, frequency, and dose. If appropriate, advice to patient not to start aspirin with a plan to reassess in future.
7. Agreement on a plan for the subsequent steps, which can include, depending on the conclusion of the discussion and counseling, initiation of aspirin therapy (with a plan for subsequent assessment of adherence and for reinforcement), agreement regarding follow-up contact (e.g., visit, phone call) prior to definitive decision regarding initiation/no initiation, no further instances of shared decision-making on the topic (because of patient preference to not engage), or the like."

Accurate Blood Pressure Measurement in the Office

The JNC7 reported: "The accurate measurement of BP is the sine qua non for successful management. The equipment — whether aneroid, mercury, or electronic —should be regularly inspected and validated. The operator should be trained and regularly retrained in the standardized technique, and the patient must be properly prepared and positioned. The auscultatory method of BP measurement should be used. Persons should be seated quietly for at least 5 minutes in a chair (rather than on an exam table), with feet on the floor, and arm supported at heart level. Caffeine, exercise, and smoking should be avoided for at least 30 minutes prior to measurement. Measurement of BP in the standing position is indicated periodically, especially in those at risk for postural hypotension, prior to necessary drug dose or adding a drug, and in those who report symptoms consistent with reduced BP upon standing. An appropriately sized cuff (cuff bladder encircling at least 80 percent of the arm) should be used to ensure accuracy. At least two measurements should be made and the average recorded. For manual determinations, palpated radial pulse obliteration pressure should be used to estimate SBP—the cuff should then be inflated 20–30 mmHg above this level for the auscultatory determinations; the cuff deflation rate for auscultatory readings should be 2 mmHg per second. SBP is the point at which the first of two or more Korotkoff sounds is heard (onset of phase 1), and the disappearance of Korotkoff sound (onset of phase 5) is used to define DBP. Clinicians should provide to patients, verbally and in writing, their specific BP numbers and the BP goal of their treatment."

Frequency of Visit

The JNC7 recommended that blood pressure screening occur "every 2 years with BP <120/80." The USPSTF has reported for aspirin use that "risk assessment and discussion should probably be held at least every 5 years with middle-aged and older people or when CVD risk factors are detected." The USPSTF did not make frequency recommendations for blood pressure screening or intensive behavioral dietary counseling for adult patients with hyperlipidemia and other known risk factors for cardiovascular and diet-related chronic disease. CMS is proposing coverage of this visit every 2 years.

Providers and Places of Services

In order to translate the USPSTF recommendations into Medicare policy, it is necessary to evaluate how the primary care component to the recommendations would be implemented for Medicare. The USPSTF references primary care as defined by the Institute of Medicine (1996) which was used as the basis for the recommendation and reads, "*primary care* is the provision of integrated, accessible health care services by clinicians who are accountable for addressing a large majority of personal health care needs, developing a sustained partnership with the patient, and practicing in the context of family and community." The Medicare program recognizes numerous places of service and many would not be considered primary care according to the Institute of Medicine definition. Therefore, we use this definition as the basis of excluding certain places of service from this proposed new benefit. We conclude that emergency departments, inpatient hospital settings, outpatient hospital settings, ambulatory surgical centers, independent diagnostic testing facilities, skilled nursing facilities, inpatient rehabilitation facilities and hospices are not considered primary care settings under this definition.

In order, then, to determine the eligible providers we again look to the primary care definition of the Institute of Medicine. Additionally, Medicare, through the Social Security Act, has already identified a list of primary care physicians and practitioners and while the purpose of such law was for incentive payments, the identified practitioners are indeed appropriate and logically fit within the scope of the USPSTF recommendations.

For the purposes of this proposed decision memorandum a primary care physician and primary care practitioner will be defined consistent with existing sections of the Social Security Act which have already provided such definitions (§1833(u)(6), §1833(x)(2)(A)(i)(I) and §1833(x)(2)(A)(i)(II)).

§1833(u)
(6) Physician Defined.—For purposes of this paragraph, the term "physician" means a physician described in section 1861(r)(1) and the term "primary care physician" means a physician who is identified in the available data as a general practitioner, family practice practitioner, general internist, or obstetrician or gynecologist.

§1833(x)(2)(A)
Primary care practitioner—The term "primary care practitioner" means an individual—
(i) who—
(I) is a physician (as described in section 1861(r)(1)) who has a primary specialty designation of family medicine, internal medicine, geriatric medicine, or pediatric medicine; or
(II) is a nurse practitioner, clinical nurse specialist, or physician assistant (as those terms are defined in section 1861(aa)(5)).

We believe that the above discussion regarding primary care settings and practitioners appropriately applies to all three services that comprise intensive behavioral counseling for cardiovascular disease. Since aspirin counseling is for the prevention of CVD and blood pressure screening is to ensure that high blood pressure is caught very early, we believe both of these services are appropriately delivered in the primary care setting. The USPSTF specifically identifies primary care in the recommendation for healthy diet counseling in addition to the service being provided (through referral) by a nutritionist or dietician.

Health Disparities in Cardiovascular Disease

Well known gender, racial, and ethnic disparities exist in adults with CVD. The rates of disease vary by these demographics. For example, the AHA reported: "The 2007 overall death rate from CVD (International Classification of Diseases 10, I00 –I99) was 251.2 per 100,000. The rates were 294.0 per 100,000 for white males, 405.9 per 100 000 for black males, 205.7 per 100,000 for white females, and 286.1 per 100 000 for black females." The risk factors for CVD vary among these groups as well. Keenan and Shaw (2011) noted: "The overall U.S. prevalence of hypertension among adults aged ≥ 18 years in 2005–2008 was 30.9% and was highest among persons aged ≥ 65 years (69.7%), non-Hispanic blacks (38.6%), and those participants with Medicare coverage (68.1%)." In general, all individuals at risk especially African American beneficiaries should be encouraged to make use of these preventive services.

Summary

As discussed by Keenan and Shaw (2011), CVD remains the leading cause of death in the United States. Cardiovascular disease and its risk factors affect all Americans. In conjunction with the published literature and professional guidelines, CMS thus believes there is adequate evidence that intensive behavioral therapy for cardiovascular disease reduces the risk of illness and disability. The evidence supports a visit that includes the following elements:

- Aspirin use: As reported by the USPSTF recommendations, encouraging a discussion of the use of aspirin when the potential benefit of cardiovascular risk reduction outweighs the potential harm of an increased gastrointestinal hemorrhage for men age 45-79 years and women age 55-79 years.
- Screening for high blood pressure for adults age 18 years and older: As the AHA Stroke Council reported "hypertension remains the most important well-documented, modifiable risk factor for stroke, and treatment of hypertension is among the most effective strategies for preventing both ischemic and hemorrhagic stroke." The Council emphasized that regular blood pressure screening and appropriate treatment, including both lifestyle modification and pharmacological therapy, are recommended. (Goldstein et al, 2011). The NIH emphasized accurate blood pressure measurements in the physician's office and stated that measurement techniques, patient positioning, and regular equipment inspection and maintenance are key features of accurate blood pressure screening.
- Intensive behavioral dietary counseling for adult patients with hyperlipidemia and other known risk factors for cardiovascular and diet-related chronic disease: The evidence supports the importance of diet in the prevention of high blood pressure and management of hyperlipidemia or hypertension. Blood pressure is also benefited by adoption of a diet rich in fruits, vegetables, and low fat dairy products, with reduced sodium intake, along with reduced consumption of dietary cholesterol and total fat.

IX. Conclusion

The evidence is adequate to conclude that intensive behavioral therapy for CVD is reasonable and necessary for the prevention or early detection of illness or disability, is appropriate for individuals entitled to benefits under Part A or enrolled under Part B and is comprised of components that are recommended with a grade of A or B by the USPSTF.

Intensive behavioral therapy consists of the following three components:

- encouraging aspirin use for the primary prevention of cardiovascular disease when the benefits outweigh the risks for men age 45-79 years and women 55-79 years;
- screening for high blood pressure in adults age 18 years and older; and
- intensive behavioral counseling to promote a healthy diet for adults with hyperlipidemia, hypertension, advancing age and other known risk factors for cardiovascular and diet-related chronic disease.

We note that only a small proportion (about 4%) of the Medicare population is under 45 years (men) or 55 years (women), therefore the vast majority of beneficiaries should receive all three components. Intensive behavioral counseling to promote a healthy diet is broadly recommended to cover close to 100% of the population due to the prevalence of known risk factors.

Therefore, CMS proposes to cover one face-to-face CVD risk reduction visit every two years for Medicare beneficiaries:

- who are competent and alert at the time that counseling is provided; and whose counseling is furnished by a qualified primary care physician or other primary care practitioner and in a primary care setting.

The behavioral counseling intervention for aspirin use and healthy diet should be consistent with the Five As approach that has been adopted by the USPSTF to describe such services:

- **Assess:** Ask about/assess behavioral health risk(s) and factors affecting choice of behavior change goals/methods.
- **Advise:** Give clear, specific, and personalized behavior change advice, including information about personal health harms and benefits.
- **Agree:** Collaboratively select appropriate treatment goals and methods based on the patient's interest in and willingness to change the behavior.
- **Assist:** Using behavior change techniques (self-help and/or counseling), aid the patient in achieving agreed-upon goals by acquiring the skills, confidence, and social/environmental supports for behavior change, supplemented with adjunctive medical treatments when appropriate.
- **Arrange:** Schedule follow-up contacts (in person or by telephone) to provide ongoing assistance/support and to adjust the treatment plan as needed, including referral to more intensive or specialized treatment.

For the purposes of this proposed decision memorandum, a primary care setting is defined as one in which there is provision of integrated, accessible health care services by clinicians who are accountable for addressing a large majority of personal health care needs, developing a sustained partnership with patients, and practicing in the context of family and community. Emergency departments, inpatient hospital settings, outpatient hospital settings, ambulatory surgical centers, independent diagnostic testing facilities, skilled nursing facilities, inpatient rehabilitation facilities and hospices are not considered primary care settings under this definition.

For the purposes of this proposed decision memorandum a "primary care physician" and "primary care practitioner" will be defined consistent with existing sections of the Social Security Act (§1833(u)(6), §1833(x)(2)(A)(i)(I) and §1833(x)(2)(A)(i)(II)).

§1833(u)
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(II) is a nurse practitioner, clinical nurse specialist, or physician assistant (as those terms are defined in section 1861(aa)(5)).

We are requesting public comments on this proposed determination pursuant to section 1862(l) of the Social Security Act. After considering the public comments, we will make a final determination and issue a final decision memorandum.

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1 Hyperlipidemia refers to an elevation of one or more blood lipid measurements such as total cholesterol, low density lipoprotein cholesterol (LDL-C) and high density lipoprotein cholesterol (HDL-C).

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