American Heart Association | American Stroke Association

September 8, 2011

Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Re: CAG-00424N

Dear Sir or Madam:

On behalf of the American Heart Association (AHA), including the American Stroke Association (ASA) and over 22.5 million AHA and ASA volunteers and supporters, we appreciate the opportunity to submit our comments in response to the Centers for Medicare and Medicaid Services (CMS) proposed coverage memo for intensive behavioral therapy for cardiovascular disease (CVD).

According to the proposed coverage decision, CMS plans to add intensive behavioral therapy for CVD as a covered benefit under the Medicare program. The benefit would include encouraging aspirin use for the primary prevention of CVD when the benefits outweigh the risks; screening for high blood pressure; 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 disease. As AHA expressed in our previous comments to the Agency in March 2011, we appreciate and support the Agency's proposal to add coverage of intensive behavioral therapy for cardiovascular disease to the Medicare program. All three services play a role in cardiovascular risk reduction, and counseling or behavioral therapy can increase the likelihood that beneficiaries will make and sustain lifestyle modifications.

We are, therefore, very supportive of a cardiovascular risk reduction benefit and we look forward to seeing one added to the Medicare program in the near future. We do, however, have a few concerns with the structure of the benefit as currently proposed. We are concerned that the proposed visit frequency of once every two years is inadequate, and we question the Agency's decision to limit this benefit to primary care practitioners. In addition, we request that the Agency clarify that this benefit is available to all Medicare beneficiaries, including for the secondary prevention of cardiovascular diseases. We expand on these comments below.

Visit Frequency

As noted above, CMS has proposed covering one face-to-face cardiovascular risk reduction visit every two years. AHA is concerned that one visit every 24 months is insufficient to produce and sustain the desired behaviors, particularly for intensive behavioral counseling for a healthy diet.

The evidence shows that frequent and prolonged contact increases the likelihood that individuals will initially achieve desired behavioral changes. The frequency of the contact also influences adherence with the desired behaviors; and as contact is reduced, adherence declines, and often when there is no contact, recidivism occurs. Thus, interventions that include scheduled follow-up visits are generally more effective.[1] If there is no follow-up, the probability that an individual will change a behavior or implement a recommended treatment plan is reduced. AHA is therefore concerned that the proposed one time visit with no required follow-up for a two-year period will have little to no sustaining effect.

We are also concerned that the proposed visit frequency does not reflect the evidence review that was conducted by the U.S. Preventive Services Task Force (USPSTF) when it developed its recommendation for intensive behavioral counseling to promote a healthy diet. The USPSTF recommendation, which served as the basis for the healthy diet component of the proposed new Medicare benefit, found that "the largest effect of dietary counseling in asymptomatic adults has been observed with more intensive interventions among patients with hyperlipidemia or hypertension and among individuals at increased risk of diet-related chronic disease."[2] The USPSTF defined "intensive interventions" as multiple sessions lasting 30 minutes or longer (emphasis added). But as noted above, the Agency is proposing a single visit. A single visit is not "intensive" behavioral therapy.

In addition, a single visit every two years does not account for the fact that older adults tend to develop risk factors more often than younger people. Consider blood pressure, for example. Blood pressure increases with age, and in women, increases at menopause. Blood pressure must be more closely monitored if the individual has other risk factors such as tobacco use, diabetes, obesity, or hypercholesterolemia, or uses a medication known to affect blood pressure, since risks for complications are increased. Older adults are also particularly vulnerable to the effects of uncontrolled risk factors. Therefore, one visit every two years is unlikely to identify adverse changes in health status – especially cardiovascular risk factors in the Medicare population – early enough.

Finally, we are concerned that one visit may not provide enough time for a health care provider to cover all three of these services (aspirin, blood pressure, healthy diet) adequately. There is a significant amount of information for the provider to assess and review with the beneficiary, especially since the proposed benefit directs providers to follow the Five As approach (assess, advise, agree, assist, and arrange) for both the aspirin and healthy diet counseling. We believe it may not be possible to appropriately address all three components during one visit. We are also concerned that addressing all three components during a single visit may overwhelm the beneficiary and adversely affect patient comprehension.

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[1] Artinian NT, et al. Interventions to Promote Physical Activity and Dietary Lifestyle Changes for Cardiovascular Risk Reduction in Adults: A Scientific Statement from the American Heart Association: 2010.

[2] U.S. Preventive Services Task Force. Behavioral Counseling in Primary Care to Promote a Healthy Diet: Recommendations and Rationale. 2003.

We therefore urge CMS to reconsider the proposed visit frequency. Intensive behavioral therapy for cardiovascular disease should, as the USPSTF evidence review indicates, include multiple visits that allow for the provision of care conveyed by the term "intensive", as well as allow for, and reimburse for, follow-up visits. Reimbursing providers for follow-up visits will increase the likelihood that ongoing assessment and support will be provided to patients.

Primary Care Practitioners

According to the proposed decision memo, the cardiovascular risk reduction visit must be conducted by a qualified primary care physician or other primary care practitioner and in a primary care setting. AHA questions the Agency's decision to limit the provision of this benefit to these practitioners and settings. CMS should not exclude cardiologists and neurologists from providing this benefit, particularly since this benefit is focused on risk reduction for cardiovascular diseases, including stroke.

We understand that the Agency is appropriately focusing on the large patient population followed by primary care providers for primary prevention, but many patients, especially those with complex dyslipidemia, refractory hypertension, or a need for intensive behavioral therapy for secondary prevention, receive the majority of their care from cardiologists and neurologists and these patients should not be excluded from this benefit.

Secondary Prevention

While the USPSTF recommendations focused on the efficacy of these interventions for the primary prevention of cardiovascular diseases, a substantial number of patients in the Medicare age group present for the first time with already established cardiovascular diseases, including TIA and stroke. Intensive behavioral therapy for prevention should, of course, be provided to these patients. Thus, we request that CMS clarify that this benefit applies to all Medicare beneficiaries for both primary and secondary prevention.

Future Expansion of the Benefit

Finally, AHA is aware that the USPSTF is currently reviewing its recommendations on physical activity and healthy diet counseling as part of an evidence review for a new recommendation on behavioral counseling to promote physical activity and a healthy diet to prevent CVD in adults. If the Task Force assigns a grade of "A" or "B" to this recommendation, we encourage the Agency to reopen this coverage determination and add behavioral counseling to promote physical activity to this benefit. Increased physical activity, in conjunction with better food habits and appropriate weight management, can substantially reduce the risk of developing CVD.

Conclusion

In closing, we reiterate our appreciation of CMS's proposed decision to add coverage of intensive behavioral therapy for cardiovascular disease to the Medicare program. All three services play a role in cardiovascular disease risk reduction and AHA has long recommended that health care providers assess patients who are at higher cardiovascular disease risk for aspirin use; measure, and if necessary treat, blood pressure in all patients; and counsel all patients to eat a healthy diet. We are hopeful that an expansion in Medicare coverage will reinforce the value of these services and increase both provider and patient participation rates.

In order to maximize this benefit, however, we recommended that the Agency increase the benefit frequency to allow for multiple visits, including follow-up visits, between the patient and the provider. As discussed above, the USPSTF found that intensive behavioral therapy with multiple visits had the greatest effect, and extensive evidence shows that frequent and prolonged contact is needed to maximize results.

In addition, we request that CMS add cardiologists and neurologists to the list of eligible providers, and clarify that the benefit is intended for both primary and secondary prevention of cardiovascular disease. And we encourage the Agency to reopen this coverage determination and add counseling to promote physical activity when the USPSTF releases its updated recommendation on physical activity counseling.

If you have any questions, please do not hesitate to contact Susan Bishop, MA, Regulatory Affairs Manager, at 202-785-7908 or susan.k.bishop@heart.org.

Thank you for consideration of our comments.

Sincerely,

Gordon F. Tomaselli, MD, FAHA
President
American Heart Association