American Heart Association | American Stroke Association

September 29, 2011

Centers for Medicare and Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244

Re: CAG-00423N

Dear Sir/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 decision for intensive behavioral therapy for obesity.

According to the proposed decision memo, CMS plans to add intensive behavioral therapy for obesity as a covered benefit under the Medicare program. The benefit would include obesity screening in adults, dietary/nutritional counseling, and intensive behavioral counseling and therapy to promote sustained weight loss through diet and exercise. AHA strongly supports this proposal.

As the Agency is aware, obesity is a significant public health problem. It is a major risk factor for cardiovascular disease, cancer, diabetes, and early death. It also leads to increased health care costs. Fortunately, obesity is a modifiable risk factor. By lowering the prevalence of overweight and obesity, we can substantially reduce Americans' risk of chronic disease, as well as improve overall health. We are therefore very pleased that CMS has proposed this new benefit to fight obesity in the Medicare population. Intensive behavioral therapy that includes both nutrition and physical activity interventions can help Medicare beneficiaries lose weight.

To further increase the effectiveness of the new benefit, however, we recommend that CMS:

- Use waist circumference measurement, in addition to body mass index (BMI), as the recommended screening tests
- Expand the duration of the benefit beyond the one-year mark to allow for continued weight loss and visits focused on weight maintenance
- Consider adding dieticians, exercise physiologists, and others with specialized expertise in obesity treatment to the list of eligible providers

We expand upon these recommendations below.

Waist Circumference as a Screening Test

The proposed decision memo directs providers to screen adults for obesity by calculating the BMI. AHA supports the use of the BMI to assess body weight. Assessing BMI is an important first step in diagnosing and managing obesity; it allows clinicians to classify levels of overweight and obesity and estimate body fat. However, the accuracy of BMI for diagnosing obesity is especially limited for individuals in the intermediate BMI ranges, those with increased muscle mass, and in the elderly, and misses more than half of people with excess fat.[i]

In addition, clinical and epidemiological evidence demonstrates that waist circumference is a better indicator than BMI of total body fat and intra-abdominal fat mass (visceral obesity).[ii] Abdominal adiposity and visceral fat provide a more refined health indicator of the risk for cardiovascular death than BMI.[iii] For example, one recent study found that individuals with a very large waist circumference had twice the risk of death during the study period. The study also found that risk of death increased in all individuals with a large waist, even if their BMI indicated a normal weight.[iv]

Adding waist circumference to the recommended BMI obesity screening could change the way clinicians assess obesity for individual patients, provide a more accurate assessment of overweight and obesity, and identify individuals whose weight and/or body fat place them at increased risk for cardiovascular disease, diabetes, and metabolic syndrome, as well as increased risk of death.

Waist circumference can easily be measured by a primary care provider and can be conducted at the same time as the proposed BMI screening. Research has shown that patients are comfortable with this measurement when the reasons for it are described to them.

We therefore request that CMS include waist circumference, in addition to the BMI, as the recommended screening tests.

Continued Weight Loss and Weight Maintenance

Under the proposed benefit, obese Medicare beneficiaries would be eligible for one face-to-face intensive behavioral counseling and therapy visit every week for the first month, one visit every other week for months two through six, and one visit every month for months seven through twelve. AHA does not have any specific concerns with this proposed visit frequency; however, we recommend that CMS consider including additional visits beyond the one-year mark for beneficiaries that have not yet met their goal weight. Additional visits – perhaps at a less frequent interval – would allow for continued weight loss. To be eligible for additional sessions past the one-year mark, the Agency could require beneficiaries to achieve a preset minimum weight loss during the first twelve months of therapy. This requirement could be structured similarly to the Agency's current proposal that beneficiaries must achieve at least a 3kg weight loss during the first six months in order to continue therapy at that point.

In addition, we recommend that CMS consider extending the benefit to focus on weight loss maintenance once the beneficiary has achieved his/her target weight or the weight loss phase has

been completed. As the U.S. Preventive Services Task Force (USPSTF) found in its evidence review, both initial interventions and maintenance interventions can help individuals sustain their weight loss over time. And as a recent study found, the practices that help people lose weight differ from those that help them maintain that weight loss.[v] Therefore, it is important that providers periodically meet with their patients to monitor weight loss and counsel them on the specific behaviors that contribute to successful weight loss maintenance. We expect that visits focused on weight loss maintenance could occur less frequently.

Professionals with Expertise in Obesity Treatment

As proposed, only primary care physicians and primary care practitioners (i.e., nurse practitioners, clinical nurse specialists, and physician assistants) would be allowed to provide intensive behavioral therapy for obesity. The benefit must also be provided in the primary care setting.

AHA agrees with CMS that primary care providers should, and do, play an important role in obesity treatment, but we question the Agency's decision to limit the provision of this benefit to the primary care setting. We are concerned that these narrow restrictions will prevent primary care providers from collaborating with or referring patients to other professionals with expertise in weight loss treatment and maintenance. As recommended by the National Institutes of Health (NIH) *Clinical Guidelines on the Identification, Evaluation, and Treatment of Overweight and Obesity in Adults*, providers may wish to "avail themselves of the various disciplines that offer expertise in dietary counseling, physical activity, and behavior change."[vi] To facilitate this type of collaboration, CMS should consider allowing nutritionists, exercise physiologists, and other experts to provide these services.

Conclusion

In closing, we applaud CMS for its efforts to address the obesity epidemic and we reiterate our strong support for the proposed benefit. We look forward to seeing intensive behavioral therapy for obesity added to the Medicare program as soon as possible.

To maximize the effectiveness of this benefit we recommended that the Agency add waist circumference measurement to BMI as the recommended screening tests; allow for additional visits beyond the one-year mark for beneficiaries who have not meet their target weight; and include additional visits specifically focused on weight loss maintenance.

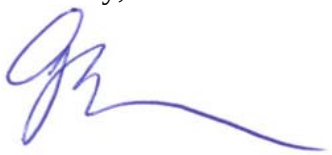
In addition, we recommend that CMS consider adding nutritionists, exercise physiologists, and other professionals with expertise in weight loss therapy and maintenance to the list of eligible providers.

Finally, as we noted in our April 2011 letter to the Agency, the NIH is currently in the process of updating its obesity guidelines. The USPSTF is also in the process of updating its recommendation for obesity screening and management. The updated guidelines and recommendations may serve as useful resources for CMS in the future. We recommend that CMS review the updated NIH guidelines and USPSTF recommendations when they are available and determine if any revisions to the benefit design are warranted at that time.

If you have any questions or need any additional information, 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

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[ii] Guagnano MT. Manigrasso MR. Capain F. Davi G. The "problem obesity": viewpoint of the internist. *Ann Ital Chir*. 2005; 76(5): 407-411.

[iii] Cornier MA, et al. Assessing Adiposity: A Scientific Statement from the American Heart Association. *Circulation.* 2011

[iv] Jacobs EJ, Newton CC, Wang Y, Patel AV, McCullough ML, Campbell P, Thun MJ, Gapstur. Waist circumference and all-cause mortality in a large US cohort. *Archives of Internal Medicine*. 2010;170(15):1293-1301.

[v] Sciamanna CN, et al. Practices Associated with Weight Loss Versus Weight Loss Maintenance. Am J Prev Med 2011;41(2):159 –166

[vi] See http://www.nhlbi.nih.gov/guidelines/obesity/ob_gdlns.htm.