In order to provide additional public input in the development of Medicare Local Coverage Determinations (LCD), Palmetto GBA will hold an Open LCD Meeting. Palmetto GBA encourages participation from the public during the Open Meeting portion of the Contractor Advisory Committee Process. Time must be scheduled in advance if interest parties want to share their views.

**Attendance is limited to those who register in advance.**

If you wish to address the public hearing, please observe the following guidelines:

1. To participate in an oral or written format, submit a written request with your name, address and telephone number to:
   
   Dr. Elaine Jeter  
   PO Box 100190  
   MailStop AG-300  
   Columbia, South Carolina 29202  
   Fax (803) 935-0199  
   e-mail: Elaine.Jeter@palmettogba.com

   Please state the nature of the presentation and the approximate time desired. If you plan to speak on behalf of an organization or group, please include the name and a brief description of the group. If you are a member of a group with more than one presenter, please list each presenter's name, address and telephone number. Submit your notification by FAX or telephone to Palmetto GBA no later than two days before the meeting. Palmetto GBA staff will make every effort to accommodate requests to speak from individuals received after the deadline. However, this may not always be possible and will depend upon the number of requests to speak.

2. Submit a copy of all written information for meeting discussion to Dr. Jeter. Palmetto GBA may distribute or mail your information to the Contractor Advisory Committee. Palmetto GBA will only transmit **scientific information relevant to the Evaluation of Evidence listed below to the CAC.** Only Palmetto GBA may distribute or mail materials to the CAC. Other interested parties or individuals may only distribute or mail information with written authorization from Palmetto GBA.

3. Once Palmetto GBA receives requests, a specific time will be allotted to each speaker. Speaker time will depend upon the number of requests received and the time assigned to the open public hearing portion of the meeting. Palmetto GBA staff will contact the speakers, by FAX or telephone, to confirm their participation, inform each speaker of the time allotted for his/her presentation, and answer questions. If time remains, we will accommodate late requests.

4. Specify the amount of time your presentation will require. Palmetto GBA staff may ask speakers with similar viewpoints to consolidate presentations.

5. Incorporate into your presentation an explanation of your financial association, if any, with the company(ies) whose products, services, or procedures are being considered by Palmetto GBA. For example, if a company has paid your transportation or other expenses to appear at the meeting or your organization receives funding from a company, this should be disclosed in your comments.
6. Prepare paper copies (20) of slides or overheads you plan to use. During the Contractor Advisory Committee meeting, we will distribute your copies to members and incorporate the information into the permanent record.

If you can’t attend the open public hearing during the time scheduled and would like to make a presentation, or if you arrive late to the meeting, please contact the designated Palmetto GBA staff person. Palmetto GBA will make every reasonable effort to arrange for you to speak at another time during the meeting, to have your statement read by a representative, or to have your complete summarized statement included in the record. However, once the public hearing portion of the meeting has ended, further oral comments from the public will be accepted only if time permits and at the discretion of the advisory committee Chairperson.

**Some Tips On Speaking At The Open Meeting:** If the Palmetto GBA staff anticipates a large audience, reserved seats will be held for speakers. Please check at the registration table to verify if reserved seating has been arranged for you. If not, you may be seated on a first come first serve basis.

When your name is called to speak, please proceed to the podium to present your remarks. The Palmetto GBA staff person will remind you when your speaking time has expired.

When you have completed your statement, Palmetto GBA staff may ask you questions. Please remain at the podium until the questioning is completed.

Thank you for your interest in participation in the Palmetto GBA Open Meeting process.

**Background:** Medicare contractors are responsible for the determination of services that are reasonable and necessary under the Social Security Act. Palmetto GBA uses the Contractor Advisory Committee (CAC) to provide advice on scientific and clinical questions regarding coverage so that Medicare beneficiaries can be better served regardless of race, ethnicity, or socioeconomic status. This coverage advice is published as a Local Carrier Decision (LCD), an administrative and educational tool, to assist providers, physicians and suppliers in submitting correct claims for payment. Local policies outline how contractors will review claims to ensure that they meet Medicare coverage requirements. LCDs must be consistent with national guidance (although they can be more detailed or specific), developed with input from medical professionals (through the CAC), and consistent with scientific evidence and clinical practice. The Open Meetings will increase the solicitation of additional information relevant to draft or suggested LCDs.

**Evaluation of Evidence:** To advise Palmetto GBA about a new medical item or service evidence at the Open Meeting, answer the following questions:

1. “Is the evidence concerning effectiveness in the Medicare population adequate to draw conclusions about magnitude of effectiveness relative to other items or services?"

2. “How does the magnitude of effectiveness of the new medical item or service compare to other available interventions?"

When assembling the body of evidence to be used in a deliberation, Open Meeting speakers should explore multiple evidence sources. The sources might include the peer-reviewed scientific literature, the recommendations of expert panels, and unpublished data used to secure FDA approval. The quality of the evidence from these sources will vary, and the panels should weigh the evidence according to its quality.
1. **Adequacy of evidence:** The speaker should demonstrate scientific evidence is adequate to draw conclusions about the effectiveness of the intervention in routine clinical use in the population of Medicare beneficiaries.

Comment: Assessing the adequacy of the evidence is a sine qua non of essentially all modern approaches to the evaluation of medical technologies. Defining what constitutes adequate evidence is a critical step. The definition of adequate evidence includes the validity of the evidence and its general applicability to the population of interest.

Many forms of rigorous evidence can be valid, or not, depending on circumstances specific to the individual study. The most rigorous type of evidence is ordinarily a large, well-designed randomized controlled clinical trial. The ideal randomized clinical trial should have appropriate endpoints, should enroll a representative sample of patients, should be conducted in clinical practice in the patient population of interest, and should evaluate interventions (diagnostic tests, surgical procedures, medical devices, drugs) as typically used in routine clinical practice.

When several such well-designed trials yield consistent results, there is likely to be a strong consensus that the evidence is sufficient. This level of evidence will likely be unavailable for many of the interventions that the carrier will evaluate. There may be randomized trials conducted in other populations (e.g., middle-aged men rather than men and women 65 years of age and older), randomized trials with important design flaws (e.g., they are not double-blinded), or nonrandomized studies with concurrent controls. Deciding whether such studies constitute valid, applicable evidence can be very difficult.

In considering the evidence from any study, whether randomized or not, the speakers should try to answer these two main questions:

**Bias:** Does the study systematically over- or underestimate the effect of the intervention because of possible bias or other errors in assigning patients to intervention and control groups?

There are many potential sources of bias. In observational study designs, the investigators simply observe patient care without intervening to allocate patients to intervention or control groups. In such studies, the investigators cannot be sure that they have observed and recorded all of the ways in which treated patients differ from untreated patients. If some of these characteristics influence both health outcomes and the likelihood of receiving the intervention, at least part of the measured treatment effect will be a result of the patient characteristics rather than the treatment itself. This particular bias is called selection bias. For example, in comparing a new, extensive surgical procedure to a less extensive operation, researchers might measure survival one year after the two procedures. Surgeons might avoid performing an extensive operation on patients with severe co-morbid illness. If, in an observational study, the researchers failed to measure co-morbid conditions, they might conclude that the patient groups were similar. If patients who got surgery for a disease had better one year survival than those who did not get surgery, the reason could be the good health of those that the surgeons selected for surgery, rather than the surgery itself.

Random allocation of patients to the intervention under study eliminates systematic selection bias. In a properly designed and conducted randomized trial, apart from random differences, the group of patients receiving the intervention and the group receiving the alternative are identical with respect to all characteristics, measured and unmeasured. The investigators can be fairly certain that any observed difference in
health outcomes is the result of the intervention. Unbalanced allocation can occur with randomized allocation of subjects, but it is very unlikely when the study groups contain a large number of patients.

In an observational, non-randomized study, it is usually very difficult to determine whether bias could account for the results. However, there may be important exceptions. For example, if a disease is uniformly fatal within six weeks, and an observational study demonstrates that half of all patients receiving a new treatment survive for at least a year, it is not necessary to conduct a randomized controlled trial to obtain adequate evidence that the treatment is effective. On the other hand, the outcomes of most diseases with and without treatment are less predictable than in this extreme case and depend upon difficult-to-measure aspects of each patient's health. In these diseases, bias can strongly influence the results of observational studies. Bias is especially likely if the intervention under study is dangerous or toxic, because physicians might avoid prescribing it for patients who are particularly likely to suffer ill effects. Clinical trials of treatments for cancers that have an unpredictable natural history, for example, have demonstrated that the results of observational studies frequently overly overestimate the size of the treatment effect.

To detect important bias in observational studies, the carrier will carefully consider all of the evidence, including the comprehensiveness of the available data, how physicians selected patients to receive the intervention, and the extent of disease in intervention and control group patients. In some cases, the panel may decide that it cannot draw firm conclusions about effectiveness without randomized trials.

Although they do not have randomized controls, all well designed observational studies include some form of control. Controls may consist of an implicit or explicit control group or statistical controls. A body of evidence consisting solely of studies with no controls whatsoever - whether based on anecdotal evidence, testimonials, or case series - is never adequate. However in many cases the panel will determine that observational evidence is sufficient to draw conclusions about effectiveness. When these circumstances apply, the panel must describe possible sources of bias and explain the basis for its decision that bias is unlikely to account for the results.

**External validity:** - Do the results apply to the Medicare population? Medicare beneficiaries include elderly, non-elderly, and disabled people. The Medicare population also may or may not include patients with co-morbid disease. Historically many controlled trials unfortunately excluded older men and women, people with disabilities, and people with co-morbid disease. Thus, these studies may have had adequate statistical power for the study population, but their results may or may not be generalizable to some portions or all of the Medicare population. If the speaker believes there is a medical benefit beyond the clinical and demographic characteristics of the study population, the speaker should state whether he/she believes the results of the studies are applicable to some groups covered by Medicare, define the groups, and explain its reasoning.

Issues of external validity also apply to the intervention. For a drug or device, the intervention is the same when used in different settings. But other interventions may differ from one site to another. For example, the outcomes of a complex surgical procedure can depend heavily on the skills of the surgeons and other staff caring for the patient. If available trials only include sites where surgeons have the best outcomes, the outcomes might be considerably better than what is possible in typical practice settings. The speaker must state whether the results are likely to apply to the general practice setting and explain its reasoning.
The second major criterion for evaluating evidence is the size and direction (more effective, as effective, or less effective) of the health effect that it demonstrates.

2. **Size of Health Effect:** Evidence from well-designed studies (meeting criterion #1 above) must establish how the effectiveness of the new intervention compares to the effectiveness of established services and medical items.

Comment: If the evidence is adequate to draw conclusions (as defined above), the next question is the size and direction of the effect compared with interventions that are widely used. In evaluating the evidence for an intervention, the speaker should place the size and direction of effectiveness, as compared to established services or medical items, into one of these seven categories:

1. Breakthrough technology: The improvement in health outcomes is so large that the intervention becomes standard of care.

2. More effective: The new intervention improves health outcomes by a significant, albeit small, margin as compared with established services or medical items.

3. As effective but with advantages: The intervention has the same effect on health outcomes as established services or medical items but has some advantages (convenience, rapidity of effect, fewer side effects, other advantages) that some patients will prefer.

4. As effective and with no advantages: The intervention has the same effect on health outcomes as established alternatives but with no advantages.

5. Less effective but with advantages: Although the intervention is less effective than established alternatives (but more effective than doing nothing), it has some advantages (such as convenience, tolerability).

6. Less effective and with no advantages: The intervention is less effective than established alternatives (but more effective than doing nothing) and has no significant advantages.

7. Not effective: The intervention has no effect or has deleterious effects on health outcomes when compared with "doing nothing, (e.g., treatment with placebo or patient management without the use of a diagnostic test).

**Web sites for evidence-based medicine** [http://cebm.jr2.ox.ac.uk/docs/levels.html](http://cebm.jr2.ox.ac.uk/docs/levels.html) (table depicting in detail evidence hierarchy. From Oxford Center on EBM).

**Books on evidence-based medicine:**