

for a service," we would publish the decision as a general notice in the **Federal Register** (64 FR 22624).

Multiple-seizure electroconvulsive therapy (MECT), sensory nerve conduction threshold testing (sNCT), and noncontact normothermic wound therapy (NNWT) did not have NCDs governing Medicare coverage prior to the effective dates noted above. Therefore, coverage for each of these services was at the discretion of the local Medicare contractor.

This notice restates our previous decisions, announced in program instructions, to withdraw coverage nationally for multiple-seizure electroconvulsive therapy (CR 2499, TR AB-03-003, 01/10/03), electrodiagnostic sensory nerve conduction threshold testing (CR 2153, TR AB-02-066, 05/02/02), and noncontact normothermic wound therapy (CR 2027, TR AB-02-025, 02/15/02). Medicare has not covered multiple-seizure electroconvulsive therapy, electrodiagnostic sensory nerve conduction threshold testing, and noncontact normothermic wound therapy as of the effective dates noted above.

#### **Multiple-Seizure Electroconvulsive Therapy (MECT)**

We have examined the medical and scientific evidence as well as the additional information obtained as a result of our own investigation. We have determined that the available evidence is adequate to conclude that MECT may pose additional safety risks over conventional electroconvulsive therapy (ECT) for patients with affective disorders or other psychiatric disorders without a balancing clinical benefit.

We have also found that the available evidence, limited to case reports, is not adequate to conclude that non-routine use of MECT is warranted for medical conditions such as neuroleptic malignant syndrome and intractable seizures that do not respond to other therapies.

Therefore, MECT (including the practice of routinely initiating treatment with double-seizure ECT) is considered not reasonable and necessary for the treatment of psychiatric and non-psychiatric conditions in the Medicare population.

#### **Sensory Nerve Conduction Threshold Testing (sNCT)**

The available scientific evidence is not adequate to demonstrate the accuracy of sNCT or the accuracy of sNCT as compared to nerve conduction studies (NCS). Unlike NCS, sNCT does not assess the integrity of motor nerves,

which is important in evaluating some patient populations, such as diabetics. In addition, it is not evident that sNCT offers any diagnostic advantages over a history and physical examination in detecting the presence of a neuropathy. There are also no clinical studies that we identified that demonstrate that the use of sNCT leads to changes in patient management in a particular Medicare subpopulation. As stated in 42 CFR 410.32, a diagnostic test is not reasonable and necessary unless its results are used by the treating physician (who also orders the test) in the management of the beneficiary's specific medical problem.

In our discussions with experts, we were also unable to identify a subpopulation with whom the results of sNCT would alter medical care. We conclude that the scientific and medical literature does not demonstrate that the use of sNCT to diagnose sensory neuropathies in Medicare beneficiaries is reasonable and necessary.

#### **Noncontact Normothermic Wound Therapy (NNWT)**

The medical literature does not support a finding that NNWT heals any wound type better than conventional treatment. While the submitted studies support better healing, due to serious methodological weaknesses, inadequate controls, and a variety of biases, the improved outcomes could also easily disappear in a properly controlled randomized trial.

We have decided to issue a national noncoverage policy for all uses of NNWT for the treatment of wounds because the medical literature is not sufficient to support a NCD.

For complete decision memoranda providing the rationale for these withdrawals, please refer to [http://www.cms.gov/ncdr/ncdr\\_index.asp](http://www.cms.gov/ncdr/ncdr_index.asp) on the Internet and scroll down to the appropriate topic under completed determinations.

**Authority:** Sections 1862, 1869(b)(3), and 1871 of the Social Security Act (42 U.S.C. 1395y, 1395ff(b)(3), and 1395hh). (Catalog of Federal Domestic Assistance Program No. 93.773 Medicare—Hospital Insurance Program; and No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: May 30, 2003.

**Thomas A. Scully,**

*Administrator, Centers for Medicare & Medicaid Services.*

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## **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### **Centers for Medicare & Medicaid Services**

[CMS-1260-N]

#### **Medicare Program; Meeting of the Advisory Panel on Ambulatory Payment Classification Groups—August 22, 2003**

**AGENCY:** Centers for Medicare & Medicaid Services (CMS), HHS.

**ACTION:** Notice of meeting.

**SUMMARY:** In accordance with section 10(a) of the Federal Advisory Committee Act (5 U.S.C. Appendix 2), this notice announces the second biannual meeting of the Advisory Panel on Ambulatory Payment Classification (APC) Groups (the Panel) for 2003.

The purpose of the Panel is to review the APC groups and their associated weights and to advise the Secretary of Health and Human Services (the Secretary) and the Administrator of the Centers for Medicare & Medicaid Services (CMS) (the Administrator) concerning the clinical integrity of the APC groups and their associated weights. The advice provided by the Panel will be considered as CMS prepares its annual updates of the hospital outpatient prospective payment system (OPPS) through rulemaking.

**DATES:** The second biannual meeting for 2003 is scheduled for Friday, August 22, 2003, from 8 a.m. to 5 p.m. (e.d.t.).

**ADDRESSES:** The meeting will be held in the Multipurpose Room, 1st Floor, at the CMS Central Office, 7500 Security Boulevard, Baltimore, Maryland 21244-1850.

**FOR FURTHER INFORMATION CONTACT:** For copies of the charter, for inquiries regarding these meetings, for meeting registration, and for submitting oral presentations or written agenda items, contact Shirl Ackerman-Ross, the meeting coordinator and Designated Federal Official, CMS, Center for Medicare Management, Hospital Ambulatory Policy Group, Division of Outpatient Care, 7500 Security Boulevard, Mail Stop C4-05-17, Baltimore, MD 21244-1850 or phone (410) 786-4474. Also, please refer to the CMS Advisory Committees' Information Line at 1-877-449-5659 (toll free) and (410) 786-9379 (local).

For additional information on the APC meeting agenda topics and/or updates to the Panel's activities, search our Internet Web site: <http://www.cms.hhs.gov/faca/apc/default.asp>.

To submit a request for a copy of the charter, search the Internet at <http://>

[www.cms.hhs.gov/faca](http://www.cms.hhs.gov/faca) or e-mail  
 SAckermannross@cms.hhs.gov.

Written materials may also be sent electronically to  
 outpatientpps@cms.hhs.gov.

News media representatives should contact our Public Affairs Office at (202) 690-6145.

## Background

**SUPPLEMENTARY INFORMATION:** The Secretary of the Department of Health and Human Services (the Secretary) is required by section 1833(t)(9)(A) of the Social Security Act (the Act), as amended by section 201(h)(1)(B) and redesignated by section 202(a)(2) of the Balanced Budget Refinement Act (BBRA) of 1999 (Pub. L. 106-113), to establish and consult with an expert, outside advisory panel on Ambulatory Payment Classification (APC) groups. The Advisory Panel on Ambulatory Payment Classification Groups (the Panel) meets up to three times annually to review the APC groups and to provide technical advice to the Secretary and to the Administrator of the Centers for Medicare & Medicaid Services (CMS) (the Administrator) concerning the clinical integrity of the groups and their associated weights. We will consider the technical advice provided by the Panel as we prepare the proposed rule that proposes changes to the Outpatient Prospective Payment System (OPPS) for the next calendar year.

The Panel may consist of up to 15 representatives of Medicare providers that are subject to the OPPS and a Chair. The Administrator selected the Panel membership based upon either self-nominations or nominations submitted by providers or organizations.

The Panel presently consists of the following members and a Chair: Paul Rudolf, M.D., J.D., Chair, a CMS medical officer; Geneva Craig, R.N., M.A.; Lora DeWald, M.Ed.; Robert E. Henkin, M.D.; Stephen T. House, M.D.; Kathleen Kinslow, C.R.N.A., Ed.D.; Mike Metro, R.N., B.S.; Gerald V. Naccarelli, M.D.; and Beverly K. Philip, M.D.

The new members recently appointed to the Panel are: Marilyn Bedell, M.S., R.N., O.C.N.; Albert Brooks Einstein, Jr., M.D.; Lee H. Hilborne, M.D., M.P.H. (reappointment); Frank G. Opelka, M.D., F.A.C.S.; Lynn R. Tomascik, R.N., M.S.N., C.N.A.A.; Timothy Gene Tyler, Pharm.D.; and William Van Decker, M.D. (reappointment).

The agenda for the August 2003 meeting will provide for discussion and comment on the following topics:

- Reconfiguration of APCs (for example, splitting of APCs, moving Healthcare Common Procedure Coding

System (HCPCS) codes from one APC to another, and moving HCPCS codes from New Technology APCs to Clinical APCs).

- Evaluation of APC weights.
- Packaging devices and drug costs into APCs: methodology, effect on APCs, and need for reconfiguring APCs based upon device and drug packaging.
- Removal of procedures from the inpatient list for payment under the OPPS.
- Use of single and multiple procedure claims data.
- Packaging of HCPCS codes.
- Other technical issues concerning APC structure.

We are soliciting comments from the public on specific proposed items falling within these agenda topics for the August 2003 Panel meeting. We will consider agenda topics for this meeting if they are submitted in writing and fall within the agenda topics listed above. We urge those who wish to comment to send comments as soon as possible, but no later than 5 p.m. (e.d.t.) on Thursday, August 14, 2003.

The meeting is open to the public, but attendance is limited to the space available. Individuals or organizations wishing to make 5-minute oral presentations should contact the meeting coordinator by 5 p.m. (e.d.t.) on Thursday, August 14, 2003, in order to be scheduled. The number of oral presentations may be limited by the time available. Oral presentations should not exceed 5 minutes.

Persons wishing to present must submit a copy of the presentation and the name, address, and telephone number of the presenter. In addition, all presentations must contain, at a minimum, the following supporting information and data:

- The presenter's financial relationship(s), if any, with any company whose products, services, or procedures are under consideration.
- Physicians' Current Procedural Terminology (CPT) codes involved.
- APC(s) affected.
- Description of the issue(s).
- Clinical description of the service under discussion (with comparison to other services within the APC).
- Recommendations and rationale for change.
- Expected outcome of change and potential consequences of not making the change.

Submit a written copy of the oral remarks or written agenda items to the meeting coordinator listed above or electronically to the address: [outpatientpps@cms.hhs.gov](mailto:outpatientpps@cms.hhs.gov). Because of staffing and resource limitations, we cannot accept comments by facsimile

(FAX) transmission and cannot acknowledge or respond individually to comments we receive.

In addition to formal presentations, there will be an opportunity during the meeting for public comment, limited to 1 minute for each individual or organization.

Persons wishing to attend this meeting, which is located on Federal property, must call the meeting coordinator, Shirl Ackerman-Ross, at (410) 786-4474, to register in advance no later than Thursday, August 14, 2003. Persons attending must present a photographic identification to the Federal Protective Service or Guard Service personnel before they will be allowed to enter the building.

Persons who are not registered in advance will not be permitted into the building and will not be permitted to attend the meeting.

A member of our staff will be stationed at the Central Building, first-floor lobby, to provide assistance to attendees. Please remember that all visitors must be escorted if they have business in areas other than the lower and first floor levels in the Central Building. Parking permits and instructions are issued upon arrival by the guards at the main entrance.

**Special Accommodation:** Individuals requiring sign language interpretation or other special accommodations should send a request for these services to the meeting coordinator by Thursday, August 14, 2003.

**Authority:** Section 1833(t) of the Act (42 U.S.C. 1395l(t), as amended by section 201(h) of the BBRA of 1999 (Pub. L. 106-113). The Panel is governed by the provisions of Pub. L. 92-463, as amended (5 U.S.C. Appendix 2).

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: July 11, 2003.

**Thomas A. Scully,**

*Administrator, Centers for Medicare & Medicaid Services.*

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