HCFA Rulings

Department of Health and Human Services

Health Care Financing Administration

Ruling No. 82-3

Date: 1982

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MEDICARE PROGRAM

Hospital Insurance Benefits (Part A)

Conditions for Medicare Coverage of Surgery to Relieve Obstructions to Vertebral Artery Blood Flow (Vertebral Artery Surgery)

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Purpose: This Ruling restates policy on Medicare coverage of vertebral artery surgery.

Citations: Section 1862(a)(1) of the Social Security Act (42 U.S.C. 1395y(a)(1)); 42 CFR 405.310(k); 42 CFR 401.108; 47 FR 54939, December 7, 1982.

Pertinent History: Section 1862(a)(1) of the Social Security Act prohibits payment for any expenses incurred for items or services "which are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member". HCFA has interpreted this provision to exclude from Medicare coverage, health care services and items that are not demonstrated by acceptable clinical evidence to be safe and effective. A variety of standards are used to determine whether there is acceptable clinical evidence to warrant a service or procedure. These include approval by the National Institutes of Health, testing by university medical centers, reports published in major medical journals, and general acceptance by the medical community. HCFA's source of medical advice on issues of medical safety and efficacy of items and services is the Public Health Service (PHS).

In 1978, in response to a request by HCFA, PHS advised that five types of vertebral artery surgery can be medically reasonable and necessary, provided that certain conditions are met. This advice was incorporated in instructions

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to carriers and intermediaries, effective for services furnished on or after September 1, 1978. (See Part A Intermediary Manual, Chapter II, Coverage of Services, Coverage Issues Appendix, §35-32; Medicare Carriers Manual, Chapter II, Coverage and Limitations, Coverage Issues Appendix, §35-32; and Medicare Hospital Manual, Chapter II, Coverage of Hospital Services, Coverage Issues Appendix, §35-32.)¹

Since that time, it has come to our attention that these instructions have been challenged in hearings before Administrative Law Judges (ALJs). These hearings provide an opportunity to appeal determinations by a carrier or intermediary that a procedure is not medically reasonable and necessary in a particular case. Because it is not feasible administratively to present expert medical advice at each hearing in which this issue may arise, we are adopting these instructions as a Ruling in order to make them binding on ALJs. This will also assure that HCFA's policy on this issue is applied uniformly.

Held: The following five surgical procedures are performed to relieve obstructions to vertebral artery blood flow –

- 1. Vertebral artery endarterectomy, a procedure that removes arteriosclerotic plaques that are inside the vertebral artery;
- 2. Vertebral artery by-pass or resection with anastomosis or graft;
- 3. Subclavian artery resection, with or without endarterectomy;

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- 4. Removal of laterally located osteophytes anywhere in the C₆(C₇)-C₂ course of the vertebral artery; and
- 5. Arteriolysis that frees the artery from surrounding tissue, with or without arteriopexy (fixation of the vessel).

These procedures are safe and effective and, as such, are covered Medicare services, only if each of the following conditions is met:

- 1. Symptoms of vertebral artery obstruction exist. These symptoms include vertigo (sometimes called "dizziness"), vision or speech defects, transient basilar ischemia, stroke, ataxia, and mental confusion. Rotation of the patient's head during physical examination may elicit or accentuate the symptoms.
- 2. Conditions other than obstructions resulting in blocked vertebral artery blood flow have been considered and ruled out. Other possible causes include orthostatic hypotension, acoustic neuroma, labyrinthitis, diabetes mellitus, various degenerative and systemic disorders of the brain and nervous system, and hypoglycemia-related disorders.

¹ These references were replaced by the Coverage Issues Manual after this Ruling's publication in the Federal Register.

- 3. There is radiographic evidence of a valid vertebral artery obstruction. If angiograms are used, they should show the aortic arch with the vessels off the arch and the vessels of the head and neck, providing biplane views of the carotid and vertebral vascular system. Serial views are also needed to be able to diagnose subclavian artery obstruction. Obstructions include
 - a. Intravascular obstructions, that is, arteriosclerotic lesions within the vertebral artery or in other arteries;

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- b. Extravascular obstructions such as
 - i. Bony tissue or osteophytes, located laterally in the $C_6(C_7)$ - C_2 cervical vertebral area course of the vertebral artery, most commonly at C_5 - C_6 ;
 - ii. Anatomical variations, that is, anomalous location of the origin of the vertebral artery, and tortuosity and kinks of the vertebral artery; and
 - iii. Fibrous tissue, that is, connective tissue changed as a result of manipulation of the neck for neck pain or injury associated with bematoma (also called "external bands", "tendinous slings", and "fibrous bands").

Connective tissue along the course of the vertebral artery and vertebral artery tortuosity and kinks only rarely result in symptoms of vertebral artery obstruction.

4. Contraindications to the procedure are not present. For example, coexistent obstructions of multiple cerebral vessels would prevent increased blood flow through the vertebral artery from significantly benefiting the patient.

Further Held: Vertebral artery surgery not meeting the conditions described in this Ruling is excluded from Medicare coverage under the authority of section 1862(a)(1) of the Act.

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Effective Date: As explained above, we have previously issued policy in general instructions providing for Medicare coverage of vertebral artery surgery within certain limitations, effective for services furnished on or after September 1, 1978. Since this Ruling is a restatement of policy that has been in effect since that date, this Ruling is effective for services furnished on or after September 1, 1978.