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# Medicare

## Intermediary Manual

### Part 3 - Claims Process

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Department of Health &  
Human Services (DHHS)  
Centers for Medicare &  
Medicaid Services (CMS)

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<u>HEADER SECTION NUMBERS</u>	<u>PAGES TO INSERT</u>	<u>PAGES TO DELETE</u>
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**NEW/REVISED MATERIAL--*EFFECTIVE DATE:* January 1, 2003**  
***IMPLEMENTATION DATE:* January 1, 2003**

Section 3157.1, Hearing Aid Exclusion, is added to clarify which devices are considered to be hearing aids and, are therefore, excluded from coverage.

**DISCLAIMER:** The revision date and transmittal number only apply to the redlined material. All other material was previously published in the manual and is only being reprinted.

**These instructions should be implemented within your current operating budget.**

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Intermediate risk groups currently identified include:

Staff in institutions for the mentally retarded; and  
Workers in health care professions who have frequent contact with blood or blood-derived body fluids during routine work.

EXCEPTION: Persons in the above-listed groups are not considered at high or intermediate risk of contracting hepatitis B, however, if there is laboratory evidence positive for antibodies to hepatitis B. (ESRD patients are routinely tested for hepatitis B antibodies as part of their continuing monitoring and therapy.)

For Medicare program purposes, the vaccine may be administered upon the order of a doctor of medicine or osteopathy by home health agencies, skilled nursing facilities, ESRD facilities, hospital outpatient departments, persons recognized under the "incident to physicians' services" provision of the law, and, of course, doctors of medicine and osteopathy.

A charge separate from the ESRD composite rate will be recognized and paid for administration of the vaccine to ESRD patients.

See §3112.4.B and Coverage Issues Manual, §50-17.

3. Influenza Virus Vaccine.--Effective for services furnished on or after May 1, 1993, the Medicare Part B program covers influenza virus vaccine and its administration when furnished in compliance with any applicable State law by any provider of services or any entity or individual with a supplier number.

Typically, these vaccines are administered once a year in the fall or winter. Medicare does not require for coverage purposes that the vaccine must be ordered by a doctor of medicine or osteopathy. Therefore, the beneficiary may receive the vaccine upon request without a physician's order and without physician supervision.

B. Antigens.--Prior to the Omnibus Reconciliation Act of 1980, a physician who prepared an antigen for a patient could not be reimbursed for that service unless the physician also administered the antigen to the patient. Effective January 1, 1981, payment may be made for a reasonable supply of antigens that have been prepared for a particular patient even though they have not been administered to the patient by the same physician who prepared them if: (1) the antigens are prepared by a physician who is a doctor of medicine or osteopathy, and (2) the physician who prepared the antigens has examined the patient and has determined a plan of treatment and a dosage regimen. The associations of allergists that we consulted advised us that a reasonable supply of antigens is considered to be not more than a 12-week supply of antigens that has been prepared for a particular patient at any one time. The purpose of the reasonable supply limitation is to assure that the antigens retain their potency and effectiveness over the period in which they are to be administered to the patient. (See §3112.4.B.)

### 3157.1 HEARING AID EXCLUSION

Section 1862(a)(7) of the Social Security Act states that no payment may be made under part A or part B for any expenses incurred for items or services "where such expenses are for . . . hearing aids or examinations therefore. . . ." This policy is further reiterated at 42 CFR 411.15(d) which specifically states that "hearing aids or examination for the purpose of prescribing, fitting, or changing hearing aids" are excluded from coverage.

At the time of passage of the hearing aid exclusion, all hearing aids utilized functional air and/or bone conduction pathways to facilitate hearing. We are clarifying that any device that does not produce as its output an electrical signal that directly stimulates the auditory nerve is a hearing aid for the purposes of Medicare payment policy. Examples of hearing aids are devices that produce air-conducted sound into the external auditory canal, devices that produce sound by mechanically vibrating bone, or devices that produce sound by vibrating the cochlear fluid through stimulation of the round window. Devices such as cochlear implants, which produce as their output an electrical signal that directly stimulates the auditory nerve, are not considered to be hearing aids for purposes of Medicare payment policy. (See Coverage Issues Manual §65-14).

Medicare contractors are to deny payment for an item or service that is associated with any hearing aid as defined above. This clarification is not meant to change policy for the medically necessary treatment of complications of implantable hearing aids, such as medically necessary removals of implantable hearing aids due to infection. See §§3101 and 3101.14 of Part 3 of the Medicare Intermediary Manual.