| CMS Manual System | Department of Health & Human Services (DHHS) |
|---|---|
| Pub 100-02 Medicare Benefit Policy | Centers for Medicare & Medicaid Services (CMS) |
| **Transmittal 186** | **Date: April 16, 2014** |
| | **Change Request 8665** |

**Transmittal 184, dated April 11, 2014, is being rescinded and replaced by Transmittal 186 to correct the Effective Date in the Pub. 100-02 manual instruction to January 1, 2001. All other information remains the same.**

**SUBJECT: Clarification to Pub. 100-02, Medicare Benefit Policy Manual Regarding Antigens and Deletion of Section 13.14 from Chapter 13 of Pub. 100-08, Medicare Program Integrity Manual**

**I. SUMMARY OF CHANGES:** This change request serves to make the Medicare Benefit Policy Manual provisions consistent with regulatory requirements. Additionally, revisions are being made to Chapter 13 of the Program Integrity Manual (PIM) to accurately reflect CMS's plan to implement section 731 of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA).

**EFFECTIVE DATE: January 1, 2001 - (Antigen Update); February 24, 2014 - (Section 13.14 deletion)**
**Unless otherwise specified, the effective date is the date of service.*
**IMPLEMENTATION DATE: May 12, 2014**

***Disclaimer for manual changes only: The revision date and transmittal number apply only to red italicized material. Any other material was previously published and remains unchanged. However, if this revision contains a table of contents, you will receive the new/revised information only, and not the entire table of contents.***

**II. CHANGES IN MANUAL INSTRUCTIONS:** (N/A if manual is not updated)
R=REVISED, N=NEW, D=DELETED

| R/N/D | CHAPTER / SECTION / SUBSECTION / TITLE |
|---|---|
| **R** | 15/50/4.4.1/Antigens |
| **R** | 16/90/Routine Services and Appliances |

**III. FUNDING:**
**For Medicare Administrative Contractors (MACs):**
The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC statement of Work. The contractor is not obliged to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the Contracting Officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the Contracting Officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

## IV. ATTACHMENTS:

**Business Requirements**
**Manual Instruction**

# Attachment - Business Requirements

| Pub. 100-02 | Transmittal: 186 | Date: April 16, 2014 | Change Request: 8665 |
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## I. GENERAL INFORMATION

**A. Background:** Section 1861(s)(2)(G) the Social Security Act (the Act) authorizes Medicare coverage of "antigens (subject to quantity limitations prescribed in regulations by the Secretary)". Implementing regulations were established at 42 CFR 410.68 to identify a reasonable supply of antigens is considered to be not more than a 12-month supply.

**B. Policy:** This change request serves to make the Medicare Benefit Policy Manual provisions regarding a reasonable supply of antigens consistent with the regulatory requirements mentioned above.

## II. BUSINESS REQUIREMENTS TABLE

*"Shall" denotes a mandatory requirement, and "should" denotes an optional requirement.*

| Number | Requirement | Responsibility | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | | A/B MAC | | | DME MAC | Shared-System Maintainers | | | | Other |
| | | A | B | HHH | | FISS | MCS | VMS | CWF | |
| 8665 - 02.1 | Contractors shall be aware of the corrections in Pub. 100-02, chapter 15, section 50.4.4.1 and chapter 16, section 90, to align with 42 CFR 410.68, which identifies a reasonable supply of antigens is considered to be not more than a 12-month supply of antigens that has been prepared for a particular patient at any one time. **NOTE:** All other aspects of these sections remain the same. | X | X | | | | | | | |

## III. PROVIDER EDUCATION TABLE

| Number | Requirement | Responsibility | | | | |
|---|---|---|---|---|---|---|
| | | A/B MAC | | | DME MAC | CEDI |
| | | A | B | HHH | | |
| 8665 - 02.2 | CR as Provider Education: Contractors shall post this entire instruction, or a direct link to this instruction, on their Web sites and include information about it in a listserv message within 1 week of the release of this instruction. In addition, the entire instruction must be included in the contractor's next regularly scheduled bulletin. Contractors are free to supplement it with localized information that would benefit their provider community in billing and administering the Medicare program correctly. | X | X | X | X | |

## IV. SUPPORTING INFORMATION

**Section A: Recommendations and supporting information associated with listed requirements:** N/A

*"Should" denotes a recommendation.*

| X-Ref Requirement Number | Recommendations or other supporting information: |
|---|---|
| | |

**Section B: All other recommendations and supporting information:** N/A

## V. CONTACTS

**Pre-Implementation Contact(s):** Cheryl Gilbreath, 410-786-5919 or Cheryl.Gilbreath@cms.hhs.gov (Coverage), Wanda Belle, 410-786-7491 or wanda.belle@cms.hhs.gov (Coverage)

**Post-Implementation Contact(s):** Contact your Contracting Officer's Representative (COR).

## VI. FUNDING

**Section A: For Medicare Administrative Contractors (MACs):**
The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC Statement of Work. The contractor is not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the Contracting Officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the Contracting Officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

# Medicare Benefit Policy Manual
## Chapter 15 – Covered Medical and Other Health Services

### 50.4.4.1 - Antigens
***(Rev. 186, Issued: 04-16-14, Effective: 01-01 01, Implementation: 05-12-14)***

Payment may be made for a reasonable supply of antigens that have been prepared for a particular patient 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.

Antigens must be administered in accordance with the plan of treatment and by a doctor of medicine or osteopathy or by a properly instructed person (who could be the patient) under the supervision of the doctor. The associations of allergists that CMS consulted advised that a reasonable supply of antigens is considered to be not more than a 12-*month* 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 §§20.2 and 50.2.)

# Medicare Benefit Policy Manual
## Chapter 16 - General Exclusions From Coverage

### 90 - Routine Services and Appliances

***(Rev. 186, Issued: 04-16-14, Effective: 01-01 01, Implementation: 05-12-14)***

Routine physical checkups; eyeglasses, contact lenses, and eye examinations for the purpose of prescribing, fitting, or changing eyeglasses; eye refractions by whatever practitioner and for whatever purpose performed; hearing aids and examinations for hearing aids; and immunizations are not covered.

The routine physical checkup exclusion applies to (a) examinations performed without relationship to treatment or diagnosis for a specific illness, symptom, complaint, or injury; and (b) examinations required by third parties such as insurance companies, business establishments, or Government agencies.

The routine physical checkup exclusion does not apply to the following services (as noted in section 42 CFR 411.15(a)(1)):

- Screening mammography,
- Colorectal cancer screening tests,
- Screening pelvic exams,
- Prostate cancer screening tests,
- Glaucoma screening exams,
- Ultrasound screening for abdominal aortic aneurysms (AAA),
- cardiovascular disease screening tests,
- diabetes screening tests,
- screening electrocardiogram,
- Initial preventive physical examinations,
- Annual wellness visits providing personalized prevention plan services, and
- Additional preventive services that meet the criteria specified in 42 CFR 410.64.

If the claim is for a diagnostic test or examination performed solely for the purpose of establishing a claim under title IV of Public Law 91-173, “Black Lung Benefits,” the service is not covered under Medicare and the claimant should be advised to contact their Social Security office regarding the filing of a claim for reimbursement under the “Black Lung” program.

The exclusions apply to eyeglasses or contact lenses, and eye examinations for the purpose of prescribing, fitting, or changing eyeglasses or contact lenses for refractive errors. The exclusions do not apply to physicians’ services (and services incident to a physicians’ service) performed in conjunction with an eye disease, as for example, glaucoma or cataracts, or to post-surgical prosthetic lenses which are customarily used during convalescence from eye surgery in which the lens of the eye was removed, or to permanent prosthetic lenses required by an individual lacking the organic lens of the eye, whether by surgical removal or congenital disease. Such prosthetic lens is a replacement for an internal body organ - the lens of the eye. (See the Medicare Benefit Policy Manual, Chapter 15, “Covered Medical and Other Health Services,” §120).

Expenses for all refractive procedures, whether performed by an ophthalmologist (or any other physician) or an optometrist and without regard to the reason for performance of the refraction, are excluded from coverage.

#### A. Immunizations

Vaccinations or inoculations are excluded as immunizations unless they are either:

- Directly related to the treatment of an injury or direct exposure to a disease or condition, such as antirabies treatment, tetanus antitoxin or booster vaccine, botulin antitoxin, antivenin sera, or immune globulin. (In the absence of injury or direct exposure, preventive immunization (vaccination or inoculation) against such diseases as smallpox, polio, diphtheria, etc., is not covered.); or

- Specifically covered by statute, as described in the Medicare Benefit Policy Manual, Chapter 15, "Covered Medical and Other Health Services," §50.4.4.2.

**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:

- The antigens are prepared by a physician who is a doctor of medicine or osteopathy, and

- The physician who prepared the antigens has examined the patient and has determined a plan of treatment and a dosage regimen.

A reasonable supply of antigens is considered to be not more than a 12-*month* 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 the Medicare Benefit Policy Manual, Chapter 15, "Covered Medical and Other Health Services," §50.4.4.1)