CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-02 Medicare Benefit Policy	Centers for Medicare & Medicaid Services (CMS)
Transmittal 11448	**Date: June 6, 2022**
	Change Request 12723

Transmittal 11399, dated May 4, 2022, is being rescinded and replaced by Transmittal 11448, dated, June 6, 2022, Year to add language that was erroneously omitted in section 50.4.4.2. All other information remains the same.

SUBJECT: Revisions to Medicare Part B Coverage of Pneumococcal Vaccinations for the Medicare Benefit Policy Manual Chapter 15, Section 50.4.4.2

I. SUMMARY OF CHANGES: The purpose of this change request (CR) is to inform contractors that effective July 1, 2021, CMS updated the Medicare coverage requirements to align with the Advisory Committee on Immunization Practices (ACIP) recommendations for Coverage of Pneumococcal Vaccinations. This CR makes the necessary updates to the Benefit Policy Manual.

EFFECTIVE DATE: July 1, 2021
**Unless otherwise specified, the effective date is the date of service.*
IMPLEMENTATION DATE: June 6, 2022

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-*Only One Per Row.*

R/N/D	CHAPTER / SECTION / SUBSECTION / TITLE
R	15/50.4.4.2/Immunizations

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 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.

IV. ATTACHMENTS:

Business Requirements
Manual Instruction

Attachment - Business Requirements

Pub. 100-02	Transmittal: 11448	Date: June 6, 2022	Change Request: 12723

Transmittal 11399, dated May 4, 2022, is being rescinded and replaced by Transmittal 11448, dated, June 6, 2022, Year to add language that was erroneously omitted in section 50.4.4.2. All other information remains the same.

SUBJECT: Revisions to Medicare Part B Coverage of Pneumococcal Vaccinations for the Medicare Benefit Policy Manual Chapter 15, Section 50.4.4.2

EFFECTIVE DATE: July 1, 2021
**Unless otherwise specified, the effective date is the date of service.*
IMPLEMENTATION DATE: June 6, 2022

I. GENERAL INFORMATION

A. Background: Section 1861(s)(10)(A) of the Social Security Act and regulations at 42 CFR 410.57 authorize Medicare coverage under Part B for pneumococcal vaccine and its administration.

For services furnished on or after May 1, 1981 through September 18, 2014, the Medicare Part B program covered pneumococcal pneumonia 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. Coverage included an initial vaccine administered only to persons at high risk of serious pneumococcal disease (including all people 65 and older; immunocompetent adults at increased risk of pneumococcal disease or its complications because of chronic illness; and individuals with compromised immune systems), with revaccination administered only to persons at highest risk of serious pneumococcal infection and those likely to have a rapid decline in pneumococcal antibody levels, provided that at least 5 years had passed since the previous dose of pneumococcal vaccine.

The 13-valent pneumococcal conjugate vaccine (PCV) (PCV13) and the 23-valent pneumococcal polysaccharide vaccine (PPSV23) were recommended for U.S. adults. Recommendations varied by age and risk groups.

On October 20, 2021, the Advisory Committee on Immunization Practices (ACIP) recommended 15-valent PCV (PCV15) or 20-valent PCV (PCV20) for PCV-naïve adults who are either aged ≥65 years or aged 19–64 years with certain underlying conditions or other risk factors. When PCV15 is used, it should be followed by a dose of PPSV23, typically ≥1 year later.

B. Policy: Effective July 1, 2021, CMS updated the Medicare coverage requirements to align with the ACIP recommendations. The ACIP recommends that adults aged ≥65 years who have not previously received PCV or whose previous vaccination history is unknown should receive 1 dose of PCV (either PCV20 or PCV15). When PCV15 is used, it should be followed by a dose of PPSV23.

For those adults aged 19–64 years with certain underlying medical conditions or other risk factors who have not previously received PCV or whose previous vaccination history is unknown should receive 1 dose of PCV (either PCV20 or PCV15). When PCV15 is used, it should be followed by a dose of PPSV23.

Clinical guidance shows that when PCV15 is used, the recommended interval between administration of PCV15 and PPSV23 is ≥1 year. A minimum interval of 8 weeks can be considered for adults with an immunocompromising condition, cochlear implant, or cerebrospinal fluid leak to minimize the risk for invasive pneumococcal disease caused by serotypes unique to PPSV23 in these vulnerable groups.

For adults who have only received PPSV23, they may receive a PCV (either PCV20 or PCV15) ≥1 year after their last PPSV23 dose. When PCV15 is used in those with history of PPSV23 receipt, it need not be followed by another dose of PPSV23.

The incremental public health benefits of providing PCV15 or PCV20 to adults who have received PCV13 only or both PCV13 and PPSV23 have not been evaluated. These adults should complete the previously recommended PPSV23 series. For adults who have received PCV13 but have not completed their recommended pneumococcal vaccine series with PPSV23, one dose of PCV20 may be used if PPSV23 is not available.

For claims processing instructions refer to the link below:

https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Transmittals/r11329cp

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	
12723.1	Contractors shall be aware that effective for dates of service on and after July 1, 2021, contractors shall pay claims for pneumococcal vaccinations under Part B as described in Pub. 100-02, Medicare Benefit Policy Manual, chapter 15, section 50.4.4.2, and Pub. 100-04, Medicare Claims Processing Manual, chapter 18, sections 1.2, 10.2.1, 10.4.1, 10.4.2 and 10.4.3.	X	X	X						
12723.2	Contractors shall not search for and adjust any claims for pneumococcal vaccines and their administration, with dates of service on and after July 1, 2021. However, contractors may adjust claims brought to their attention.	X	X	X						

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility				
		A/B MAC			DME MAC	CEDI
		A	B	HHH		
12723.3	Medicare Learning Network® (MLN): CMS will market provider education content through the MLN Connects® newsletter shortly after CMS releases the CR. MACs shall follow IOM Pub. No. 100-09 Chapter 6, Section 50.2.4.1	X	X	X		

Number	Requirement	Responsibility				
		A/B MAC			DME MAC	CEDI
		A	B	HHH		
	instructions for distributing the MLN Connects newsletter information to providers and link to relevant information on your website. You may supplement MLN content with your local information after we release the MLN Connects newsletter. Subscribe to the "MLN Connects" listserv to get MLN content notifications. You don't need to separately track and report MLN content releases when you distribute MLN Connects newsletter content per the manual section referenced above.					

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): Lisa Davis, lisa.davis@cms.hhs.gov (Coverage and Analysis) , Wanda Belle, Wanda.belle@cms.hhs.gov (Coverage and Analysis) , Patricia Brocato-Simons, Patricia.BrocatoSimons@cms.hhs.gov (Coverage and Analysis)

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.

ATTACHMENTS: 0

50.4.4.2 – Immunizations

(Rev. 11448; Issued: 06-06-22, Effective: 07-01-21, Implementation:06-06-22)

Vaccinations or inoculations are excluded as immunizations unless they are directly related to the treatment of an injury or direct exposure to a disease or condition, such as anti-rabies 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. However, pneumococcal, hepatitis B, and influenza virus vaccines are exceptions to this rule. (See items A, B, and C below.) In cases where a vaccination or inoculation is excluded from coverage, related charges are also not covered.

A. Pneumococcal Pneumonia Vaccinations

1. Background and History of Coverage:

Section 1861(s)(10)(A) of the Social Security Act and regulations at 42 CFR 410.57 authorize Medicare coverage under Part B for pneumococcal vaccine and its administration.

For services furnished on or after May 1, 1981 through September 18, 2014, the Medicare Part B program covered pneumococcal pneumonia 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. Coverage included an initial vaccine administered only to persons at high risk of serious pneumococcal disease (including all people 65 and older; immunocompetent adults at increased risk of pneumococcal disease or its complications because of chronic illness; and individuals with compromised immune systems), with revaccination administered only to persons at highest risk of serious pneumococcal infection and those likely to have a rapid decline in pneumococcal antibody levels, provided that at least 5 years had passed since the previous dose of pneumococcal vaccine.

Those administering the vaccine did not require the patient to present an immunization record prior to administering the pneumococcal vaccine, nor were they compelled to review the patient's complete medical record if it was not available, relying on the patient's verbal history to determine prior vaccination status.

Effective for claims with dates of service on and after September 19, 2014, an initial pneumococcal vaccine may be administered to all Medicare beneficiaries who have never received a pneumococcal vaccination under Medicare Part B. A different, second pneumococcal vaccine may be administered 1 year after the first vaccine was administered (i.e., 11 full months have passed following the month in which the last pneumococcal vaccine was administered).

Effective July 1, 2000, Medicare no longer required for coverage purposes that a doctor of medicine or osteopathy order the vaccine. Therefore, a beneficiary could receive the vaccine upon request without a physician's order and without physician supervision.

2. Coverage Requirements:

Effective July 1, 2021, the Centers for Medicare & Medicaid Services updated the Medicare coverage requirements to align with the ACIP recommendations. The ACIP recommends that adults aged ≥65 years who have not previously received pneumococcal conjugate vaccine (PCV) or whose previous vaccination history is unknown should receive 1 dose of PCV (either PCV20 or PCV15).

When PCV15 is used, it should be followed by a dose of 23-valent pneumococcal polysaccharide vaccine (PPSV23).

For those adults aged 19–64 years with certain underlying medical conditions or other risk factors who have not previously received PCV or whose previous vaccination history is unknown should receive 1 dose of PCV (either PCV20 or PCV15). When PCV15 is used, it should be followed by a dose of PPSV23. Underlying medical conditions or other risk factors include alcoholism, chronic heart disease, chronic liver disease, chronic lung disease, cigarette smoking, diabetes mellitus, cochlear implant, cerebrospinal fluid leak, congenital or acquired asplenia, sickle cell disease or other hemoglobinopathies, chronic renal failure, congenital or acquired immunodeficiencies, generalized malignancy, HIV infection, Hodgkin disease, iatrogenic immunosuppression, leukemia, lymphoma, multiple myeloma, nephrotic syndrome and solid organ transplant.

Clinical guidance shows that when PCV15 is used, the recommended interval between administration of PCV15 and PPSV23 is ≥1 year. A minimum interval of 8 weeks can be considered for adults with an immunocompromising condition, cochlear implant, or cerebrospinal fluid leak to minimize the risk for invasive pneumococcal disease caused by serotypes unique to PPSV23 in these vulnerable groups. Immunocompromising conditions include chronic renal failure, congenital or acquired immunodeficiencies, generalized malignancy, HIV infection, Hodgkin disease, iatrogenic immunosuppression, leukemia, lymphoma, multiple myeloma, nephrotic syndrome, solid organ transplant, congenital or acquired asplenia, sickle cell disease, or other hemoglobinopathies.

For adults who have only received PPSV23, they may receive a PCV (either PCV20 or PCV15) ≥1 year after their last PPSV23 dose. When PCV15 is used in those with history of PPSV23 receipt, it need not be followed by another dose of PPSV23.

The incremental public health benefits of providing PCV15 or PCV20 to adults who have received PCV13 only or both PCV13 and PPSV23 have not been evaluated. These adults should complete the previously recommended PPSV23 series. For adults who have received PCV13 but have not completed their recommended pneumococcal vaccine series with PPSV23, one dose of PCV20 may be used if PPSV23 is not available.

Those administering the vaccine should not require the patient to present an immunization record prior to administering the pneumococcal vaccine, nor should they feel compelled to review the patient's complete medical record if it is not available. Instead, provided that the patient is competent, it is acceptable to rely on the patient's verbal history to determine prior vaccination status.

Medicare does not require for coverage purposes that a doctor of medicine or osteopathy order the vaccine. Therefore, the beneficiary may receive the vaccine upon request without a physician's order and without physician supervision.

B. Hepatitis B Vaccine

Effective for services furnished on or after September 1, 1984, P.L. 98-369 provides coverage under Part B for hepatitis B vaccine and its administration, furnished to a Medicare beneficiary who is at high or intermediate risk of contracting hepatitis B. High-risk groups currently identified include (see exception below):

- ESRD patients;
- Hemophiliacs who receive Factor VIII or IX concentrates;

- Clients of institutions for the mentally retarded;
- Persons who live in the same household as a Hepatitis B Virus (HBV) carrier;
- Homosexual men;
- Illicit injectable drug abusers; and
- Persons diagnosed with diabetes mellitus.

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 both of the above-listed groups in paragraph B, would not be considered at high or intermediate risk of contracting hepatitis B, however, if there were 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 a doctor of medicine or osteopathy, or by home health agencies, skilled nursing facilities, ESRD facilities, hospital outpatient departments, and persons recognized under the incident to physicians' services provision of law.

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

C. 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 flu season. Medicare does not require, for coverage purposes, that a doctor of medicine or osteopathy order the vaccine. Therefore, the beneficiary may receive the vaccine upon request without a physician's order and without physician supervision.