CMS Manual System	**Department of Health & Human Services (DHHS)**
Pub 100-02 Medicare Benefit Policy	**Centers for Medicare & Medicaid Services (CMS)**
Transmittal:11355	**Date: April 14, 2022**
	Change Request 12634

SUBJECT: Update to Publication 100-04, Chapter 18 and Publication 100-02, Chapter 15, Section to Add Data Regarding Novel Coronavirus (COVID-19) and its Administration to Current Claims Processing Requirements and Other General Updates

I. SUMMARY OF CHANGES: This change request (CR) will update the benefit policy manual to add data for coverage of the novel Coronavirus (COVID-19).

EFFECTIVE DATE: May 16, 2022
**Unless otherwise specified, the effective date is the date of service.*
IMPLEMENTATION DATE: May 16, 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	15/10/Supplementary Medical Insurance (SMI) Provisions
R	15/50/50.4.4.2 - Immunizations
R	15/60 - Services and Supplies Furnished Incident To a Physician's/NPP's Professional Service
R	15/280/Preventive and Screening Services

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: 11355	Date: April 14, 2022	Change Request: 12634

SUBJECT: Update to Publication 100-04, Chapter 18 and Publication 100-02, Chapter 15, Section to Add Data Regarding Novel Coronavirus (COVID-19) and its Administration to Current Claims Processing Requirements and Other General Updates

EFFECTIVE DATE: May 16, 2022

**Unless otherwise specified, the effective date is the date of service.*
IMPLEMENTATION DATE: May 16, 2022

I. GENERAL INFORMATION

A. Background: On March 11, 2020, the World Health Organization declared the Novel Coronavirus Disease COVID-19 as an infectious disease. On March 13, 2020, a national emergency was declared in the United States concerning the COVID-19 pandemic.

In response to the COVID-19 public health emergency, CMS created new Category II Healthcare Common Procedure Coding System (HCPCS) codes for COVID-19 vaccines and their administration. The purpose of this CR is to establish coverage policy instructions for the COVID-19 vaccines and their administration. Medicare coverage for the COVID-19 vaccines and their administration will be covered in the same manner as influenza and pneumococcal vaccines.

B. Policy: Pursuant to Section 3713 of the Coronavirus Aid, Relief, and Economic Security Act (CARES Act), once the Food and Drug Administration has approved a COVID-19 vaccine, the vaccine, and its administration, will be added to the list of preventive vaccines that are covered under Medicare Part B without coinsurance or deductible. The CARES Act provision amended Section 1861(s)(10)(A) of the Social Security Act.

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	
12634 - 02.1	Contractors shall update operational procedures, as necessary, to accommodate the following revisions to Chapter 15 of the Benefit Policy Manual: - Modify existing preventive vaccine coverage language to add COVID-19 vaccines and COVID-19 vaccine administration; and	X	X	X						

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
	- Establish a subsection with background information related specifically to the COVID-19 vaccine benefit coverage;									

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility				
		A/B MAC			DME MAC	CEDI
		A	B	HHH		
12634 - 02.2	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 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.	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): Michelle Cruse, 410-786-7540 or Michelle.Cruse@cms.hhs.gov

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

Medicare Benefit Policy Manual

Chapter 15 – Covered Medical and Other Health Services

Table of Contents
(Rev.11355; Issued:04-14-22)

10 - Supplementary Medical Insurance (SMI) Provisions

(Rev. 11355; Issued:04-14-22; Effective: 05-16-22; Implementation: 05-16-22)

The supplementary medical insurance plan covers expenses incurred for the following medical and other health services under Part B of Medicare:

- Physician's services, including surgery, consultation, office and institutional calls, and services and supplies furnished incident to a physician's professional service;
- Outpatient hospital services furnished incident to physicians services;
- Outpatient diagnostic services furnished by a hospital;
- Outpatient physical therapy, outpatient occupational therapy, outpatient speech-language pathology services;
- Diagnostic x-ray tests, laboratory tests, and other diagnostic tests;
- X-ray, radium, and radioactive isotope therapy;
- Surgical dressings, and splints, casts, and other devices used for reduction of fractures and dislocations;
- Rental or purchase of durable medical equipment for use in the patient's home;
- Ambulance service;
- Prosthetic devices, other than dental, which replace all or part of an internal body organ;
- Leg, arm, back and neck braces and artificial legs, arms, and eyes including adjustments, repairs, and replacements required because of breakage, wear, loss, or change in the patient's physical condition;
- Certain medical supplies used in connection with home dialysis delivery systems;
- Rural health clinic (RHC) services;
- Federally Qualified Health Center (FQHC) services;
- Ambulatory surgical center (ASC) services;
- Screening mammography services;
- Screening pap smears and pelvic exams;
- Screening glaucoma services;
- Influenza, pneumococcal pneumonia, hepatitis B*, and COVID-19* vaccines;
- Colorectal screening;
- Bone mass measurements;
- Diabetes self-management services;

- Prostate screening; and

- Home health visits after all covered Part A visits have been used.

See §250 for provisions regarding supplementary medical insurance coverage of certain of these services when furnished to hospital and SNF inpatients.

Payment may not be made under Part B for services furnished an individual if the individual is entitled to have payment made for those services under Part A. An individual is considered entitled to have payment made under Part A if the expenses incurred were used to satisfy a Part A deductible or coinsurance amount, or if payment would be made under Part A except for the lack of a request for payment or lack of a physician certification.

Some medical services may be considered for coverage under more than one of the above-enumerated categories. For example, electrocardiograms (EKGs) can be covered as physician's services or as other diagnostic tests. It is sufficient to determine that the requirements for coverage under one category are met to permit payment.

Membership dues, subscription fees, charges for service policies, insurance premiums, and other payments analogous to premiums which entitle enrollees to services or to repairs or replacement of devices or equipment or parts thereof without charge or at a reduced charge, are not considered expenses incurred for covered items or services furnished under such contracts or undertakings. Examples of such arrangements are memberships in ambulance companies, insurance for replacement of prosthetic lenses, and service contracts for durable medical equipment.

50.4.4.2 - Immunizations

(Rev. 11355; Issued:04-14-22; Effective: 05-16-22; Implementation: 05-16-22)

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, influenza virus*, and COVID-19* vaccines are exceptions to this rule. (See items A, B, C*, and D* 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 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 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).

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.

D. COVID-19 Vaccine

Effective for services furnished on or after November 2, 2020, under the authority of section 1861(s)(10)(A) of the Act as amended by section 3713 of P.L. 116-136, the Medicare Part B program covers COVID-19 vaccines and their administration when furnished in compliance with any applicable State law by any provider of services or any entity or individual with a supplier number.

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.

60 - Services and Supplies *Furnished Incident To a Physician's/NPP's Professional Service*

(Rev. 11355; Issued:04-14-22; Effective: 05-16-22; Implementation: 05-16-22)

B3-2050

A - Noninstitutional Setting

For purposes of this section a noninstitutional setting means all settings other than a hospital or skilled nursing facility

Medicare pays for services and supplies (including drug and biologicals which are not usually self-administered) that are furnished incident to a physician's or other practitioner's services, are commonly included in the physician's or practitioner's bills, and for which payment is not made under a separate benefit category listed in §1861(s) of the Act. A/B MACs (A) and (B) must not apply incident to requirements to services having their own benefit category. Rather, these services should meet the requirements of their own benefit category. For example, diagnostic tests are covered under §1861(s)(3) of the Act and are subject to their own coverage requirements. Depending on the particular tests, the supervision requirement for diagnostic tests or other services may be more or less stringent than supervision requirements for services and supplies furnished incident to physician's or other practitioner's services. Diagnostic tests need not also meet the incident to requirement in this section. Likewise, pneumococcal, influenza, hepatitis B*, and COVID-19* vaccines are covered under §1861(s)(10) of the Act and need not also meet incident to requirements. (Physician assistants, nurse practitioners, clinical nurse specialists, certified

nurse midwives, clinical psychologists, clinical social workers, physical therapists and occupational therapists all have their own benefit categories and may provide services without direct physician supervision and bill directly for these services. When their services are provided as auxiliary personnel (see under direct physician supervision, they may be covered as incident to services, in which case the incident to requirements would apply.

For purposes of this section, physician means physician or other practitioner (physician, physician assistant, nurse practitioner, clinical nurse specialist, nurse midwife, and clinical psychologist) authorized by the Act to receive payment for services incident to his or her own services.

To be covered incident to the services of a physician or other practitioner, services and supplies must be:

- An integral, although incidental, part of the physician's professional service (see §60.1);
- Commonly rendered without charge or included in the physician's bill (see §60.1A);
- Of a type that are commonly furnished in physician's offices or clinics (see §60.1A);
- Furnished by the physician or by auxiliary personnel under the physician's direct supervision (see §60.1B).

B - Institutional Setting

Hospital services incident to physician's or other practitioner's services rendered to outpatients (including drugs and biologicals which are not usually self-administered by the patient), and partial hospitalization services incident to such services may also be covered.

The hospital's A/B MAC (A) makes payment for these services under Part B to a hospital.

280 – Preventive and Screening Services

(Rev. 11355; Issued:04-14-22; Effective: 05-16-22; Implementation: 05-16-22)

See section 50.4.4.2 for coverage requirements for PPV, hepatitis B vaccine, Influenza Virus Vaccine*, and COVID-19 vaccines*.

See Pub. 100-04, Medicare Claims Processing Manual, Chapter 18, "Preventive and Screening Services," for coverage requirements for the following:

- §40 for screening pelvic examinations,
- §50 for prostate cancer screening test and procedures,
- §60 for colorectal cancer screening, and,
- §70.4 for glaucoma screening.