



EFFECTIVE DATE: 12|11|2020
POLICY LAST UPDATED: 02|17|2021

OVERVIEW

This policy documents Blue Cross & Blue Shield of Rhode Island (BCBSRI) coverage of and cost share waiver for US Food and Drug Administration (FDA) approved vaccines and the associated administration services for COVID-19.

This policy applies to BCBSRI participating providers as well as non-participating or Out-of-Network providers with BCBSRI.

BCBSRI reserves the right to implement changes to this policy without the contractual sixty-day (60) notification that is normally required under BCBSRI contracts with its providers due to the urgent nature of a pandemic related service.

Note: This policy is NOT effective for any specific vaccine until such time as the vaccine is approved by the FDA. The effective date for any specific vaccine shall align with the FDA approval date. As a result, each vaccine may have a different effective date. As FDA approval is issued, BCBSRI will include the effective date for each vaccine in the BACKGROUND section of this Policy.

MEDICAL CRITERIA

Not applicable

PRIOR AUTHORIZATION

Not applicable

POLICY STATEMENT

Medicare Advantage Plans and Commercials Products

FDA approved vaccines for COVID-19 are covered when recommended by the Centers for Disease Control and Prevention (CDC) and the American Academy of Pediatrics (AAP) and when FDA guidelines are met.

Evaluation & Management and Vaccine Administration

Evaluation & Management (E/M) services should not be filed along with the vaccine administration unless the E/M represents a separately identifiable service and modifier 25 is appended to the E/M code.

The submission of modifier 25 appended to a procedure code indicates that documentation is available in the patient's records, which supports the distinct, significant, separately identifiable nature of the E&M service submitted with modifier 25, and the fact that these records will be provided in a timely manner for review upon request.

Based on American Medical Association (AMA) CPT Coding guidelines, the CPT codes for the administration of the vaccine includes vaccine risk/benefit counseling when performed, and the time needed to monitor the member for any adverse reactions.

Example: It is considered incorrect coding to file code 99211 or any other E/M code when the intent of the visit is for the administration of COVID-19 vaccination only.

BCBSRI policy is consistent with the Centers for Medicare & Medicaid Services (CMS) National Correct Coding Initiative (NCCI) Program. BCBSRI will be performing routine reviews of claim submissions for compliance with this Policy as well as correct coding and adherence to other BCBSRI policies. BCBSRI maintains the right to audit the services provided to our members, regardless of the participation status of the provider. All documentation must be available to BCBSRI upon request. Failure to produce the requested information may result in denial or retraction of payment.

COVERAGE

BCBSRI will not impose any cost sharing (e.g. deductibles, copayments, and coinsurance) on vaccines or administration related services for COVID-19 during the timeframe this policy is in effect.

BACKGROUND

On December 11, 2020, the U.S. Food and Drug Administration issued the first emergency use authorization (EUA) for a vaccine for the prevention of coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 16 years of age and older. The emergency use authorization allows the Pfizer-BioNTech COVID-19 Vaccine to be distributed in the U.S.

The FDA has determined that Pfizer-BioNTech COVID-19 Vaccine has met the statutory criteria for issuance of an EUA. The totality of the available data provides clear evidence that Pfizer-BioNTech COVID-19 Vaccine may be effective in preventing COVID-19.

The Pfizer-BioNTech COVID-19 Vaccine contains messenger RNA (mRNA), which is genetic material. The vaccine contains a small piece of the SARS-CoV-2 virus's mRNA that instructs cells in the body to make the virus's distinctive "spike" protein. When a person receives this vaccine, their body produces copies of the spike protein, which does not cause disease, but triggers the immune system to learn to react defensively, producing an immune response against SARS-CoV-2. Pfizer BioNTech COVID-19 Vaccine is administered as a series of two doses, three weeks apart.

On December 18, 2020, the U.S. Food and Drug Administration issued an EUA for the second vaccine for the prevention of coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). The emergency use authorization allows the Moderna COVID-19 Vaccine to be distributed in the U.S. for use in individuals 18 years of age and older.

The FDA has determined that the Moderna COVID-19 Vaccine has met the statutory criteria for issuance of an EUA. The totality of the available data provides clear evidence that the Moderna COVID-19 Vaccine may be effective in preventing COVID-19. The data also show that the known and potential benefits outweigh the known and potential risks—supporting the company's request for the vaccine's use in people 18 years of age and older. In making this determination, the FDA can assure the public and medical community that it has conducted a thorough evaluation of the available safety, effectiveness, and manufacturing quality information.

The Moderna COVID-19 Vaccine contains messenger RNA (mRNA), which is genetic material. The vaccine contains a small piece of the SARS-CoV-2 virus's mRNA that instructs cells in the body to make the virus's distinctive "spike" protein. After a person receives this vaccine, their body produces copies of the spike protein, which does not cause disease, but triggers the immune system to learn to react defensively, producing an immune response against SARS-CoV-2.

U.S. FDA COVID-19 Vaccine Emergency Use Authorization Dates

Pfizer-BioNTech COVID-19 Vaccine – December 11, 2020

Moderna COVID-19 Vaccine – December 18, 2020

NOTE: As of December 18, 2020, the AstraZeneca COVID-19 Vaccine and the Janssen COVID-19 Vaccine have **not** received FDA Emergency Use Authorization.

Medicare Advantage Plans

*In accordance with Center for Medicare and Medicaid Services (CMS) billing guidelines, codes for the vaccine and the administration of COVID-19 vaccines **must be submitted to Original Medicare for all patients enrolled in Medicare Advantage in 2020 and 2021.***

*As a result, providers **should not bill BCBSRI for any Medicare Advantage Plan services.***

CODING

Medicare Advantage Plans and Commercial Products

As with all services, providers should report the most appropriate ICD-10 diagnostic code(s) for any patient encounter. However, the following ICD-10 code is acceptable for administration of COVID-19 vaccine:

Z23 Encounter for immunization

Claims Filing/Reimbursement Information

Vaccines Supplied at No Cost to Provider

Vaccines supplied to providers at no cost will not have any reimbursement made if filed by a provider. If a provider elects to submit a claim for the vaccine code itself, the claim will indicate a denial for the vaccine code/line item as a provider liability with no member liability as the member is not liable for any costs related to the actual vaccine.

Note: Providers should not append modifier 22 to the following vaccine codes, indicating the vaccine was purchased by the provider.

CPT Codes for Vaccine Products and Vaccine Administration

<u>COVID-19 Vaccine and Administration CPT Codes</u>	<u>Medicare Advantage Plans</u>	<u>Commercial Products</u>
Pfizer-BioNTech COVID-19 (Pfizer, Inc.) FDA EUA Approval Date: 12/11/2020		
91300 Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]) vaccine , mRNA-LNP, spike protein, preservative free, 30 mcg/0.3mL dosage, diluent reconstituted, for intramuscular use	Per CMS billing guidelines, submit to Original Medicare Do Not Bill to BCBSRI	No reimbursement for claims submitted to BCBSRI for vaccine products health care providers receive at no cost
0001A Immunization administration by intramuscular injection of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]) vaccine, mRNA-LNP, spike protein, preservative free, 30 mcg/0.3mL dosage, diluent reconstituted; first dose	Per CMS billing guidelines, submit to Original Medicare Do Not Bill to BCBSRI	Covered and Separately Reimbursed
0002A Immunization administration by intramuscular injection of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]) vaccine, mRNA-LNP, spike protein, preservative free, 30 mcg/0.3mL dosage, diluent reconstituted; second dose	Per CMS billing guidelines, submit to Original Medicare Do Not Bill to BCBSRI	Covered and Separately Reimbursed
Moderna COVID-19 (Moderna, Inc.) FDA EUA Approval Date: 12/18/2020		

91301 Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]) vaccine , mRNA-LNP, spike protein, preservative free, 100 mcg/0.5mL dosage, for intramuscular use	Per CMS billing guidelines, submit to Original Medicare Do Not Bill to BCBSRI	No reimbursement for claims submitted to BCBSRI for vaccine products health care providers receive at no cost
0011A Immunization administration by intramuscular injection of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]) vaccine, mRNA-LNP, spike protein, preservative free, 100 mcg/0.5mL dosage; first dose	Per CMS billing guidelines, submit to Original Medicare Do Not Bill to BCBSRI	Covered and Separately Reimbursed
0012A Immunization administration by intramuscular injection of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]) vaccine, mRNA-LNP, spike protein, preservative free, 100 mcg/0.5mL dosage; second dose	Per CMS billing guidelines, submit to Original Medicare Do Not Bill to BCBSRI	Covered and Separately Reimbursed
AstraZeneca COVID-19 (AstraZeneca, Inc.) FDA EUA Approval Date: PENDING		
91302 Severe acute respiratory syndrome coronavirus 2 (SARSCoV-2) (coronavirus disease [COVID-19]) vaccine , DNA, spike protein, chimpanzee adenovirus Oxford 1 (ChAdOx1) vector, preservative free, 5x10 ¹⁰ viral particles/0.5mL dosage, for intramuscular use	N/A	N/A
0021A Immunization administration by intramuscular injection of severe acute respiratory syndrome coronavirus 2 (SARSCoV-2) (coronavirus disease [COVID-19]) vaccine, DNA, spike protein, chimpanzee adenovirus Oxford 1 (ChAdOx1) vector, preservative free, 5x10 ¹⁰ viral particles/0.5mL dosage; first dose	N/A	N/A
0022A Immunization administration by intramuscular injection of severe acute respiratory syndrome coronavirus 2 (SARSCoV-2) (coronavirus disease [COVID-19]) vaccine, DNA, spike protein, chimpanzee adenovirus Oxford 1 (ChAdOx1) vector, preservative free, 5x10 ¹⁰ viral particles/0.5mL dosage; second dose	N/A	N/A
Janssen COVID-19 Vaccine (Janssen) FDA EUA Approval Date: PENDING		
91303 Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19]) vaccine , DNA, spike protein, adenovirus type 26 (Ad26) vector, preservative free, 5x10 ¹⁰ viral particles/0.5mL dosage, for intramuscular use	N/A	N/A
0031A Immunization administration by intramuscular injection of severe acute respiratory syndrome coronavirus 2 (SARSCoV-2) (coronavirus disease [COVID-19]) vaccine, DNA, spike protein, adenovirus type 26 (Ad26) vector, preservative free, 5x10 ¹⁰ viral particles/0.5mL dosage, single dose	N/A	N/A

RELATED POLICIES

Coding and Payment Guidelines

COVID-19 Monoclonal Antibody Treatment

TEMPORARY Cost Share Waiver for Treatment of Confirmed Cases of COVID-19 During the COVID-19 Crisis

TEMPORARY COVID-19 Diagnostic Testing

TEMPORARY Timely Filing Limit Extension Policy – Additional 180 Days During the COVID-19 Crisis

TEMPORARY Encounter for Determination of Need for COVID-19 Diagnostic Testing

PUBLISHED

BCBSRI's website

Provider Update, February 2021

REFERENCES

U.S. Food and Drug Administration. FDA Takes Key Action in Fight Against COVID-19 By Issuing Emergency Use Authorization for First COVID-19 Vaccine | FDA

U.S. Food and Drug Administration. FDA Takes Additional Action in Fight Against COVID-19 By Issuing Emergency Use Authorization for Second COVID-19 Vaccine | FDA

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