



EFFECTIVE DATE: 12 | 11 | 2020
POLICY LAST UPDATED: 04 | 20 | 2022

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.

Third doses, as well as booster doses of COVID-19 vaccines are covered when their use/administration is supported by federal, state and/or local guidelines, and/or established and accepted standard of care practice.

COVID-19 Vaccination Administration in the Home

COVID-19 vaccines and associated administration are covered when administered in a member's home.

Claims for in-home administration of the COVID-19 vaccine should only be billed:

- if the sole purpose of the visit is to administer the vaccine.
 - If other services are provided in the same home, during the visit on the same date, the in-home administration of the COVID-19 vaccine should not be billed.
- For dates of service between June 8, 2021 and August 24, 2021, once per home per date of service.

- If the COVID-19 vaccine is administered to more than one member in a single home, on the same date of service, the in-home administration service should only be billed once for one member.
- **For dates of service on or after August 24, 2021**, in-home administration of the COVID-19 vaccine can be billed for up to a maximum of 5 vaccine administration services per home unit or communal space within a single group living location; but only when fewer than 10 Medicare members receive a COVID-19 vaccine dose on the same day at the same group living location.
- Examples Effective August 24, 2021:
 - COVID-19 vaccine administered on the same date to 2 members in the same home, both in-home administrations are eligible for reimbursement.
 - COVID-19 vaccine administered on the same date to 9 members in the same home (including a communal space in a group living setting), 5 in-home administrations are eligible for reimbursement.
 - COVID-19 vaccine administered on the same date to 12 members in the same home (including a communal space in a group living setting), 1 in-home administration is eligible for reimbursement. Only one in-home administration is billable in this circumstance because 10 or more members were vaccinated at the same location on the same date.
 - COVID-19 vaccine administered on the same date to 5 members in a communal space in a group living setting, and to 3 additional members in their individual rooms, all 8 administrations are eligible for reimbursement. All 5 administrations are billable, following the maximum allowance of 5 services per communal living space, plus 3 administrations provided to members in their individual rooms, and the total is not greater than 10.

In-home administration of COVID-19 vaccines is applicable to the following places of service:

- Homeless Shelter
- Prison/Correctional Facility
- Home
- Assisted Living Facility
- Group Home
- Temporary Lodging
- Nursing Facility
- Custodial Care Facility
- Ambulance-Land

See the Coding section for additional details regarding in-home administration.

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

Pfizer-BioNTech COVID-19 Vaccine

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.

On May 10, 2021, the FDA expanded the emergency use authorization for the Pfizer-BioNTech COVID-19 Vaccine to include adolescents 12 through 15 years of age.

On June 25, 2021, the FDA revised the patient and provider fact sheets regarding the suggested increased risks of myocarditis (inflammation of the heart muscle) and pericarditis (inflammation of the tissue surrounding the heart) following vaccination.

On August 12, 2021, the FDA amended the Pfizer-BioNTech COVID-19 Vaccine EUA to allow for an additional dose.

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 August 23, 2021, the U.S. Food and Drug Administration approved the first COVID-19 vaccine. The vaccine has been known as the Pfizer-BioNTech COVID-19 Vaccine, and will now be marketed as Comirnaty (koe-mir'-na-tee), for the prevention of COVID-19 disease in individuals 16 years of age and older. The vaccine also continues to be available under emergency use authorization (EUA), including for individuals 12 through 15 years of age and for the administration of a third dose.

On September, 22, 2021, the U.S. Food and Drug Administration amended the emergency use authorization (EUA) for the Pfizer-BioNTech COVID-19 Vaccine to allow for use of a single booster dose, to be administered at least six months after completion of the primary series in:

- individuals 65 years of age and older;
- individuals 18 through 64 years of age at high risk of severe COVID-19; and
- individuals 18 through 64 years of age whose frequent institutional or occupational exposure to SARS-CoV-2 puts them at high risk of serious complications of COVID-19 including severe COVID-19.

On October 20, 2021, the FDA authorized the use of a heterologous (or “mix and match”) booster dose in eligible populations with currently available (i.e., FDA-authorized or approved) COVID-19 vaccines. Therefore, Pfizer-BioNTech COVID-19 vaccine recipients falling into one of the authorized categories for boosters may receive the Moderna COVID-19 Vaccine (half dose), Pfizer-BioNTech COVID-19 Vaccine or Janssen COVID-19 Vaccine and should be given at least six months after completing the primary vaccination.

On October 29, 2021 the FDA authorized the emergency use of the Pfizer-BioNTech COVID-19 Vaccine for the prevention of COVID-19 to include children 5 through 11 years of age. The authorization was based on the FDA’s thorough and transparent evaluation of the data that included input from independent advisory committee experts who overwhelmingly voted in favor of making the vaccine available to children in this age group.

On October 29, 2021 the FDA also authorized a manufacturing change for the vaccine to include a formulation that uses a different buffer; buffers help maintain a vaccine’s pH (a measure of how acidic or alkaline a solution is) and stability. This new formulation is more stable at refrigerated temperatures for longer periods of time, permitting greater flexibility for vaccination providers. The new formulation of the vaccine developed by Pfizer Inc. contains Tris buffer, a commonly used buffer in a variety of other FDA-approved vaccines and other biologics, including products for use in children. The FDA evaluated manufacturing data to support the use of Pfizer-BioNTech COVID-19 Vaccine containing Tris buffer and concluded it does not present safety or effectiveness concerns.

Since Dec. 11, 2020, the Pfizer-BioNTech COVID-19 Vaccine has been available under EUA in individuals 16 years of age and older, and the authorization was expanded to include those 12 through 15 years of age on May 10, 2021. EUAs can be used by the FDA during public health emergencies to provide access to medical products that may be effective in preventing, diagnosing, or treating a disease, provided that the FDA determines that the known and potential benefits of a product, when used to prevent, diagnose, or treat the disease, outweigh the known and potential risks of the product.

FDA-approved vaccines undergo the agency’s standard process for reviewing the quality, safety and effectiveness of medical products. For all vaccines, the FDA evaluates data and information included in the manufacturer’s submission of a biologics license application (BLA). A BLA is a comprehensive document that is submitted to the agency providing very specific requirements. For Comirnaty, the BLA builds on the extensive data and information previously submitted that supported the EUA, such as preclinical and clinical data and information, as well as details of the manufacturing process, vaccine testing results to ensure vaccine quality, and inspections of the sites where the vaccine is made. The agency conducts its own analyses of the information in the BLA to make sure the vaccine is safe and effective and meets the FDA’s standards for approval.

Comirnaty contains messenger RNA (mRNA), a kind of genetic material. The mRNA is used by the body to make a mimic of one of the proteins in the virus that causes COVID-19. The result of a person receiving this vaccine is that their immune system will ultimately react defensively to the virus that causes COVID-19. The mRNA in Comirnaty is only present in the body for a short time and is not incorporated into - nor does it alter - an individual’s genetic material. Comirnaty has the same formulation as the EUA vaccine and is administered as a series of two doses, three weeks apart.

Moderna COVID-19 Vaccine

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).

On June 25, 2021, the FDA revised the patient and provider fact sheets regarding the suggested increased risks of myocarditis (inflammation of the heart muscle) and pericarditis (inflammation of the tissue surrounding the heart) following vaccination.

On August 12, 2021, the FDA amended the Moderna COVID-19 Vaccine EUA to allow for an additional dose to be given to certain immunocompromised individuals.

On October 20, 2021, the FDA amended the Moderna COVID-19 Vaccine EUA to allow for a single booster dose of the Moderna COVID-19 Vaccine administered at least 6 months after completion of the primary series to individuals:

- 65 years of age and older
- 18 through 64 years of age at high risk of severe COVID-19
- 18 through 64 years of age with frequent institutional or occupational exposure to SARS-CoV-2

On March 29, 2022, having concluded that revising this EUA is appropriate to protect the public health or safety under section 564(g)(2) of the Act, the FDA is reissuing the March 15, 2022 letter of authorization in its entirety with revisions incorporated to authorize:

1) the administration of a second booster dose of SPIKEVAX (COVID-19 Vaccine, mRNA) or the Moderna COVID-19 Vaccine at least 4 months after receipt of a first booster dose of any FDA authorized or approved COVID-19 vaccine to:

a) individuals 50 years of age and older; and

b) individuals 18 years of age or older who have undergone solid organ transplantation, or individuals 18 years of age or older who have been diagnosed with conditions that are considered to have an equivalent level of immunocompromise; and

2) a manufacturing change to include an additional presentation of the Moderna COVID-19 Vaccine for booster vaccination doses only, which is supplied in multiple dose vials with dark blue caps and labels with a purple border.

This booster dose only presentation of the Moderna COVID-19 Vaccine is not authorized to provide a primary series dose.

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.

Janssen COVID-19 Vaccine

On February 27, 2021, the U.S. Food and Drug Administration issued an EUA for the third vaccine for the prevention of coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2).

On April 23, 2021, the FDA amended the EUA to include information about a very rare and serious type of blood clot in people who receive the vaccine.

On October 20, 2021, the FDA authorized a single booster dose of the Janssen (Johnson and Johnson) COVID-19 Vaccine administered at least 2 months after completion of the single-dose primary regimen to individuals 18 years of age and older. Also on October 20, 2021, the FDA authorized the use of a heterologous (or "mix and match") booster dose for currently available (i.e., FDA-authorized or approved) COVID-19 vaccines. Therefore, Janssen COVID-19 Vaccine recipients 18 years of age and older may receive a single booster dose of Janssen COVID-19 Vaccine, Moderna COVID-19 Vaccine (half dose) or Pfizer-BioNTech COVID-19 Vaccine at least two months after receiving their Janssen COVID-19 Vaccine primary vaccination.

The EUA allows the Janssen 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 Janssen COVID-19 Vaccine has met the statutory criteria for issuance of an EUA. The totality of the available data provides clear evidence that the Janssen COVID-19 Vaccine may be effective in preventing COVID-19. The data also show that the vaccine's known and potential benefits outweigh its 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 Janssen COVID-19 Vaccine is manufactured using a specific type of virus called adenovirus type 26 (Ad26). The vaccine uses Ad26 to deliver a piece of the DNA, or genetic material, that is used to make the distinctive "spike" protein of the SARS-CoV-2 virus. While adenoviruses are a group of viruses that are relatively common, Ad26, which can cause cold symptoms and pink eye, has been modified for the vaccine so that it cannot replicate in the human body to cause illness. After a person receives this vaccine, the body can temporarily make 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 First and Second Dose (diluent reconstituted formulation), Ages 16 and older – December 11, 2020
- Pfizer-BioNTech COVID-19 Vaccine First and Second Dose (diluent reconstituted formulation), Ages 12 – 15 – May 10, 2021
- Pfizer-BioNTech COVID-19 Vaccine Third Dose (diluent reconstituted formulation), Ages 12 and older – August 12, 2021
- Pfizer-BioNTech COVID-19 Vaccine Booster Dose (diluent reconstituted formulation), Ages 18 and older - September 22, 2021

- Pfizer-BioNTech COVID-19 Vaccine First and Second Dose (tris-sucrose formulation), Ages 5-11 years old – October 29, 2021
- Pfizer-BioNTech COVID-19 Vaccine Third Dose (tris-sucrose formulation), Ages 5-11 years old – January 3, 2022
- Moderna COVID-19 Vaccine First and Second Dose, Ages 16 and older – December 18, 2020
- Moderna COVID-19 Vaccine Third Dose, Ages 16 and older – August 12, 2021
- Moderna COVID-19 Vaccine Booster Dose – October 20, 2021
- Janssen COVID-19 Vaccine Single Dose, Ages 16 and older – February 27, 2021
- Janssen COVID-19 Vaccine – Booster Dose – October 20, 2021

NOTE: As of October 5, 2021, the following have **NOT** received FDA Emergency Use Authorization.

- AstraZeneca COVID-19 Vaccine
- Novavax COVID-19 Vaccine

U.S. FDA COVID-19 Vaccine Approval Dates

Pfizer-BioNTech COVID-19 Vaccine First and Second Dose (diluent reconstituted formulation), for ages 16 years and older – August 23, 2021

FDA Authorizes Additional Vaccine Dose for Certain Immunocompromised Individuals

On August 12, 2021, the U.S. Food and Drug Administration amended the emergency use authorizations (EUAs) for both the Pfizer-BioNTech COVID-19 Vaccine and the Moderna COVID-19 Vaccine to allow for the use of an additional dose.

The Pfizer-BioNTech COVID-19 Vaccine is currently authorized for emergency use in individuals ages 12 and older, and the Moderna COVID-19 Vaccine is authorized for emergency use in individuals ages 18 and older. Both vaccines are administered as a series of two shots: the Pfizer-BioNTech COVID-19 Vaccine is administered three weeks apart, and the Moderna COVID-19 Vaccine is administered one month apart. The authorizations for these vaccines have been amended to allow for an additional, or third, dose to be administered at least 28 days following the two-dose regimen of the same vaccine to individuals 18 years of age or older (ages 12 or older for Pfizer-BioNTech).

According to the Centers for Disease Control and Prevention (CDC), the additional mRNA COVID-19 vaccine dose should be the same vaccine product as the initial 2-dose mRNA COVID-19 primary vaccine series (Pfizer-BioNTech or Moderna). If the mRNA COVID-19 vaccine product given for the first two doses is not available, the other mRNA COVID-19 vaccine product may be administered. A person should not receive more than three mRNA COVID-19 vaccine doses.

Until additional data are available, the additional dose of an mRNA COVID-19 vaccine should be administered at least 28 days after completion of the initial 2-dose mRNA COVID-19 vaccine series, based on expert opinion.

Currently there are insufficient data to support the use of an additional mRNA COVID-19 vaccine dose after a single-dose Janssen COVID-19 vaccination series in immunocompromised people. FDA and CDC are actively working to provide guidance on this issue.

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.

COVID-19 Vaccination Administration in the Home

When filing HCPCS code **M0201** for in-home administration of a COVID-19 vaccine, all the following must be filed:

- The appropriate CPT code for the specific vaccine product (see coding below), and
- The appropriate CPT code for the dose-specific COVID-19 vaccine administration (see coding below), and
- HCPCS code M0201 to identify that the vaccine was administered in the home.

See Policy Statement for guidelines regarding when it is appropriate to file for in-home administration.

See grid below for M0201 code description.

CPT Codes for Vaccine Products and Vaccine Administration

See Background section for FDA Emergency Use Authorization and Approval dates.

In-Home Administration of COVID-19 Vaccine See additional coding instructions above.	<u>Medicare Advantage Plans</u>	<u>Commercial Products</u>
M0201 COVID-19 vaccine administration inside a patient's home; reported only once per individual home, per date of service, when only COVID-19 vaccine administration is performed at the patient's home	Effective 10/11/20-12/31/21 - Per CMS billing guidelines, submit to Original Medicare Do Not Bill to BCBSRI Effective 1/1/22 - Covered and Separately Reimbursed	Covered and Separately Reimbursed
Pfizer-BioNTech COVID-19 Vaccine/Comirnaty (Pfizer, Inc.) VACCINE	<u>Medicare Advantage Plans</u>	<u>Commercial Products</u>
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, <i>diluent reconstituted</i> , for intramuscular use	Effective 10/11/20-12/31/21 - Per CMS billing guidelines, submit to Original Medicare Do Not Bill to BCBSRI Effective 1/1/22 - No reimbursement for claims submitted to BCBSRI for vaccine products health care providers receive at no cost	No reimbursement for claims submitted to BCBSRI for vaccine products health care providers receive at no cost

<p>91305 Severe acute respiratory syndrome coronavirus 2 (SARS-CoV2) (coronavirus disease [COVID-19]) vaccine, mRNA-LNP, spike protein, preservative free, 30 mcg/0.3 mL dosage, tris-sucrose formulation, for intramuscular use</p>	<p>Effective 10/11/20-12/31/21 - Per CMS billing guidelines, submit to Original Medicare Do Not Bill to BCBSRI</p> <p>Effective 1/1/22 – No reimbursement for claims submitted to BCBSRI for vaccine products health care providers receive at no cost</p>	<p>No reimbursement for claims submitted to BCBSRI for vaccine products health care providers receive at no cost</p>
<p>91307 Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19]) vaccine, mRNA-LNP, spike protein, preservative free, 10 mcg/0.2 mL dosage, diluent reconstituted, tris-sucrose formulation, for intramuscular use</p>	<p>Effective 10/11/20-12/31/21 - Per CMS billing guidelines, submit to Original Medicare Do Not Bill to BCBSRI</p> <p>Effective 1/1/22 – No reimbursement for claims submitted to BCBSRI for vaccine products health care providers receive at no cost</p>	<p>No reimbursement for claims submitted to BCBSRI for vaccine products health care providers receive at no cost</p>

<p>Pfizer-BioNTech COVID-19 Vaccine/Comirnaty (Pfizer, Inc.) ADMINISTRATION</p>	<p>Medicare Advantage Plans</p>	<p>Commercial Products</p>
<p>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</p>	<p>Effective 10/11/20-12/31/21 - Per CMS billing guidelines, submit to Original Medicare Do Not Bill to BCBSRI</p> <p>Effective 1/1/22 - Covered and Separately Reimbursed</p>	<p>Covered and Separately Reimbursed</p>
<p>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</p>	<p>Effective 10/11/20-12/31/21 - Per CMS billing guidelines, submit to Original Medicare Do Not Bill to BCBSRI</p> <p>Effective 1/1/22 - Covered and Separately Reimbursed</p>	<p>Covered and Separately Reimbursed</p>
<p>0003A 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; third dose</p>	<p>Effective 10/11/20-12/31/21 - Per CMS billing guidelines, submit to Original Medicare Do Not Bill to BCBSRI</p> <p>Effective 1/1/22 - Covered and Separately Reimbursed</p>	<p>Covered and Separately Reimbursed</p>
<p>0004A Immunization administration by intramuscular injection of severe acute respiratory syndrome coronavirus 2 (SARSCoV-2) (coronavirus disease [COVID-19]) vaccine, mRNA-LNP, spike protein, preservative free, 30 mcg/0.3 mL dosage, diluent reconstituted; booster dose</p>	<p>Effective 10/11/20-12/31/21 - Per CMS billing guidelines, submit to Original Medicare Do Not Bill to BCBSRI</p> <p>Effective 1/1/22 - Covered and Separately Reimbursed</p>	<p>Covered and Separately Reimbursed</p>

<p>0051A Immunization administration by intramuscular injection of severe acute respiratory syndrome coronavirus 2 (SARSCoV-2) (coronavirus disease [COVID-19]) vaccine, mRNA-LNP, spike protein, preservative free, 30 mcg/0.3 mL dosage, tris-sucrose formulation; first dose</p>	<p>Effective 10/11/20-12/31/21 - Per CMS billing guidelines, submit to Original Medicare Do Not Bill to BCBSRI</p> <p>Effective 1/1/22 - Covered and Separately Reimbursed</p>	<p>Covered and Separately Reimbursed</p>
<p>0052A Immunization administration by intramuscular injection of severe acute respiratory syndrome coronavirus 2 (SARSCoV-2) (coronavirus disease [COVID-19]) vaccine, mRNA-LNP, spike protein, preservative free, 30 mcg/0.3 mL dosage, tris-sucrose formulation; second dose</p>	<p>Effective 10/11/20-12/31/21 - Per CMS billing guidelines, submit to Original Medicare Do Not Bill to BCBSRI</p> <p>Effective 1/1/22 - Covered and Separately Reimbursed</p>	<p>Covered and Separately Reimbursed</p>
<p>0053A Immunization administration by intramuscular injection of severe acute respiratory syndrome coronavirus 2 (SARSCoV-2) (coronavirus disease [COVID-19]) vaccine, mRNA-LNP, spike protein, preservative free, 30 mcg/0.3 mL dosage, tris-sucrose formulation; third dose</p>	<p>Effective 10/11/20-12/31/21 - Per CMS billing guidelines, submit to Original Medicare Do Not Bill to BCBSRI</p> <p>Effective 1/1/22 - Covered and Separately Reimbursed</p>	<p>Covered and Separately Reimbursed</p>

<p>0054A Immunization administration by intramuscular injection of severe acute respiratory syndrome coronavirus 2 (SARSCoV-2) (coronavirus disease [COVID-19]) vaccine, mRNA-LNP, spike protein, preservative free, 30 mcg/0.3 mL dosage, tris-sucrose formulation; booster dose</p>	<p>Effective 10/11/20-12/31/21 - Per CMS billing guidelines, submit to Original Medicare Do Not Bill to BCBSRI</p> <p>Effective 1/1/22 - Covered and Separately Reimbursed</p>	<p>Covered and Separately Reimbursed</p>
<p>0071A 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, 10 mcg/0.2 mL dosage, diluent reconstituted, tris-sucrose formulation; first dose</p>	<p>Effective 10/11/20-12/31/21 - Per CMS billing guidelines, submit to Original Medicare Do Not Bill to BCBSRI</p> <p>Effective 1/1/22 - Covered and Separately Reimbursed</p>	<p>Covered and Separately Reimbursed</p>
<p>0072A 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, 10 mcg/0.2 mL dosage, diluent reconstituted, tris-sucrose formulation; second dose</p>	<p>Effective 10/11/20-12/31/21 - Per CMS billing guidelines, submit to Original Medicare Do Not Bill to BCBSRI</p> <p>Effective 1/1/22 - Covered and Separately Reimbursed</p>	<p>Covered and Separately Reimbursed</p>
<p>0073A 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, 10 mcg/0.2 mL dosage, diluent reconstituted, tris-sucrose formulation; third dose</p>	<p>Effective 10/11/20-12/31/21 - Per CMS billing guidelines, submit to Original Medicare Do Not Bill to BCBSRI</p> <p>Effective 1/3/22 - Covered and Separately Reimbursed</p>	<p>Covered and Separately Reimbursed</p>

Moderna COVID-19 Vaccine (Moderna, Inc.) VACCINE	Medicare Advantage Plans	Commercial Products
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	Effective 10/11/20-12/31/21 - Per CMS billing guidelines, submit to Original Medicare Do Not Bill to BCBSRI Effective 1/1/22 – No reimbursement for claims submitted to BCBSRI for vaccine products health care providers receive at no cost	No reimbursement for claims submitted to BCBSRI for vaccine products health care providers receive at no cost
91306 Severe acute respiratory syndrome coronavirus 2 (SARS-CoV2) (coronavirus disease [COVID-19]) vaccine , mRNA-LNP, spike protein, preservative free, 50 mcg/0.25 mL dosage, for intramuscular use	Effective 10/11/20-12/31/21 - Per CMS billing guidelines, submit to Original Medicare Do Not Bill to BCBSRI Effective 1/1/22 – No reimbursement for claims submitted to BCBSRI for vaccine products health care providers receive at no cost	No reimbursement for claims submitted to BCBSRI for vaccine products health care providers receive at no cost
91309 Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19]) vaccine , mRNA-LNP, spike protein, preservative free, 50 mcg/0.5 mL dosage, for intramuscular use	Effective 3/29/22 – No reimbursement for claims submitted to BCBSRI for vaccine products health care providers receive at no cost	No reimbursement for claims submitted to BCBSRI for vaccine products health care providers receive at no cost
Moderna COVID-19 Vaccine (Moderna, Inc.) ADMINISTRATION	Medicare Advantage Plans	Commercial Products
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	Effective 10/11/20-12/31/21 - Per CMS billing guidelines, submit to Original Medicare Do Not Bill to BCBSRI Effective 1/1/22 - Covered and Separately Reimbursed	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	Effective 10/11/20-12/31/21 - Per CMS billing guidelines, submit to Original Medicare Do Not Bill to BCBSRI Effective 1/1/22 - Covered and Separately Reimbursed	Covered and Separately Reimbursed
0013A 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; third dose	Effective 10/11/20-12/31/21 - Per CMS billing guidelines, submit to Original Medicare Do Not Bill to BCBSRI Effective 1/1/22 - Covered and Separately Reimbursed	Covered and Separately Reimbursed
0064A Immunization administration by intramuscular injection of severe acute respiratory syndrome coronavirus 2 (SARSCoV-2) (coronavirus disease [COVID-19]) vaccine , mRNA-LNP, spike protein, preservative free, 50 mcg/0.25 mL dosage, booster dose	Effective 10/11/20-12/31/21 - Per CMS billing guidelines, submit to Original Medicare Do Not Bill to BCBSRI Effective 1/1/22 - Covered and Separately Reimbursed	Covered and Separately Reimbursed

0094A 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, 50 mcg/0.5 mL dosage, booster dose	Effective 3/29/22 Covered and Separately Reimbursed	Covered and Separately Reimbursed
Janssen COVID-19 Vaccine (Janssen) VACCINE	<u>Medicare Advantage Plans</u>	<u>Commercial Products</u>
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, 5x1010 viral particles/0.5mL dosage, for intramuscular use	Effective 10/11/20-12/31/21 - Per CMS billing guidelines, submit to Original Medicare Do Not Bill to BCBSRI Effective 1/1/22 – No reimbursement for claims submitted to BCBSRI for vaccine products health care providers receive at no cost	No reimbursement for claims submitted to BCBSRI for vaccine products health care providers receive at no cost
Janssen COVID-19 Vaccine (Janssen) ADMINISTRATION - SINGLE DOSE	<u>Medicare Advantage Plans</u>	<u>Commercial Products</u>
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, 5x1010 viral particles/0.5mL dosage, single dose	Effective 10/11/20-12/31/21 - Per CMS billing guidelines, submit to Original Medicare Do Not Bill to BCBSRI Effective 1/1/22 - Covered and Separately Reimbursed	Covered and Separately Reimbursed
0034A Immunization administration by intramuscular injection of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19]) vaccine, DNA, spike protein, adenovirus type 26 (Ad26) vector, preservative free, 5x1010 viral particles/0.5 mL dosage; booster dose	Effective 10/11/20-12/31/21 - Per CMS billing guidelines, submit to Original Medicare Do Not Bill to BCBSRI Effective 1/1/22 - Covered and Separately Reimbursed	Covered and Separately Reimbursed

AstraZeneca COVID-19 Vaccine (AstraZeneca, Inc.) VACCINE	<u>Medicare Advantage Plans</u>	<u>Commercial Products</u>
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, 5x1010 viral particles/0.5mL dosage, for intramuscular use	PENDING FDA EUA APPROVAL	PENDING FDA EUA APPROVAL
AstraZeneca COVID-19 Vaccine (AstraZeneca, Inc.) ADMINISTRATION - FIRST and SECOND DOSE	<u>Medicare Advantage Plans</u>	<u>Commercial Products</u>

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	PENDING FDA EUA APPROVAL	PENDING FDA EUA APPROVAL
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	PENDING FDA EUA APPROVAL	PENDING FDA EUA APPROVAL
Novavax COVID-19 Vaccine (Novavax, Inc.) VACCINE	<u>Medicare Advantage Plans</u>	<u>Commercial Products</u>
91304 Severe acute respiratory syndrome coronavirus 2 (SARSCoV-2) (coronavirus disease [COVID-19]) vaccine, recombinant spike protein nanoparticle, saponin-based adjuvant, preservative free, 5 mcg/0.5mL dosage, for intramuscular use	PENDING FDA EUA APPROVAL	PENDING FDA EUA APPROVAL
Novavax COVID-19 Vaccine (Novavax, Inc.) ADMINISTRATION - FIRST and SECOND DOSE	<u>Medicare Advantage Plans</u>	<u>Commercial Products</u>
0041A Immunization administration by intramuscular injection of severe acute respiratory syndrome coronavirus 2 (SARSCoV-2) (coronavirus disease [COVID-19]) vaccine, recombinant spike protein nanoparticle, saponin-based adjuvant, preservative free, 5 mcg/0.5mL dosage, first dose	PENDING FDA EUA APPROVAL	PENDING FDA EUA APPROVAL
0042A Immunization administration by intramuscular injection of severe acute respiratory syndrome coronavirus 2 (SARSCoV-2) (coronavirus disease [COVID-19]) vaccine, recombinant spike protein nanoparticle, saponin-based adjuvant, preservative free, 5 mcg/0.5mL dosage, second dose	PENDING FDA EUA APPROVAL	PENDING FDA EUA APPROVAL

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 June 2022

Provider Update, January 2022

Provider Update, February 2021

REFERENCES

1. 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

2. 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
3. U.S. Food and Drug Administration. FDA Issues Emergency Use Authorization for Third COVID-19 Vaccine | FDA
4. Centers for Medicare and Medicaid Services. Medicare Billing for COVID-19 Vaccine Shot Administration | CMS
5. American Medical Association. AMA announces update to COVID-19 vaccine CPT codes | American Medical Association (ama-assn.org)
6. U.S. Food and Drug Administration. Coronavirus (COVID-19) Update: FDA Authorizes Additional Vaccine Dose for Certain Immunocompromised Individuals | FDA
7. U.S. Food and Drug Administration. FDA Approves First COVID-19 Vaccine | FDA
8. Centers for Medicare and Medicaid Services. Medicare COVID-19 Vaccine Shot Payment | CMS
9. Centers for Disease Control and Prevention. Interim Clinical Considerations for Use of COVID-19 Vaccines | CDC
10. U.S. Food and Drug Association. FDA Authorizes Booster Dose of Pfizer-BioNTech COVID-19 Vaccine for Certain Populations | FDA

CLICK THE ENVELOPE ICON BELOW TO SUBMIT COMMENTS

This medical policy is made available to you for informational purposes only. It is not a guarantee of payment or a substitute for your medical judgment in the treatment of your patients. Benefits and eligibility are determined by the member's subscriber agreement or member certificate and/or the employer agreement, and those documents will supersede the provisions of this medical policy. For information on member-specific benefits, call the provider call center. If you provide services to a member which are determined to not be medically necessary (or in some cases medically necessary services which are non-covered benefits), you may not charge the member for the services unless you have informed the member and they have agreed in writing in advance to continue with the treatment at their own expense. Please refer to your participation agreement(s) for the applicable provisions. This policy is current at the time of publication; however, medical practices, technology, and knowledge are constantly changing. BCBSRI reserves the right to review and revise this policy for any reason and at any time, with or without notice. Blue Cross & Blue Shield of Rhode Island is an independent licensee of the Blue Cross and Blue Shield Association.

