Drug and Biologic Coverage Policy

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Coverage Policy Number 2029

COVID-19 Vaccine

Table of Contents

Related Coverage Resources

Clinical Trials
COVID-19: In Vitro Diagnostic Testing
COVID-19 Drug and Biologic Therapeutics

INSTRUCTIONS FOR USE
The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

Overview

This Coverage Policy addresses U.S. Food and Drug Administration Emergency Use Authorization COVID-19 vaccine products.

The use of therapeutic products for COVID-19 are addressed in a separate coverage policy. Please refer to the related coverage policy link above.

Coverage Policy

Coronavirus Disease Vaccines are considered medically necessary for the prevention of COVID-19 infection when the vaccine receives U.S. Food and Drug Administration (FDA) Emergency Use Authorization (EUA) and is used in accordance with the specifications of the EUA and recommendation by the Centers for Disease Control and Prevention's (CDC) Advisory Committee on Immunization Practices (ACIP).

General Background

U.S. Food and Drug Administration (FDA)

The FDA regulates vaccines which undergo a rigorous review of laboratory and clinical data to ensure the safety and effectiveness of these products. Vaccines approved for marketing may also be required to undergo additional studies to further evaluate the vaccine and often to address specific questions about the vaccine's safety, effectiveness, or possible side effects.

In certain types of emergencies, the FDA can issue an emergency use authorization, or EUA, to provide more timely access to critical medical products that may help during the emergency when there are no adequate, approved, and available alternative options. The EUA process is different than full FDA approval, clearance, or licensing because the EUA standard requires significantly less data than otherwise would be required for approval, clearance, or licensing by the FDA. This enables the FDA to authorize the emergency use of medical products that meet the criteria for issuance within weeks rather than months to years. Under the EUA authority, the FDA evaluates requests for authorization very quickly using the evidence that is available, carefully balancing the risks and benefits of the product, in addition to evaluating other criteria. EUAs are in effect until the emergency declaration ends but can be revised or revoked during the emergency, or as products meet the criteria to become approved, cleared, or licensed by the FDA.

On February 4, 2020, the HHS Secretary determined that there is a public health emergency involving COVID-19, and subsequently issued declarations justifying the use of EUAs for medical products to prevent, treat and diagnose COVID-19. To date, over 100 EUAs have been issued to allow emergency access to tests, medical devices, personal protective equipment and therapeutics.

The FDA is expediting clinical trials for vaccines by providing timely advice to and interactions with vaccine developers. The FDA is also supporting product development and scaling up of manufacturing capacity for high priority vaccines for COVID-19.

In October 2020 the FDA issued guidance to provide sponsors of requests for Emergency Use Authorization for COVID-19 vaccines with recommendations regarding the data and information needed to support the issuance of an EUA for an investigational vaccine to prevent COVID-19 for the duration of the COVID-19 public health emergency.

Candidate vaccines for EUA are reviewed by the FDA's Vaccines and Related Biological Products Advisory Committee. The Committee reviews and evaluates data concerning the safety, effectiveness, and appropriate use of vaccines and related biological products which are intended for use in the prevention, treatment, or diagnosis of human diseases.The Committee also considers the quality and relevance of FDA's research program which provides scientific support for the regulation of these products and makes appropriate recommendations to the Commissioner of Food and Drugs. Two vaccine developers have submitted candidate vaccines for Emergency Use Authorization:

Vaccine Developer	Vaccine Name	Date of FDA review for EUA
Pfizer/BioNTech	BNT-162	December 10, 2020
Moderna	mRNA-1273	December 17, 2020

Professional Societies/Organizations

Advisory Committee on Immunization Practices (ACIP)

On December 1, 2020, the ACIP voted to approve when a COVID-19 vaccine is authorized by FDA and recommended by ACIP, vaccination in the initial phase of the COVID-19 vaccination program (Phase 1a) should be offered to both health care personnel and residents of long-term care facilities. This recommendation has been adopted by the CDC Director.

Health care personnel are defined as paid and unpaid persons serving in health care settings who have the potential for direct or indirect exposure to patients or infectious materials. Long-term care facility residents are defined as adults who reside in facilities that provide a variety of services, including medical and personal care, to persons who are unable to live independently.

Subsequent to the FDA's EUA of a new vaccine the ACIP provides recommendations of use for each specific product.

Coding/Billing Information

Note: 1) This list of codes may not be all-inclusive.
2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

COVID-19 EUA Prevention Vaccines[†]

CPT®* Codes	Description
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 (Report 91300 with administration codes 0001A, 0002A)
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 (Report 91301 with administration codes 0011A, 0012A)

[†]**Note: Government supplied vaccine. Codes are effective on date of EUA.**

Vaccine Administration Codes [††]

CPT®* Codes	Description
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 (Report 0001A, 0002A for the administration of vaccine 91300)
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 (Report 0001A, 0002A for the administration of vaccine 91300)
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 (Report 0011A, 0012A for the administration of vaccine 91301)
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 (Report 0011A, 0012A for the administration of vaccine 91301)

[††]**Note: Codes are effective on date of EUA.**

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