Pfizer Logo

Pfizer and BioNTech Receive U.S. FDA Approval for XFG-adapted COVID-19 Vaccine

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- *2026-2027 COVID-19 vaccine formula targets the XFG variant, in line with FDA guidance to more closely match contemporary circulating variants*
- *Shipping will begin immediately to ensure rapid access to this season's vaccine*

NEW YORK & MAINZ, Germany--(BUSINESS WIRE)-- Pfizer Inc. (NYSE: PFE, "Pfizer") and BioNTech SE (Nasdaq: BNTX, "BioNTech") announced today that the U.S. Food and Drug Administration (FDA) has approved the supplemental Biologics License Application (sBLA) for the companies' 2026-2027 COVID-19 vaccine formula targeting the XFG variant (COMIRNATY® XFG; COVID-19 Vaccine, mRNA) for use in adults ages 65 years and older, as well as in individuals ages 5 through 64 years with at least one underlying condition that puts them at high risk for severe outcomes from COVID-19.[1]

The FDA approval is based on the cumulative body of evidence previously submitted by Pfizer and BioNTech that includes clinical, non-clinical and real-world data supporting the safety and effectiveness of COMIRNATY, as well as manufacturing/quality and non-clinical data showing that the XFG-adapted COVID-19 vaccine generated strong immune responses against currently circulating SARS-CoV-2 variants, including XFG, XFG.1.1, NB.1.8.1, PQ.17, PQ.2.8.1 and other contemporary lineages.[2]

The selection of the XFG variant is based on guidance from the FDA as the preferred composition of COVID-19 vaccines for use in the U.S. beginning in fall 2026.[3] This season's Pfizer and BioNTech COVID-19 vaccine will begin shipping immediately and will be available in pharmacies, hospitals, and clinics across the U.S. in the coming days.

To date, more than five billion doses of COMIRNATY have been distributed globally, and it continues to demonstrate a favorable safety and efficacy profile supported by extensive real-world evidence as well as clinical, non-clinical, pharmacovigilance, and manufacturing data.[2] The COVID-19 vaccines by Pfizer and BioNTech are based on BioNTech's proprietary mRNA technology and were developed by both companies. BioNTech is the Marketing Authorization Holder for the Pfizer-BioNTech COVID-19 vaccine and its adapted vaccines in the United States, the EU, the United Kingdom, and other countries, and the holder of emergency use authorizations or equivalents in other countries.

U.S. INDICATION AND IMPORTANT SAFETY INFORMATION
INDICATION

COMIRNATY (COVID-19 VACCINE, mRNA) is a vaccine to protect against coronavirus disease 2019 (COVID-19).

COMIRNATY is for people who are:

- 65 years of age and older, or
- 5 years through 64 years of age with at least one underlying condition that puts them at high risk for severe outcomes from COVID-19.

IMPORTANT SAFETY INFORMATION

- You or your child should **NOT** get COMIRNATY ® (COVID-19 Vaccine, mRNA) if you or your child had a severe allergic reaction after a previous dose of COMIRNATY or any Pfizer-BioNTech COVID-19 vaccine or to any ingredient in these vaccines
- There is a remote chance that COMIRNATY could cause a severe allergic reaction. A severe allergic reaction would usually occur within a few minutes to 1 hour after getting a dose. For this reason, the vaccination provider may ask you or your child to stay at the place where you or your child received the vaccine for monitoring after vaccination. Signs of a severe allergic reaction can include:
    - Difficulty breathing
    - Swelling of the face and throat
    - A fast heartbeat
    - A bad rash all over the body
    - Dizziness and weakness
- Myocarditis (inflammation of the heart muscle) and pericarditis (inflammation of the lining outside the heart) have occurred in some people who have received mRNA COVID-19 vaccines, including COMIRNATY and Pfizer-BioNTech COVID-19 vaccines. Myocarditis and pericarditis following administration of mRNA COVID-19 vaccines have occurred most commonly in males 12 years through 24 years of age. In most of these people, symptoms began within a week following vaccination. You should seek medical attention right away if you or your child have any of the following symptoms after receiving the COMIRNATY, particularly during the 2 weeks after receiving a dose of the vaccine:
    - Chest pain
    - Shortness of breath
    - Feelings of having a fast-beating, fluttering, or pounding heart
    - Additional symptoms, particularly in children, may include:
        - Fainting
        - Unusual and persistent fatigue or lack of energy
        - Persistent vomiting
        - Persistent pain in the abdomen
        - Unusual and persistent cool, pale skin
- Fainting can happen after getting injectable vaccines including COMIRNATY. Your vaccination provider may ask you to sit or lie down
- People with weakened immune systems may have a reduced immune response to COMIRNATY
- Vaccination with COMIRNATY may not protect all people who receive the vaccine

Before getting COMIRNATY, tell your vaccination provider about all of your or your child's medical conditions, including if you or your child:

- have any allergies
- had a severe allergic reaction after receiving a previous dose of any COVID-19 vaccine
- have had myocarditis (inflammation of the heart muscle) or pericarditis (inflammation of the lining outside the heart)
- have a fever
- have a bleeding disorder or are on a blood thinner
- are immunocompromised or are on a medicine that affects your immune system

- are pregnant, plan to become pregnant, or are breastfeeding
- have received another COVID-19 vaccine
- have ever fainted in association with an injection

Additional side effects that have been reported with COMIRNATY or Pfizer-BioNTech COVID-19 vaccines include:

- Non-severe allergic reactions such as rash, itching, hives, or swelling of the face
- Injection site reactions: pain, swelling, redness, arm pain
- General side effects: tiredness, headache, muscle pain, chills, joint pain, fever, nausea, feeling unwell, swollen lymph nodes (lymphadenopathy), decreased appetite, diarrhea, vomiting, dizziness
- Febrile seizures (convulsions during a fever) in children 5 through 11 years of age

These may not be all the possible side effects of COMIRNATY. Ask your or your child's healthcare provider about any side effects that concern you.

You may report side effects to FDA/CDC Vaccine Adverse Event Reporting System (VAERS). The VAERS toll-free number is 1?800?822?7967 or report online to www.vaers.hhs.gov/reportevent.html.

In addition, you can report side effects to Pfizer Inc. at 1-800-438-1985 or www.pfizersafetyreporting.com.

Please click here for full Prescribing Information and Patient Information for COMIRNATY.

About Pfizer: Breakthroughs That Change Patients' Lives

At Pfizer, we apply science and our global resources to bring therapies to people that extend and significantly improve their lives. We strive to set the standard for quality, safety and value in the discovery, development and manufacture of health care products, including innovative medicines and vaccines. Every day, Pfizer colleagues work across developed and emerging markets to advance wellness, prevention, treatments and cures that challenge the most feared diseases of our time. Consistent with our responsibility as one of the world's premier innovative biopharmaceutical companies, we collaborate with health care providers, governments and local communities to support and expand access to reliable, affordable health care around the world. For more than 175 years, we have worked to make a difference for all who rely on us. We routinely post information that may be important to investors on our website at www.Pfizer.com. In addition, to learn more, please visit us on www.Pfizer.com and follow us on X at @Pfizer and @Pfizer News, LinkedIn, YouTube and like us on Facebook at Facebook.com/Pfizer.

Pfizer Disclosure Notice

The information contained in this release is as of August 27, 2026. Pfizer assumes no obligation to update forward-looking statements contained in this release as the result of new information or future events or developments.

This release contains forward-looking information about COMIRNATY® (COVID-19 VACCINE, mRNA), including its potential benefits, manufacturing and supply and an approval by the U.S. Food and Drug Administration of the supplemental Biologics License Application for the companies' 2026-2027 COVID-19 vaccine formula targeting the XFG variant for use in adults ages 65 years and older, as well as in individuals ages 5 through 64 years with at least one underlying condition that puts them at high risk for severe outcomes from COVID-19, that involves substantial risks and uncertainties that could cause actual results to differ materially from those expressed or implied by such statements. Risks and uncertainties include, among other

things, uncertainties regarding the commercial success of COMIRNATY; the uncertainties inherent in research and development, including the ability to meet anticipated clinical endpoints, commencement and/or completion dates for our clinical trials, regulatory submission dates, regulatory approval dates and/or launch dates, as well as the possibility of unfavorable new clinical data and further analyses of existing clinical data; the risk that clinical trial data are subject to differing interpretations and assessments by regulatory authorities; whether regulatory authorities will be satisfied with the design of and results from our clinical studies; whether and when applications may be filed with regulatory authorities in particular jurisdictions for COMIRNATY for any potential indication, including for the 2026-2027 COVID-19 vaccine formula; whether and when any such applications that may be pending or filed for COMIRNATY may be approved by regulatory authorities, which will depend on myriad factors, including making a determination as to whether the product's benefits outweigh its known risks and determination of the product's efficacy and, if approved, whether COMIRNATY will be commercially successful; decisions by regulatory authorities impacting labeling, manufacturing processes, safety and/or other matters that could affect the availability or commercial potential of COMIRNATY; risks and uncertainties related to changes to vaccine or other healthcare policy in the U.S. or other jurisdictions; the risk that demand for any products may be reduced or no longer exist or not meet expectations which may lead to reduced revenues, excess inventory on-hand/or in the channel or other unanticipated charges; uncertainties related to recommendations and coverage for, and the public's adherence to vaccines, boosters, treatments or combinations; risks related to our ability to accurately predict or achieve our revenue forecasts for COMIRNATY or any potential future COVID-19 vaccines; risks and uncertainties related to issued or future executive orders or other new, or changes in, laws or regulations; uncertainties regarding the impact of COVID-19 on our business, operations and financial results; and competitive developments.

A further description of risks and uncertainties can be found in Pfizer's Annual Report on Form 10-K for the fiscal year ended December 31, 2025, and in its subsequent reports on Form 10-Q, including in the sections thereof captioned "Risk Factors" and "Forward-Looking Information and Factors That May Affect Future Results", as well as in its subsequent reports on Form 8-K, all of which are filed with the U.S. Securities and Exchange Commission and available at www.sec.gov and www.pfizer.com.

About BioNTech

Biopharmaceutical New Technologies (BioNTech) is a global next generation immunotherapy company pioneering novel investigative therapies for cancer and other serious diseases. BioNTech exploits a wide array of computational discovery and therapeutic modalities with the intent of rapid development of novel biopharmaceuticals. Its diversified portfolio of oncology product candidates aiming to address the full continuum of cancer includes mRNA cancer immunotherapies, next-generation immunomodulators and targeted therapies such as antibody-drug conjugates (ADCs) and innovative chimeric antigen receptor (CAR) T cell therapies. Based on its deep expertise in mRNA development and in-house manufacturing capabilities, BioNTech and its collaborators are researching and developing multiple mRNA vaccine candidates for a range of infectious diseases alongside its diverse oncology pipeline. BioNTech has established a broad set of relationships with multiple global and specialized pharmaceutical collaborators, including Bristol Myers Squibb, Duality Biologics, Genentech, a member of the Roche Group, Genmab, MediLink, OncoC4, and Pfizer.

For more information, please visit www.BioNTech.com.

BioNTech Forward-looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, as amended, including, but not limited to, statements concerning: BioNTech's efforts to combat COVID-19; the collaboration between BioNTech and Pfizer; regulatory submissions and regulatory approvals or authorizations, including the U.S. Food and Drug Administration's approval of the supplemental

Biologics License Application for the companies' 2026-2027 COVID-19 vaccine formula targeting the XFG variant for use in adults ages 65 years and older, as well as in individuals ages 5 through 64 years with at least one underlying condition that puts them at high risk for severe outcomes from COVID-19; expectations regarding manufacturing, distribution and supply; qualitative assessments of available data and expectations of potential benefits, including the adapted vaccine's response against multiple SARS-CoV-2 variants, including the XFG variant and other currently circulating variants; expectations regarding anticipated changes in COVID-19 vaccine demand, including changes to the ordering environment; and expected regulatory recommendations to adapt vaccines to address new variants or sublineages. In some cases, forward-looking statements can be identified by terminology such as "will," "may," "should," "expects," "intends," "plans," "aims," "anticipates," "believes," "estimates," "predicts," "potential," "continue," or the negative of these terms or other comparable terminology, although not all forward-looking statements contain these words.

The forward-looking statements in this press release are neither promises nor guarantees, and you should not place undue reliance on these forward-looking statements because they involve known and unknown risks, uncertainties, and other factors, many of which are beyond BioNTech's control and which could cause actual results to differ materially from those expressed or implied by these forward-looking statements. These risks and uncertainties include, but are not limited to: the uncertainties inherent in research and development, including the ability to meet anticipated clinical endpoints, commencement and/or completion dates for clinical trials, regulatory submission dates, regulatory approval dates and/or launch dates, as well as risks associated with preclinical and clinical data, including the data discussed in this release, and including the possibility of unfavorable new preclinical, clinical or safety data and further analyses of existing preclinical, clinical or safety data; the nature of the clinical data, which is subject to ongoing peer review, regulatory review and market interpretation; BioNTech's pricing and coverage negotiations with governmental authorities, private health insurers and other third-party payors; the future commercial demand and medical need for initial or booster doses of a COVID-19 vaccine; the impact of tariffs and escalations in trade policy; the availability of raw materials to manufacture a vaccine; our vaccine's formulation, dosing schedule and attendant storage, distribution and administration requirements, including risks related to storage and handling after delivery; competition from other COVID-19 vaccines or related to BioNTech's other product candidates, including those with different mechanisms of action and different manufacturing and distribution constraints, on the basis of, among other things, efficacy, cost, convenience of storage and distribution, breadth of approved use, side-effect profile and durability of immune response; the ability to obtain recommendations from vaccine advisory or technical committees and other public health authorities and uncertainties regarding the commercial impact of any such recommendations; the timing of and BioNTech's ability to obtain and maintain regulatory approval for BioNTech's product candidates; the ability of BioNTech's COVID-19 vaccines to prevent COVID-19 caused by emerging virus variants; BioNTech's ability to identify research opportunities and discover and develop investigational medicines; the ability and willingness of BioNTech's third-party collaborators to continue research and development activities relating to BioNTech's development candidates and investigational medicines; the impact of COVID-19 on BioNTech's development programs, supply chain, collaborators and financial performance; unforeseen safety issues and potential claims that are alleged to arise from the use of BioNTech's COVID-19 vaccine and other products and product candidates developed or manufactured by BioNTech; BioNTech's and its collaborators' ability to commercialize and market BioNTech's COVID-19 vaccine and, if approved, its product candidates; BioNTech's ability to manage its development and related expenses; regulatory developments in the United States and other countries; BioNTech's ability to effectively scale its production capabilities and manufacture its products and BioNTech's product candidates; risks relating to the global financial system and markets; and other factors not known to BioNTech at this time.

You should review the risks and uncertainties described under the heading "Risk Factors" in BioNTech's Report on Form 6-K for the period ended June 30, 2026, and in subsequent filings made by BioNTech with the SEC, which are available on the SEC's website at https://www.sec.gov/. These forward-looking statements speak only

as of the date hereof. Except as required by law, BioNTech disclaims any intention or responsibility for updating or revising any forward-looking statements contained in this press release in the event of new information, future developments or otherwise.

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[1] CDC. Underlying Conditions and the Higher Risk for Severe COVID-19. Updated February 6, 2025. Accessed July 24, 2026. https://www.cdc.gov/covid/hcp/clinical-care/underlying-conditions.html

[2] Vaccines and Related Biological Products Advisory Committee. Meeting Presentation - 2026-2027 COVID-19 Vaccine Formula: Pfizer/BioNTech Supportive Data. May 28, 2026. Accessed July 24, 2026. https://www.fda.gov/media/192765/download

[3] FDA. COVID-19 Vaccines (2026-2027 Formula) for Use in the United States Beginning in Fall 2026. Updated May 29, 2026. Accessed July 24, 2026. https://www.fda.gov/vaccines-blood-biologics/industry-biologics/covid-19-vaccines-2026-2027-formula-use-united-states-beginning-fall-2026

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