

UNDERSTANDING RECENT GUIDANCE

Individuals Who Should Receive COVID-19 Vaccination

What is the FDA's regulatory framework for COVID-19 vaccination?¹

On May 20, 2025, the FDA published an updated policy position in the *New England Journal of Medicine* on an evidence-based approach to COVID-19 vaccination.

The following patient populations are at elevated risk for severe outcomes from COVID-19 infection¹:



Adults aged ≥65 years

~61 million (nearly 1 in 4 adults in the US)²



Individuals aged ≥6 months who have
≥1 underlying condition that puts them at
high risk for severe COVID-19 outcomes

~100–200 million Americans^{1,3}

What underlying conditions increase the risk of severe COVID-19?

CDC 2025 List of Underlying Medical Conditions That Increase a Person's Risk of Severe COVID-19¹

Asthma	Disabilities, [†] including Down's syndrome
Cancer Hematologic malignancies	Heart conditions (such as heart failure, coronary artery disease, or cardiomyopathies)
Cerebrovascular disease	HIV (human immunodeficiency virus)
Chronic kidney disease* People receiving dialysis	Mental health conditions limited to the following: Mood disorders, including depression Schizophrenia spectrum disorders
Chronic lung diseases limited to the following: Bronchiectasis COPD (chronic obstructive pulmonary disease) Interstitial lung disease Pulmonary embolism Pulmonary hypertension	Neurologic conditions limited to dementia [†] and Parkinson's disease
Chronic liver diseases limited to the following: Cirrhosis Nonalcoholic fatty liver disease Alcoholic liver disease Autoimmune hepatitis	Obesity (BMI ≥30 kg/m ² or ≥95th percentile in children)
Cystic fibrosis	Physical inactivity
Diabetes mellitus, type 1	Pregnancy and recent pregnancy [‡]
Diabetes mellitus, type 2*	Primary immunodeficiencies
Gestational diabetes	Heart conditions (such as heart failure, coronary artery disease, or cardiomyopathies)
	Smoking, current and former
	Solid-organ or blood stem-cell transplantation
	Tuberculosis
	Use of corticosteroids or other immunosuppressive medications

*Indicates presence of evidence for pregnant and nonpregnant women.¹

[†]Underlying conditions for which there is evidence in pediatric patients.¹

[‡]As of May 27, 2025, the US Secretary of Health and Human Services, Robert F. Kennedy Jr., announced that the COVID-19 vaccine will no longer be recommended for healthy pregnant women.⁴

UNDERSTANDING RECENT FEDERAL GUIDANCE

COVID-19 Vaccination in Children and Adolescents

What is the updated CDC recommendation on vaccinating children and adolescents against COVID-19?

As of May 28, 2025, the CDC recommends shared clinical decision making for vaccinating individuals ages 6 months–17 years who are NOT moderately or severely immunocompromised.⁵



Shared clinical decision-making vaccinations are individually based and informed by a decision process between the healthcare provider and the patient or parent/guardian. Where the parent presents with a desire for their child to be vaccinated, children 6 months and older may receive COVID-19 vaccination, informed by the clinical judgment of a healthcare provider and personal preference and circumstances.

Where can I find more information?



FDA Policy Position: An Evidence-Based Approach to COVID-19 Vaccination



CDC 2025 Child and Adolescent Immunization Schedule

BMI, body mass index; CDC, Centers for Disease Control and Prevention; COVID-19, coronavirus disease 2019; FDA, US Food and Drug Administration.

References: 1. Prasad V, et al. *N Engl J Med*. Published online May 20, 2025. doi:10.1056/NEJMs2506929 2. U.S. Census Bureau. Accessed May 12, 2025. <https://www.census.gov/data/tables/time-series/demo/popest/2020s-national-detail.html>. 3. Adams ML, et al. *Emerg Infect Dis*. 2020;26(8):1831-1833. 4. Schwartz JL. *N Engl J Med*. Published online June 18, 2025. doi:10.1056/NEJMp2507766. 5. CDC. Accessed June 4, 2025. <https://www.cdc.gov/vaccines/hcp/imz-schedules/downloads/child/0-18yrs-child-combined-schedule.pdf>