

COVID-19 Vaccine Information

Vaccine		Trial			Efficacy				Efficacy at Preventing Symptomatic Infection with Variants (1 dose vs. 2 doses)				Additional/Booster Dose Recommendations			Vaccine Specifics					Looking Ahead		
Type	Developer (Name)	Investigational Status (Participants)	EUA Submission	Full FDA/BLA Approval	First dose efficacy	Second dose efficacy	Prevention of severe disease	Pediatric Efficacy (95% CI)	*ALPHA B.1.1.7	*BETA B.1.351	*GAMMA P.1	*DELTA B.1.617	Population	Timing	Route/# of doses	Timing of Doses	Vial Size	Storage requirements	Preparation & Handling	Stability after opening		Can overfill be used as extra doses?	
mRNA	Pfizer-BioNTech (BNT162b2) (brand name Comirnaty, pronounced Koe-Mir-na-tee)	Phase 2 & 3 with EUA (44,000)	EUA approved for ages 12-15 and third dose in immunocompromised individuals	FDA approved for the prevention of COVID-19 disease in those 16 years of age and older	52%	95%	95%	100% (available for age 12+). Vaccine was shown to be safe in participants from 5-11 y/o	93%	100%	A single dose of Pfizer provided 83% effectiveness against Gamma, and second dose was 98% effective	33% - 88%	96% (from hospitalization)	<ul style="list-style-type: none"> 65 years and older and residents in long-term care settings should receive a booster shot 50-64 years with underlying medical conditions should receive a booster shot 18-49 years with underlying medical conditions may receive a booster shot at, based on their individual benefits and risks 18-64 years who are at increased risk for COVID-19 exposure and transmission because of occupational or institutional setting may receive a booster shot, based on their individual benefits and risks 	At least 6 months after primary series	IM/2 doses	0, 21 days ²	MDV (5 doses) / 30 mcg/0.3mL ¹³	<ul style="list-style-type: none"> Ultra-cold storage (-80 to -60°C) until expiration date Thermal shippers replenished with dry ice for 30 days Freezer (-25 to -15°C) for up to 2 weeks Refrigeration (2-8°C) for up to 1 month,²¹ if not used, discard. Room Temp: thawed vials must be used within 2 hours Do not refreeze once thawed. 	<ul style="list-style-type: none"> Thawing and reconstitution required. Reconstitute with 1.8 mL of 0.9% sodium chloride 	Stable up to 6 hours after dilution.	Yes	Expect approval for 5-11 y/o age group for 2 dose pending FDA review
		Phase 3 with EUA (30,000)	EUA approved for ages 18 and above	Application submitted in June (pending approval)	80%	90%	95%	EUA Application submitted 6/10 for 12 to 17 year olds.	88-100%	61-96%	Moderna vaccine antibodies maintains 93% efficacy against variants	Moderna vaccine antibodies maintains 93% efficacy against variants	Under EUA: Additional dose for patients 18+ years of age, who have undergone solid organ transplantation, or who are diagnosed with conditions that are considered to have an equivalent level of immunocompromise	At least 28 days following the second dose	IM/2 doses	0, 28 days ²	MDV (10 doses) / 100 mcg/0.5 mL ¹³	<ul style="list-style-type: none"> Freezer (-50 to -15°C) for 7 months Refrigeration (2-8°C) for up to 3 months prior to first use. Room Temp (8-25°C): 24 hours (unpunctured) Do not refreeze once thawed. 	<ul style="list-style-type: none"> Thawing required. Vaccine may be thawed in the refrigerator or at room temperature. Refrigerator: 2.5 hours Room temperature: 1 hour Vials that have not been punctured may be kept between 8°C and 25°C for up to 24 hours 	Stable up to 12 hours after puncture.	Yes	Full BLA approval and booster dose pending FDA review. Phase 3 trial shows 93% efficacy through six months after second dose	
Viral Vector	Janssen/J&J (Ad26.COV2.S)	Phase 3 (44,325)	EUA approved 2/27 for 18 years and older (11 day pause for safety monitoring, resumed 4/23)	N/A	79%	94% (Booster dose data)	74%	Safety and efficacy of this vaccine has not been established in individuals younger than 18 y/o	Single dose J&J elicited dual mechanisms of protection against COVID-19 and variants	Single dose J&J elicited dual mechanisms of protection against COVID-19 and variants	Single dose J&J elicited dual mechanisms of protection against COVID-19 and variants	(9/21 press release) No reduction in effectiveness including against Delta variant	No authorized additional or booster doses	4x increase in antibodies when given at 2 mos., 12x increase when given at 6 mos	IM/1 dose	0 day ⁶	MDV (5 doses)	Refrigerator (2-8°C) for up to 6 months	Mix contents of vial gently by swirling before withdrawing. DO NOT SHAKE.	2 hours at room temperature, or 6 hours at 2-8°C	No	Full BLA approval and booster dose pending FDA review. Evidence of benefit with booster dose in two Phase 1/2a trials	
		Phase 3 (30,000)	Considering bypassing EUA approval and going for BLA approval	Considering bypassing EUA approval and going for BLA approval	79%	82%	100%	N/A	Vaccine has been seen to neutralize against multiple COVID-19 variants	Vaccine has been seen to neutralize against multiple COVID-19 variants	Vaccine has been seen to neutralize against multiple COVID-19 variants	Vaccine has been seen to neutralize against multiple COVID-19 variants	N/A	Not in the US, but in the UK per provider's discretion	IM/2 doses	0, 28 days ⁶	MDV (10 doses) ⁵	Refrigerator (2-8°C) for up to 6 months	N/A	N/A	Yes	Will seek FDA authorization in second half of 2021	
Protein Subunit	Novavax (NVX-CoV2373)	Phase 3 (30,000)	Likely seek EUA Q4 2021	N/A	Not quantified	89.70%	100%	N/A (currently studying in 12: 17 y/o)	93.0%	93.0%	N/A	N/A	N/A	6 months after initial regimen had a 4.6 fold increase in antibodies	IM/2 doses	0, 21 days ⁵	MDV (10 doses)	Refrigerator (2-8°C) up to 6 months Room temp for 24 hours	N/A	N/A	N/A	N/A	Likely seek EUA Q4 2021

Disclaimer

The information contained in this vaccine informational sheet is emerging and rapidly evolving because of ongoing research and events and is subject to the professional judgment and interpretation of the practitioner due to the uniqueness of the needs of individual patients. ASHP provides this information to help practitioners better understand the current status of COVID-19 vaccine testing. ASHP has made reasonable efforts to ensure the accuracy and appropriateness of the information presented. However, any reader of this information is advised that ASHP is not responsible for the currency of the information, for any errors or omissions, and/or for any consequences arising from the use of the information for any purpose. Any reader of this document is cautioned that ASHP makes no representation, guarantee, or warranty, express or implied, as to the accuracy and appropriateness of the information contained in this vaccine information sheet and will bear no responsibility or liability for the results or consequences of its use.

References

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- Janssen EUA https://www.fda.gov/media/146304/download
- Moderna EUA (Mar 31 2021) https://www.fda.gov/media/144637/download
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- Pfizer EUA 12-15 years https://www.fda.gov/media/144412/download
- Pfizer EUA Storage https://www.fda.gov/media/148877/download
- Sanofi Pasteur/GSK start Phase 3 https://mi.eu.globenewswire.com/Resource/Download/c8640d60-4f51-4b9f-9b65-b76b16d80555
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- https://www.gov.uk/government/news/vaccines-highly-effective-against-b-1-617-2-variant-after-2-doses
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- https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-additional-vaccine-dose-certain-immunocompromised
- Pfizer Vaccine Updated EUA (8/12/21): https://www.fda.gov/media/150386/download
- Moderna Vaccine Updated EUA (8/12/21): https://www.fda.gov/media/144636/download
- SARS-CoV-2 Variants of Concern (VOCs) according to WHO

Useful Resources

ASHP COVID Vaccine Info Website
[ASHP COVID Vaccine Info Website](#)
[Centers for Disease Control and Prevention \(CDC\) Weekly COVID Data Tracker - Updated information on COVID-19 reported cases, variants, testing, and hospitalizations](#)
[Johns Hopkins Coronavirus Resource Center - National and global map with up to date numbers and visualized COVID-19 tracking](#)
[Bloomberg COVID-19 Tracker - interactive world and US maps with up to date country and state vaccination rates accompanied by news and other links](#)
[WHO Tracking Variants](#)

ASHP Statement

ASHP will continue to advocate on behalf of our members and support COVID-19 vaccine planning efforts; a number of resources, including ASHP's Principles for COVID-19 Vaccine Distribution, Allocation, and Mass Immunization, are available on our COVID-19 vaccine page

<https://www.ashp.org/COVID-19/Vaccines>



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