

2025–26 COVID-19 Vaccine Products Clinical/Operational Reference

Insurance Coverage	- Health plans will continue to cover all ACIP-recommended immunizations that were recommended as of September 1, 2025, including updated formulations of the COVID-19 and influenza vaccines, with no cost-sharing for patients through the end of 2026 - statement from America's Health Insurance Plans (AHIP). - Federally regulated insurance plans: fully-insured plans subject to the Affordable Care Act (ACA), shared clinical decision making is required to be covered through ACA. - State-regulated insurance programs will cover; Illinois Department of Public Health (IDPH) standing order and state legislation supporting coverage.		
Documentation	- Documenting Shared Clinical Decision Making (SCDM): The AAP recommends documenting that discussion about the vaccine occurred and a decision to vaccinate followed shared clinical decision making. - No additional documentation is required for health insurance - bill as you would other vaccines. - In IL, PCPs, specialty physicians, PAs, NPs, RNs, and pharmacists can conduct SCDM (MAs and pharmacy techs cannot). SCDM does not need to be a face-to-face conversation and does not need to take place on the same day as administration. Example: <i>A RN has a conversation on the phone with the parent or patient when they make the appointment, then an MA could administer the vaccine at the visit.</i> - As always, patients must receive a Vaccine Information Statement (VIS); record publication date and date given. - More information on SCDM from Common Health Coalition here.		
Informed Consent	- Standard informed consent processes should be followed for any vaccine administration and no new forms are required to meet the SCDM standard. - The AAP recommends considering signed consent forms particularly for patients who receive the vaccine for “off label” indications. - Informed consent should be documented to minimize liability.		
Malpractice Considerations	SPIKEVAX (Moderna, 2025/26 Formula)	COMIRNATY (Pfizer, BioNTech, 2025/26 Formula)	NUVAXOVID (Novavax, 2025/26 Formula)
	FDA-approved: 6mo–64 years with ≥ 1 underlying condition and all those 65+.	FDA-approved: 5–64 years with ≥ 1 underlying condition and all those 65+.	FDA-approved: 12–64 years with ≥ 1 underlying condition and all those 65+.
	- Consult the CDC Underlying Conditions website referred to in the FDA package inserts for all COVID-19 vaccine formulations for a list of high risk conditions, including asthma, mood disorders, and physical inactivity. - Off label use is common and legally permissible if aligned with standard of care (SOC) - state and professional society recommendations help support SOC. FDA and ACIP recommendations do not determine SOC. - Recommendations from the American Academy of Pediatrics (AAP) and the IDPH. - Consult your own malpractice insurance with special attention to areas added for COVID-19. Example of message from malpractice coverage supplier to member on 2025/26 COVID-19 vaccines: <i>“Clinicians should seek guidance from their professional association and follow best judgment and guidance from the clinical experts. There is no prohibitive law or regulation. As relating to MPL coverage, we will stand behind clinical judgment.”</i> - More information on medical liability from the AAP here.		