
A Guide to Vaccine Coverage Policies

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Large, 3D, blue letters spelling out the word "VACCINES" are positioned in the bottom right corner of the page, partially overlapping the footer text.

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Background

Until recently, vaccine coverage and cost-sharing requirements varied widely across commercial, Medicaid, and Medicare markets. For example, vaccines covered by Medicare Part B (i.e., influenza, pneumococcal, and hepatitis B for medium- and high-risk individuals) were covered without cost-sharing, while vaccines covered by Medicare Part D (i.e., all commercially available vaccines not covered by Part B) often required beneficiary cost-sharing.

Key policy developments over several decades expanded coverage for adults and children across markets and increased coverage consistency. For example, the Vaccines for Children (VFC) program guarantees access to Advisory Committee on Immunization Practices (ACIP)-recommended vaccines without cost-sharing for Medicaid-eligible, uninsured, under-insured, and American Indian/Alaska Native children. Additionally, the Affordable Care Act (ACA) requires commercial, employer, marketplace, and Medicaid expansion plans to cover all ACIP-recommended vaccines, including those with shared clinical decision-making (SCDM) recommendations, with no cost-sharing. More recently, the Inflation Reduction Act (IRA) mandated vaccine coverage without cost-sharing in Medicare Part D and Medicaid, two markets with historical vaccine coverage gaps.

These and other key policies have, over time, expanded access to recommended vaccines without cost-sharing for all children and nearly all insured adults in the United States. Despite these changes, some requirements vary across markets and for under- and uninsured individuals.

Summary of Federal Policies and Trends Across Markets

A variety of federal policies govern vaccine coverage across markets, including which products coverage requirements apply to, the timing for coverage of new products, and where and from whom patients can access products.

Table 1. Federal Vaccine Coverage Provisions Across Markets and Programs

Market and Enrollment (Millions) ¹	Covered Products	Coverage Timing for New Products	Other Access Considerations
Commercial: 207.35M in 2020 ²	<ul style="list-style-type: none"> All ACIP-recommended products listed on the immunization schedules, including those with SCDM recommendations 	<ul style="list-style-type: none"> By the first day of the plan year that begins one year after the ACIP recommendation is published in the Morbidity and Mortality Weekly Report (MMWR) or on the Immunization Schedule, whichever happens sooner COVID-19 vaccines must be covered immediately upon Food and Drug Administration (FDA) approval /authorization (e.g., emergency use authorization) 	<ul style="list-style-type: none"> No specific limitations on sites of care (SOCs), though plans may impose restrictions Out-of-network (OON) coverage is not required Grandfathered and non-compliant plans are exempt from these coverage provisions Travel vaccines are not listed on the schedules, and are therefore not included
Medicare Part B: 60.25M in 2023 ³	<ul style="list-style-type: none"> Vaccines for influenza, pneumococcal, COVID-19, and hepatitis B (for individuals considered at intermediate- to high-risk only)⁴ 	<ul style="list-style-type: none"> After FDA approval, coverage cannot be effectuated until reimbursement is established in the Centers for Medicare and Medicaid Services' (CMS) quarterly pricing file 	<ul style="list-style-type: none"> Providers must be registered as Medicare providers or as mass immunizers (e.g., pharmacists)
Medicare Part D: 51.74M in 2023 ⁵	<ul style="list-style-type: none"> All commercially available vaccines 	<ul style="list-style-type: none"> Once an ACIP recommendation is adopted by the 	<ul style="list-style-type: none"> No specific limitations on SOCs

¹ Enrollment numbers reflect most recently available data for each market.

² US Census Bureau. "Health Insurance Coverage in the United States: 2020." Issued Sep. 2021. [Available here](#).

³ Centers for Medicare & Medicaid Services. "Medicare Monthly Enrollment." May 2023. [Available here](#).

⁴ There are certain cases where other products may be covered under Part B. For example, Medicare Part B can cover the Tdap vaccine when administered as a direct result of illness or injury. In these cases, standard Medicare Part B cost-sharing applies.

⁵ Centers for Medicare & Medicaid Services. "Medicare Monthly Enrollment." May 2023. [Available here](#).

	not covered by Medicare Part B	Centers for Disease Control and Prevention (CDC) Director (i.e., published on the CDC website with a notice confirming Director adoption)	<ul style="list-style-type: none"> Pharmacies are traditionally considered in-network, while medical providers (e.g., physicians) are considered OON Billing pathways are simpler for in-network providers
Medicaid: 57.92M in 2020 ⁶	<ul style="list-style-type: none"> All ACIP-recommended vaccines, including those with SCDM recommendations 	<ul style="list-style-type: none"> No guidance for non-COVID-19 vaccines; however, it is assumed newly recommended vaccines will be included in a state's next fee schedule update COVID-19 vaccines must be covered immediately upon FDA approval/authorization 	<ul style="list-style-type: none"> No specific limitations on SOCs, though plans may impose restrictions Providers receive vaccines for individuals under the age of 19 free of cost via the VFC program
Active-Duty Military & Veterans <ul style="list-style-type: none"> TRICARE: 9.18M in 2020⁷ Department of Veterans Affairs (VA): 2.98M in 2020⁸ 	<ul style="list-style-type: none"> TRICARE: All ACIP-recommended vaccines; travel vaccine coverage is restricted based on deployment needs VA: All ACIP-recommended vaccines 	<ul style="list-style-type: none"> TRICARE: No guidance provided VA: Once the product is included on the immunization schedule COVID-19 vaccines must be covered immediately upon FDA approval/authorization 	<ul style="list-style-type: none"> TRICARE: Limited to authorized providers or in-network pharmacies VA: Limited to VA care facilities and network pharmacies/urgent care centers

⁶ US Census Bureau. "Health Insurance Coverage in the United States: 2020." Issued Sep. 2021. [Available here](#).

⁷ Ibid.

⁸ Ibid.

Covered Products

Following approval or authorization from the FDA, vaccine products undergo review by ACIP. ACIP issues recommendations on the use of immunizations for children, adolescents, and adults, including those with certain risk factors. ACIP issues different types of recommendations, including routine based on age and/or risk, SCDM, and travel recommendations. For these recommendations to be deemed final, the CDC Director must approve them.

Across markets, coverage policies for adult vaccines are commonly tied to a product's ACIP recommendation. For example, section 2713 of the Public Health Service Act (PHSA), as amended by the ACA, requires commercial payers to provide coverage without cost-sharing for all products recommended by ACIP and included on CDC immunization schedules. Similarly, VA facilities and TRICARE cover immunizations included in the CDC schedules. Notably, as travel vaccines are not included in the immunization schedules, these requirements apply only to routine and SCDM recommendations. However, federal policy requires separate coverage of travel vaccines for TRICARE beneficiaries and their families in the event of permanent duty station change or other official travel.

Following ACA passage in 2010, CMS statute extended section 2713 coverage requirements to Medicaid expansion adults, while allowing states the ability to determine vaccine coverage in the traditional market.⁹ The IRA, enacted in 2022, further expanded Medicaid coverage by requiring state Medicaid programs to cover all ACIP-recommended vaccines for both expansion and traditional populations. CMS guidance further expanded Medicaid vaccine coverage by specifying that coverage must include all ACIP-recommendation types, including routine, SCDM, and travel/occupational.¹⁰

There are some markets where coverage is not directly tied to a product's ACIP recommendation. For example, per section 11401 of the Social Security Act (SSA), Medicare Part B covers influenza, pneumococcal, and COVID-19 vaccines, as well as hepatitis B vaccines for intermediate- and high-risk patients without cost-sharing.¹¹ Prior to the IRA, Medicare Part D coverage also deviated from the commercial and Medicaid markets; Part D plans were required to cover all "commercially-available" vaccines not covered by Part B, though plans could impose cost-sharing. The IRA modified Part D coverage by requiring plans to cover without cost-sharing all ACIP-recommended vaccines not covered under Part B. Similar to guidance issued for the Medicaid market, CMS interpreted this requirement to apply to routine, SCDM, and travel/occupational recommendations.¹²

For children, vaccine coverage is generally tied to ACIP recommendations. Commercial market coverage requirements for children are also governed by section 2713 of the PHSA, meaning that payers must cover without cost-sharing all on-schedule products with routine and SCDM

⁹ The American Rescue Plan Act [requires](#) no cost-sharing for COVID-19 vaccines for all Medicaid beneficiaries through September 2024, after which the IRA will continue to require that Medicaid plans cover COVID-19 vaccines.

¹⁰ CMS. "Mandatory Medicaid and Children's Health Insurance Program Coverage of Adult Vaccinations under the Inflation Reduction Act." June 27, 2023. [Available here](#).

¹¹ There are certain cases where other products may be covered under Part B. For example, Medicare Part B can cover the Tdap vaccine when administered as a direct result of illness or injury. In these cases, standard Medicare Part B cost-sharing applies.

¹² CMS. "Contract Year 2023 Program Guidance Related to Inflation Reduction Act Changes to Part D Coverage of Vaccines and Insulin." Sep. 26, 2022. [Available here](#).

recommendations. For Medicaid-eligible, under- and uninsured, and American Indian/Alaska Native children, vaccine coverage is provided via the VFC program, which includes all ACIP-recommended pediatric and adolescent products.

No federal policies require vaccine coverage for uninsured adults. Similarly, section 2713 of the PHSA does not apply to adults in non-ACA-compliant or grandfathered commercial plans. Some under- and uninsured adults can access vaccines without cost-sharing via the Section 317 Program, which is administered at the state/jurisdiction level. States can choose which vaccines to supply under their respective programs and may not cover all ACIP-recommended or FDA authorized/approved products. Medicare beneficiaries not enrolled in Part B and/or Part D may lack coverage for certain vaccines.

Product Coverage Timelines

Federal policy parameters vary regarding when payers and programs must cover newly FDA-approved/authorized and ACIP-recommended products. This variation could influence when individuals across markets can access new vaccines, with some accessing new vaccines sooner than others.

Similar to policies governing covered products, federal coverage timing requirements are often linked to the ACIP recommendation process. After ACIP votes on a recommendation, the CDC Director formally adopts the recommendation. This adoption can occur via MMWR publication (typically several weeks or months following a vote) or a notice on the CDC website (typically within days). Coverage timing is often linked to this adoption date. For example, guidance from CMS's Center for Consumer Information and Insurance Oversight specifies that commercial market coverage for new adult and childhood vaccines must be in place, at the latest, by the first day of the plan year that begins on or after the date that is one year following MMWR publication or the publication of the immunization schedule.¹³ In practice, once the MMWR is published, plans have a year or more until the product must be covered without cost-sharing.

Since IRA implementation, Medicare Part D coverage timing is also tied to CDC Director adoption of an ACIP recommendation; however, instead of tying coverage to MMWR publication, CMS requires Part D plans to implement coverage without cost-sharing as soon as the adopted recommendation is published on the CDC website.¹⁴ As a result, coverage of new vaccines in Part D will often occur sooner than coverage in the commercial market.

CMS did not specify coverage timeline parameters for the Medicaid market. Instead, CMS directed states to establish a process for covering newly recommended adult vaccines in a State Plan Amendment. As a result, coverage timelines will likely continue to vary state-by-state.¹⁵

Medicare Part B vaccines are covered following FDA approval, though coverage cannot be effectuated until CMS updates relevant pricing and recommendation information for the new

¹³ CMS. "Affordable Care Act Implementation FAQs – Set 12." Page last modified Sep. 6, 2023. [Available here](#).

¹⁴ CMS. "REVISION – Contract Year 2023 Program Guidance Related to Inflation Reduction Act Changes to Part D Coverage of Vaccines." Jul. 24, 2023. [Available here](#).

¹⁵ CMS. "Mandatory Medicaid and Children's Health Insurance Program Coverage of Adult Vaccinations Under the Inflation Reduction Act." Jun. 27, 2023. [Available here](#).

vaccine. As such, a new vaccine may not be reimbursable until pricing information is published in the quarterly drug pricing files and the ACIP's recommendation is incorporated into the Medicare Benefit Policy Manual and Medicare Claims Processing Manual. Traditionally, CMS has backdated coverage for new vaccine products to the product's FDA approval date and processed any claims that were denied between the FDA approval date and quarterly pricing file release and/or MMWR publication. This process can result in an initial access gap of several months depending on a product's approval date. Influenza vaccine coverage does not follow this same process, with coverage beginning August 1 of each year.

VFC program coverage depends on when CDC updates the pediatric/VFC Vaccine Price List to include a new product; this can take weeks or months after an ACIP VFC Resolution vote.¹⁶ Similarly, Section 317 coverage depends on a product's addition to the Adult Vaccine Price List.

Other Access Considerations

In some markets, federal policies and systems may limit coverage to certain settings or providers. For example, coverage requirements in the commercial market do not apply to OON providers, and plans may not provide coverage across all settings, such as the pharmacy. Similarly, state Medicaid programs have discretion to cover products under the medical or pharmacy benefit, although CMS guidance encourages states to consider policies that facilitate widespread access across care settings and provider types.¹⁷ For those covered under the VA, vaccine access is largely limited to VA care facilities and VA community care network pharmacies and urgent care centers. TRICARE enrollees must receive vaccines from an authorized provider or an in-network pharmacy. TRICARE beneficiaries can also receive care on military bases.

Federal policies also affect where Medicare beneficiaries access vaccines. Medicare Part D is a pharmacy benefit; as such, pharmacies are the most common provider of Part D-covered vaccines. OON providers (e.g., physicians) can still bill for Part D vaccines, although many have reported difficulties in doing so.¹⁸

While not explored in this paper, federal policies related to provider reimbursement also vary across markets, and in some cases may impact patient access to recommended vaccines.¹⁹

COVID-19 Vaccines

Specific policies issued during the COVID-19 pandemic, in addition to the policies previously discussed, govern COVID-19 vaccine coverage across markets. For example, the Coronavirus Aid, Relief, and Economic Security (CARES) Act requires commercial plans to cover new COVID-19 vaccines and amends the SSA to require coverage of COVID-19 vaccines under Medicare Part B, ensuring coverage without cost-sharing for Medicare beneficiaries prior to IRA passage. The American Rescue Plan Act requires state Medicaid programs to cover COVID-19

¹⁶ CDC. "CDC Vaccine Price List." Prices last reviewed/updated Sep. 15, 2023. [Available here.](#)

¹⁷ CMS. "Mandatory Medicaid and Children's Health Insurance Program Coverage of Adult Vaccinations Under the Inflation Reduction Act." Jun. 27, 2023. [Available here.](#)

¹⁸ CMS' Medicaid Learning Network [Fact Sheet](#) details OON provider billing.

¹⁹ Avalere. "50-State Comparison of Medicaid Adult Vaccine Provider Reimbursement." April 17, 2023. [Available here.](#)

vaccines without cost-sharing through September 2024, and beginning in October 2024, the IRA requires permanent Medicaid coverage of COVID-19 vaccines without cost-sharing.

Coverage timing for COVID-19 vaccines is also distinct from that for other immunizations. While the CARES Act required coverage of the first COVID-19 vaccines within 15 days of initial ACIP recommendations, subsequent FAQs from the Department of Labor clarified that coverage of new COVID-19 vaccines must be effective immediately after FDA approval or authorization.²⁰ As such, commercially covered patients may be able to access new COVID-19 vaccines sooner than other vaccines.

During the public health emergency (PHE), the federal government agreed to purchase and distribute COVID-19 vaccines to ensure universal access without cost-sharing. Following the PHE and before a complete transition to traditional market coverage, the Department of Health and Human Services developed the Bridge Access Program, which provides COVID-19 vaccines at no cost to under- and uninsured adults.²¹ This coverage is available until December 31, 2024, and adults may access vaccines through physician offices, retail pharmacies, and federally funded health centers participating in the program.

Conclusion

Federal policy changes have generally expanded vaccine coverage to nearly all populations in the United States; however, an examination of the specific laws, regulations, and guidance governing vaccine coverage highlights several areas where variation exists across markets. In some cases, this variation may limit the types of products individuals can access (e.g., travel vaccines) or when and where individuals can access new products.

²⁰ Department of Labor. “FAQs About Affordable Care Act Implementation Part 50, Health Insurance Portability and Accountability Act and Coronavirus Aid, Relief, and Economic Security Act Implementation.” Oct. 4, 2021. [Available here.](#)

²¹ CDC. “CDC’s Bridge Access Program.” Last reviewed Sep. 14, 2023. [Available here.](#)

Appendix

Table 2. Federal Statute, Regulation, and Sub-Regulation Governing Vaccine Coverage Across Markets

Policy Type	Citation	Description
Commercial		
Statute	42 USC 30gg-13(a)(2))	Establishes that commercial health plans must cover all ACIP-recommended immunizations
Regulation	29 CFR 2590.715-2713	Governs statutory preventive service coverage requirements
Sub-Regulation/ Guidance	ACA Implementation FAQs - Set 12, Question 8	Clarifies that all recommendation types (e.g., SCDM, risk-based) must be covered; further clarifies that coverage timeline begins “the earlier of: the date the recommendation is published in the MMWR or the date the recommendation is reflected in the Immunization Schedules of the CDC”
	FAQs About ACA Implementation Part 50, Health Insurance Portability and Accountability Act, and CARES Implementation	Clarifies that coverage of new COVID-19 vaccines must be effective immediately following FDA approval or authorization
Medicare Part B		
Statute	42 USC 1395x(s)(10)	Establishes coverage of certain preventive vaccines under the Medicare Part B benefit
Regulation	42 CFR 410.57	Governs Medicare Part B coverage of preventive vaccines
Sub-Regulation/ Guidance	Medicare Benefit Policy Manual Chapter 15 – Covered Medical and Other Health Services 50.4.4.2 - Immunizations	Outlines coverage requirements for preventive vaccines, including indicated populations
	Medicare Claims Processing Manual Chapter 18 - Preventive and Screening Services 10 - Pneumococcal Pneumonia, Influenza Virus, Hepatitis B, and Coronavirus	Outlines billing requirements for preventive vaccines

	Disease (COVID-19) Vaccines and Administration	
Medicare Part D		
Statute	42 USC 1395w-102(e)	Establishes certain vaccines as covered Part D drugs and requires coverage without cost-sharing for vaccines recommended by ACIP
Sub-Regulation/ Guidance	Medicare Prescription Drug Benefit Manual Chapter 6 – Part D Drugs and Formulary Requirements 10.14 - Vaccine Administration	Outlines coverage and billing requirements for covered Part D vaccines, including that vaccines should be covered “consistent with [ACIP] recommendations”
	Contract Year 2023 Program Guidance Related to IRA Changes to Part D Coverage of Vaccines and Insulin	Clarifies cost-sharing requirements for covered Part D vaccines, including indicated populations
	REVISION - Contract Year 2023 Program Guidance Related to IRA Changes to Part D Coverage of Vaccines	Clarifies that Part D plans must cover a new vaccine after its recommendation is adopted by the CDC director and that the “date of the MMWR publication of approved vaccines [is not a] factor in the effective date of an ACIP recommendation”
Medicaid/CHIP		
Statute	42 USC 30gg-13(a)(2) 42 USC 30gg-13(a)(2)	Establishes that Medicaid expansion plans must cover all ACIP-recommended immunizations
	42 USC 1396o(j) 42 USC 1396o(j)	Establishes vaccine coverage without cost-sharing for all adult Medicaid and Children’s Health Insurance Program beneficiaries
	42 USC 1396r-8(k)(2)(B)	Establishes that vaccines are excluded from the Medicaid Drug Rebate Program
Sub-Regulation/ Guidance	SHO#23-003	Outlines the application and implementation of IRA section 11405, including clarifying that all recommendations (e.g., SCDM) must be covered by state Medicaid programs
TRICARE		
Statute	10 USC, Subtit. A, Pt. II, Ch. 55	Establishes the TRICARE benefit

Regulation	32 CFR 199.4(e)(28)	Governs the implementation of TRICARE benefit and notes the coverage of immunizations without cost-sharing for TRICARE beneficiaries
	32 CFR 199.21(h)(4)	Establishes coverage of certain vaccines administered in TRICARE retail network pharmacies
Veterans Affairs		
Statute	38 USC 1701(9)	Establishes vaccine coverage for eligible patients seeking care at VA facilities, which includes all immunizations on the adult schedule
Sub-Regulation/ Guidance	VHA Directive 1013(4)	Establishes mandatory VA policy and protocol for implementing seasonal influenza vaccination across VA medical facilities
Section 317		
Statute	42 USC 247b	Authorizes federal funding for state vaccine purchase for uninsured adults and for supporting immunization program operations
Vaccines For Children		
Statute	42 USC 1396s	Establishes the VFC program to include no cost vaccines for Medicaid-eligible, under- and uninsured, and American Indian and Alaska Native individuals
Regulation	42 CFR 441.600-441.615	Governs implementation of the VFC program, including establishing the vaccine administration fee rate

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