

Vaccine Coverage & Access Landscape: Opportunities & Challenges

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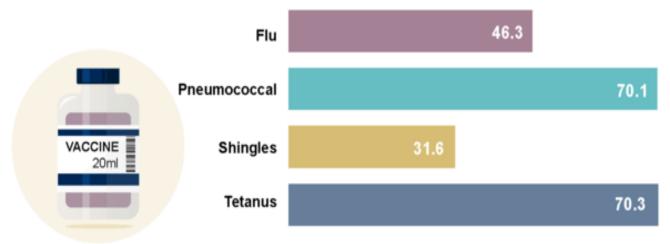
AVAC is fighting to make necessary policy changes to increase vaccination rates — saving lives and money.

Adult Vaccine Access Coalition (AVAC)

 Established in 2015 to strengthen and enhance access to and increase utilization of vaccines among adults.

 AVAC is made up of a diverse group of health care providers, vaccine innovators, public health organizations, patient and consumer groups.

Estimated Adult Vaccination Rates for Four Vaccines, 2020



Vaccination rates (percentage)

Source: GAO analysis of Behavioral Risk Factor Surveillance System data. | GAO-22-105334

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Preventive Medicine





THE NATIONAL COALITION FOR









Infection Control and Epidemiology





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Meningitis B

Action Project













Barriers to Adult Immunizations

Financial	Inability for individuals to pay due to co-pays / gaps in coverage		
Hesitancy	Regarding vaccine safety and effectiveness among patients		
Provider	Financial barriers for health care providers to stock and administer vaccines		
Lack of awareness	Regarding recommended vaccines and the risk/consequences of vaccine- preventable diseases		
Coordination	Lack of coordination among health care providers – many adults see multiple providers – and across the health care system		
Legal/Policy	Systematic at the federal and state levels restricting which providers can immunize		
Missed Opportunities	For immunization assessment, counseling and recommendations by health care providers		
Infrastructure	Lack of or underuse of immunization data systems that document vaccination histories		

Vaccine Coverage Landscape

Insurance Type	Age	What Vaccines are Covered?	Zero Out of Pocket Cost for Patients
Private Insurance	0-64 years old	"Routinely recommended" ACIP- recommended vaccines	Yes, for vaccines on the schedule
Medicare Part B	65+	Influenza, Pneumonia, Hepatitis B and Covid-19 vaccines	~
Medicare Part D	65+	All other ACIP-recommended vaccines	/
Medicaid VFC	0-18 years old	All ACIP-recommended vaccines through the federal Vaccines for Children Program (VFC)	
Medicaid Adults	19-64 years old	All other ACIP-recommended vaccines (begins Oct 2023)	/
Uninsured	0-18 years old	All ACIP-recommended vaccines through the federal Vaccines for Children Program (VFC)	
Uninsured Adults	19 – 64 years old	Covid 19, limited other vaccine through immunization programs (where funding is available)	

Private Sector: Insurance Coverage of Vaccines

- The Affordable Care Act or "ACA" was the comprehensive health care reform law enacted in March 2010
 - ➤ Made affordable health insurance available to millions of people.
 - Expanded the Medicaid program to cover all adults with income below 138% of the FPL. Not all states have expanded their Medicaid programs. ACIP-recommended vaccines were included in the expansion populations
- As part of the ACA (Sec. 2713), most private health plans must provide coverage for recommended preventive services to individuals without cost-sharing (such as copayments, deductibles, or coinsurance). Vaccines recommended by the ACIP for routine use are covered under this section (ie. Vaccines listed on the child/adolescent or adult immunization table**)

^{**} Travel and occupational vaccines are not listed and therefore subject to cost sharing

Medicare & Medicaid

Recent Changes Expand Vaccination Coverage

Medicare-Sec 11401

Eliminates copays/out of pocket expenses for ACIP-recommended vaccines under Medicare Part D.

Medicaid- Sec 11405

Requires coverage for ACIP recommended adult vaccines in traditional Medicaid and CHIP programs.

Cost
Sharing
and
Vaccines



With the new Inflation Reduction Law, now Medicare Part D beneficiaries won't face high out-of-pocket costs for their vaccines.



MARKET	VACCINES	OUT-OF-POCKET
Commercial	All CDC-Recommended	\$0
Medicaid Expansion	All CDC-Recommended	\$0
Traditional Medicaid	Determined by state	\$ 50 \$3.40
Medicare Part B	Pneumococcal, influenza, hepatitis B	\$0
Medicare Part D	All other CDC recommended vaccines, shingles, Tdap, future vaccines	\$0 <u>\$160</u>

Source: Alexandra Stewart, https://doi.org/10.1016/j.vaccine.2013.11.050
Mannatt, https://www.manatt.com/Insights/White-Papers/2018/Medicare-Part-D-Cost-Sharing-Trends-for-Adult-Vacc

Medicare

Previously:

- Medicare Part B
 - Covered certain vaccines at no cost:
 - Influenza, Pneumonia and Hepatitis B vaccines
 - C-19 added during Pandemic
- Medicare Part D
 - All other vaccines had cost sharing

Now:

- January 1, 2023
- Adult vaccines recommended by the CDC/ACIP are now available to people with Medicare Prescription Drug Coverage (Part D) at no cost (\$0)
- Includes: Shingles, Tetanus-Diphtheria-Whooping Cough, RSV, future vaccines

Medicare

- "CMS interprets "adult vaccine" and "vaccine ... for use by adult populations," solely for the purposes of section 1860D-2(b)(8) of the Act, to refer to those vaccines licensed by the FDA and recommended by ACIP for use in "adults," as described by the CDC/ACIP in the Adult Immunization Schedule or other applicable ACIP recommendations. We also interpret the term "recommended" to mean all categories of ACIP recommendations, including those that are specified as based on shared clinical decision-making.
- We note that the ACIP Vaccine Recommendations and Guidelines also provide recommendations for use in limited populations and circumstances for certain other vaccines that are not on the CDC/ACIP Adult Immunization Schedule for routine immunization. We interpret the requirements of section 1860D-2(b)(8) of the Act also to apply to vaccines provided in such limited populations and circumstances, when used for adults in accordance with ACIP recommendations."

subsidy created by the IRA is paid by Medicare does not meet the definition of allowable risk corridor costs provided at section 1860D-15(e)(1)(B) of the Act and § 423.308. Part D sponsors are not expected to update their formularies based on these new requirements, and any changes should be submitted only if they are in accordance with existing formulary update policy.

Medicare Plan Finder

The CY 2023 Medicare Plan Finder (MPF) will reflect Part D sponsors' insulin and vaccine benefits and cost sharing as they were submitted in their 2023 bid and formulary submissions. For October 1, 2022, CMS is updating MPF to include new insulin and vaccine drug footnotes and other help features to explain the benefit changes resulting from the IRA.

Requirements Applicable to Section 11401 (Coverage of Adult Vaccines Recommended by the Advisory Committee on Immunization Practices under Medicare Part D)

Section 11401 of the IRA amends section 1860D-2 of the Act by adding paragraphs (b)(8) and (c)(5) and making other conforming amendments to require that, effective for plan years beginning on or after January 1, 2023, the deductible shall not apply to, and there is no cost sharing for, an adult vaccine recommended by the Advisory Committee on Immunization Practices (ACIP). Section 1860D-2(b)(8)(B) of the Act specifies that for purposes of section 1860D-2(b)(8) of the Act, the term "adult vaccine recommended by [ACIP]" means a covered Part D drug that is a vaccine licensed by the US Food and Drug Administration (FDA) under section 351 of the Public Health Service Act (PHSA) for use by adult populations and administered in accordance with recommendations of ACIP.

CMS interprets "adult vaccine" and "vaccine ... for use by adult populations," solely for the purposes of section 1860D-2(b)(8) of the Act, to refer to those vaccines licensed by the FDA and recommended by ACIP for use in "adults," as described by the CDC/ACIP in the Adult Immunization Schedule² or other applicable ACIP recommendations. We also interpret the term "recommended" to mean all categories of ACIP recommendations, including those that are specified as based on shared clinical decision-making.

We note that the ACIP Vaccine Recommendations and Guidelines³ also provide recommendations for use in limited populations and circumstances for certain other vaccines that are not on the CDC/ACIP Adult Immunization Schedule for routine immunization. We interpret the requirements of section 1860D-2(b)(8) of the Act also to apply to vaccines provided in such limited populations and circumstances, when used for adults in accordance with ACIP recommendations.

Part D vaccines are not subject to the requirements of section 1860D-2(b)(8) of the Act if they are (1) not recommended by ACIP for use in adults, or (2) administered to an individual who is not an adult, even if such use is supported by ACIP recommendations (e.g., according to the CDC/ACIP child and adolescent immunization schedule⁴). For example, certain Meningococcal

² https://www.cdc.gov/vaccines/schedules/hcp/imz/adult.html

³ https://www.cdc.gov/vaccines/hcp/acip-recs/index.html

⁴ https://www.cdc.gov/vaccines/schedules/hcp/imz/child-adolescent.html

Medicaid

Previously:

Vaccine coverage (and cost sharing) varied by state

Now:

- October 1, 2023
- Adult vaccines recommended by the CDC/ACIP are now available at no cost (\$0) across all Medicaid programs and populations.

Medicaid

"There are multiple categories of ACIP recommendations for adult vaccines, including recommendations described on the Centers for Disease Control and Prevention (CDC)/ ACIP adult immunization schedule (as determined by age and risk and recommendations for shared clinical decision-making), as well as recommendations based on risk due to health condition, occupation, and travel. Some recommendations are for routine use, and some are not. Because CMS interprets the IRA coverage requirement to include any category of ACIP recommendations, that **coverage requirement is not** limited to vaccines that CDC/ACIP include on the immunization schedules or recommend for routine use."

Fact Sheet: Inflation Reduction Act changes to Medicaid & Children's Health Insurance Program (CHIP) Adult Vaccine Coverage



In August 2022, President Biden signed the Inflation Reduction Act (IRA) of 2022 (P.L. 117-169) into law. The IRA amended the Medicaid and Children's Health Insurance Program (CHIP) statutes to require Medicaid and CHIP coverage and payment without cost sharing beginning October 1, 2023 for U.S. Food and Drug Administration approved adult vaccines recommended by the Advisory Committee on Immunization Practices (ACIP) and their administration.

Which vaccines do states have to cover beginning October 1, 2023?

Beginning October 1, 2023, state Medicaid and CHIP programs must cover vaccines that are approved by the FDA for use by adult populations and administered in accordance with ACIP recommendations. As explained in the [SHO letter], CMS does not interpret the IRA-required coverage to include vaccines that FDA has authorized for use under emergency use authorization, but has not approved. CMS interprets the statutory references to "adults" to mean persons age 19 and older.

Additionally, beginning October 1, 2023, CMS interprets the statutory reference to ACIP recommendations to include any category of ACIP recommendations. There are multiple categories of ACIP recommendations for adult vaccines, including recommendations described on the Centers for Disease Control and Prevention (CDC)/ ACIP adult immunization schedule (as determined by age and risk and recommendations for shared clinical decision-making), as well as recommendations based on risk due to health condition, occupation, and travel. Some recommendations are for routine use, and some are not. Because CMS interprets the IRA coverage requirement to include any category of ACIP recommendations, that coverage requirement is not limited to vaccines that CDC/ACIP include on the immunization schedules or recommend for routine use. It would include approved vaccines identified on the CDC/ACIP adult immunization schedule, such as the shingles and influenza vaccines, as well as approved vaccines recommended for specific populations, such as the mpox vaccines, as long as the beneficiary meets the ACIP recommendation's criteria.

Who is eligible to receive these mandatory vaccination services?

This new mandatory coverage applies to nearly all full-benefit beneficiaries aged 19 and older covered under traditional Medicaid, and CHIP beneficiaries aged 19 and older.

Will Medicaid and CHIP beneficiaries who are eligible for the newly required coverage have to pay anything for these newly covered vaccines or their administration?

No. Medicaid and CHIP beneficiaries age 19 and older who are eligible for the newly required coverage will have no cost sharing for any FDA-approved adult vaccines that are administered in accordance with any category of ACIP recommendations, and will also have no cost-sharing for the administration of these vaccines.

Is there enhanced federal funding for state expenditures on these adult vaccines?

States will receive the applicable regular Medicaid federal medical assistance percentage (FMAP) and CHIP FMAP for their expenditures on the adult vaccinations they are required to cover under the IRA. In addition, states that, as of August 16, 2022, were covering approved, ACIP-recommended adult vaccinations, without cost sharing, can claim a one percentage point increase in the FMAP for their Medicaid expenditures on these vaccination services for the first eight fiscal quarters that begin on or after October 1, 2023.

At the conclusion of the eight fiscal quarters (September 30, 2025), these states' Medicaid expenditures for vaccines and vaccine administration described in section 1905(a)(13)(B) of the Act will be matched at the applicable regular FMAP.

Where can I find more information?

Please see the Mandatory Medicaid and Children's Health Insurance Program Coverage of Adult Vaccinations under the Inflation Reduction Act for more information.

June 2023



CMS Guidance- June23 https://www.medicaid.gov/medicaid/quality-of-care/downloads/vaccinations-fact-sheet-06272023.pdf

Vaccine Coverage Landscape: A Few Bumps along the Way

- Narrow interpretation of ACA limited vaccine coverage with no cost sharing to only ACIPrecommended vaccines on CDC child/adolescent or adult immunization table.*
- ACA also granted plans a full year to implement new vaccine recommendations. How plans are taking advantage:
 - Coverage delays for new RSV vaccine
 - Imposing cost sharing for vaccines with shared clinical decision-making recommendation (eg. HPV catch up and RSV for adults)

The Administration has an opportunity to bring ACA vaccine coverage regulations in line with more recent Medicare/Medicaid guidance that clarifies coverage for shared clinical decision-making recommendations and is inclusive of recommended travel and occupational vaccines.



Questions/Discussion

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