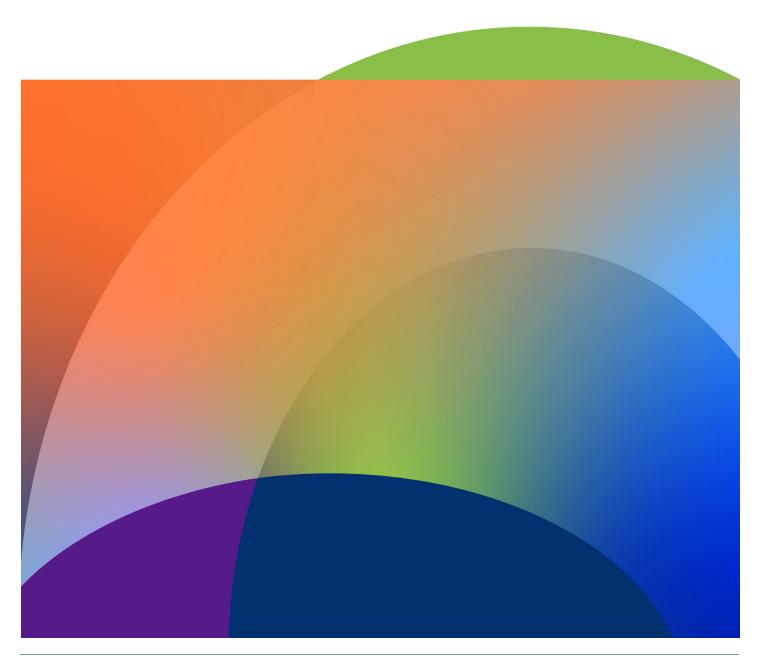
Avalere eBook

## Navigating the Immunization Ecosystem





## Introduction

In this eBook, Avalere experts discuss the evolving vaccines ecosystem, including novel pipeline products and modalities, the role of the Advisory Committee on Immunization Practices (ACIP), coverage and reimbursement policies, and factors influencing patient access and uptake.

Since Dr. Edward Jenner's <u>development</u> of the first smallpox vaccine in 1796, vaccines have revolutionized public health, saving at least 154 million <u>lives</u> globally over the past 50 years. Available vaccines now protect against more than 20 infectious diseases.

The COVID-19 pandemic saw rapid development of vaccines using a novel platform—mRNA—resulting in an unprecedented initial dose administration just 11 months after identifying the virus's genetic sequence. Researchers are now developing immunizations using innovative technologies and administration routes to combat emerging infectious diseases while continuing to develop vaccines for routine immunization across the life course. This rapid evolution demands novel solutions to market barriers and creative approaches to drive uptake.

To learn more about how Avalere's vaccines experts can support you with influencing policy, shaping access channels, and translating evidence for strong recommendations, connect with us.

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**Pipeline Planning** 

# Adult Seasonal Combination Respiratory Vaccines: Policy Considerations

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In 2024, Avalere experts considered key questions related to strain selection, ACIP recommendation, and coverage and reimbursement for adult combination respiratory vaccines in development.

Combination vaccines can protect against and potentially prevent multiple diseases through a single vaccination. Multiple adult combination vaccines are emerging in development pipelines and are expected to launch in the next decade, including products that confer protection against several respiratory illnesses such as influenza, COVID-19, and respiratory syncytial virus (RSV). Stakeholders have noted the potential benefits of adult combination vaccines, citing several

advantages documented in the childhood market, which includes various combination products. These benefits include improved vaccine coverage rates, timely vaccination for under-vaccinated individuals, decreased shipping/stocking costs, and reduced costs associated with multiple healthcare visits.

As stakeholders prepare for the launch of combination vaccines, they must consider key questions surrounding product approval, recommendation development, coverage, and reimbursement pathways. In a white paper, Avalere discussed these questions and identified the issues and considerations featured in the table on the following page.



## Summary of Access Considerations for Combination Influenza-COVID-19 Vaccines and Key Stakeholders

Issue Area	Considerations	Key Stakeholders
Strain Selection Timeline	<ul> <li>Stakeholders will need to consider how to approach strain selection for combination vaccines, as current influenza and COVID-19 processes vary</li> <li>Balancing strain selection timeliness with precision may be more consequential for combination vaccines due to differences in disease patterns and seasonal debut</li> <li>Stakeholders may explore streamlined approaches, e.g., a single review timeline based on vaccine type or platform</li> </ul>	<ul> <li>World Health         Organization, Technical         Advisory Group on         COVID-19 Vaccine         Composition</li> <li>FDA, Vaccines and         Related Biological         Products Advisory         Committee</li> </ul>
ACIP Review	<ul> <li>ACIP will need to decide whether to form a new Adult Combination Vaccine WG or rely on existing WGs</li> <li>If relying on existing WGs, ACIP may need to establish new approaches to working and collaboration when two or more WGs are reviewing the same combination product</li> <li>ACIP and other stakeholders will also need to consider recommendation timing; a later recommendation for either component could impact payer coverage and patient access</li> </ul>	• CDC, ACIP
Product Coverage and Reimbursement	<ul> <li>Clarity is needed to understand if influenza/COVID-19 combination vaccine coverage will be limited to a certain window/season</li> <li>While Part B coverage is likely, CMS may need to clarify when product payment is anticipated</li> <li>CMS's Center for Consumer Information and Insurance Oversight (CCIIO) may need to clarify whether commercial market coverage timelines for COVID-19 vaccines applies to combination products</li> <li>CDC and other stakeholders may need to assess strategies to provide access for uninsured adults</li> </ul>	<ul> <li>Commercial insurers</li> <li>CMS</li> <li>CCIIO</li> <li>Medicaid agencies</li> <li>Managed care organizations</li> <li>CDC</li> </ul>
Payment for Administration	Stakeholders may consider changes to facilitate multi- component billing for combination vaccines	<ul><li>AMA, CPT Editorial Panel</li><li>CMS</li><li>Providers</li></ul>

ACIP: Advisory Committee on Immunization Practices; AMA: American Medical Association; CCIIO: Center for Consumer Information and Insurance Oversight; CDC: Centers for Disease Control and Prevention; CMS: Centers for Medicare & Medicaid Services; CPT: Current Procedural Terminology; FDA: Food and Drug Administration

Download the white paper: <u>Adult Seasonal Combination Respiratory Vaccines: Policy Considerations.</u>
Funding for this research was provided by Pfizer. Avalere retained full editorial control.

#### **Pipeline Planning**

# Navigating the Road to RSV Prevention

Next Up		

In 2022, Avalere experts discussed coverage and reimbursement implications of potential regulatory and recommendation pathways for novel RSV products in development.

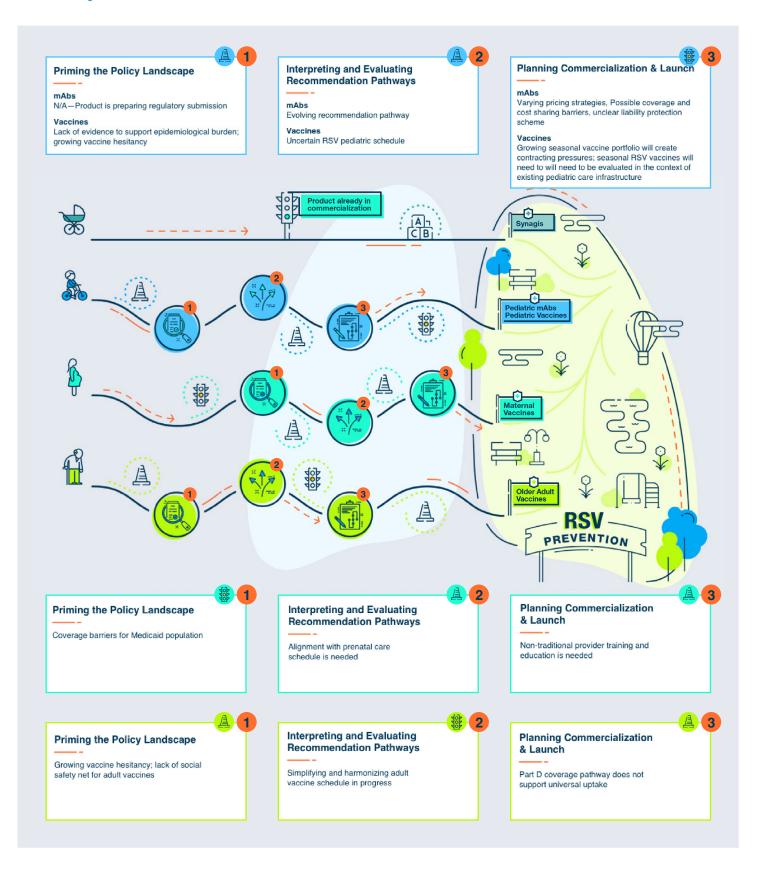
Since the discovery of RSV in the 1960s, lower respiratory illness disease burden has consistently increased globally. On average, RSV leads to approximately 2.1 million pediatric outpatient visits and more than 170,000 hospitalizations among adults 65 years of age and older.

A non-vaccine preventive product, palivizumab, was approved in 1998 and is part of a therapeutic group of products with the potential to prevent RSV infections. More recently, several vaccines and vaccine-like antibody products have progressed through development and are in testing phases. All of these products will be novel and will require adaptations to the immunization system. They will be associated with unique coverage and access considerations as well as uptake barriers.

- RSV monoclonal antibodies (mAbs) are the first preventive mAbs intended for routine use in a broader population of infants. <u>Learn</u> more in this video.
- RSV maternal vaccines are the first vaccines intended for administration to pregnant people primarily for neonatal and infant protection.
- RSV older adult vaccines add to the growing pipeline of adult life course vaccines and have the potential to be combined with influenza or COVID-19 vaccines. <u>Learn more</u> in this video.
- RSV pediatric vaccines will be the first pediatric vaccines to launch after another preventive product is being routinely used.

Avalere can help organizations and companies address the roadblocks they may encounter on the path to developing next-generation RSV prevention products (see figure on next page) and can provide further support in understanding how to strategically differentiate and position certain comparable products.

#### Pathways to RSV Prevention



Navigating the Road to RSV Prevention



### Planning for Reviews of Mixed Modality Immunizations

Avalere helped a vaccine manufacturer plan for regulatory reviews of its mixed-modality immunization products.

#### **Challenge**

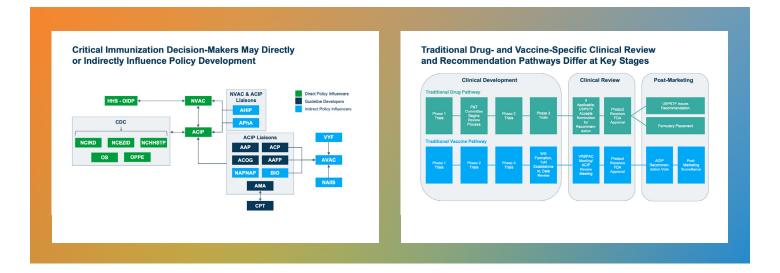
Manufacturers of mixed modality immunizations, which differ from traditional vaccines, face questions of how regulators will route them through approval pathways. A vaccine manufacturer sought to understand how immunizations in its pipeline may be routed through such pathways and how and whether it should engage with different reviewers, aiming to use this knowledge to strengthen product development.

#### **Solution**

Avalere mapped the full landscape of decisionmakers involved in review and approval of mixed modality immunizations, created a detailed model of each review and approval pathway highlighting key decision points, conducted primary research with real decisionmakers to assess how products are routed to different pathways, and modeled review scenarios and likely outcomes against the client's pipeline immunizations.

#### **Results**

The client can use this information to understand challenges its mixed modality products may face during review and to prepare for those reviews to increase the likelihood of desirable outcomes.



**ACIP** and Policy Recommendations

# ACIP Contends with Cost, Accessibility, and Equity

Next Up	

Following ACIP's June 2023 meeting, Avalere experts analyzed the Committee's evolving discussions on cost, accessibility, and equity.

ACIP met June 21–23, 2023, to discuss updates and review new immunizations for the prevention of RSV, polio, influenza, pneumococcal, dengue, chikungunya, mpox, meningococcal and COVID-19 infections. The Committee significantly influences immunization guidelines, which, after receiving CDC endorsement, become national immunization policy and determine product coverage across markets. These recommendations sometimes differ from indications for use that are developed and approved by the Food and Drug Administration.

At its June meeting, ACIP voted on recommendations for four therapeutic areas:

- RSV: Adults aged ≥60 years may receive a single dose of RSV vaccine, using shared clinical decision making (SCDM).
- Polio: Adults who are known or suspected

to be unvaccinated or incompletely vaccinated against polio should complete a primary vaccination series with inactivated polio vaccine (IPV). Individuals at increased risk of poliovirus exposure may receive another dose of IPV.

- Influenza: All persons aged ≥6 months with egg allergy should receive any influenza vaccine that is otherwise appropriate for the recipient's age and health status (egg based or non-egg based).
- Pneumococcal: For pediatric pneumococcal vaccination, use of 20-valent pneumococcal conjugate vaccine was added as an option.

## Future Considerations for Vaccine Manufacturers and Other Stakeholders

In addition to voting on recommendations and preparing for the review of additional pipeline products, the Committee's discussions over the three-day meeting highlighted several questions that are important for vaccine manufacturers and stakeholders to consider.

 Safety of Respiratory Vaccines in Older Adults: With the approval of new RSV vaccines for adults, is the concurrent administration of RSV, influenza, and COVID-19 vaccines safe and well characterized? What is the impact of effectiveness and the level of lasting protection for adults who receive multiple vaccines at the same time? What supplemental data would ACIP need from manufacturers and other stakeholders to address current gaps in coadministration?

- Vaccine Cost Effectiveness and Value: How does the committee use vaccine prices in its development of recommendations for use? What is considered the threshold for cost-saving vs. cost-effective vaccines? In the absence of a defined threshold to guide decision making, how has ACIP's review of cost-effectiveness changed over time? Should manufacturers with pipeline vaccines adjust anticipated launch pricing based on the committee's feedback on approved products, and if so how?
- Shared Clinical Decision-Making (SCDM): How will an SCDM recommendation for older adult RSV vaccines impact access and uptake? In practice, how well are such recommendations understood and implemented? Given coverage under Medicare Part D, how will pharmacies approach SCDM discussions with patients? What tools may support vaccine clinical decision making for patients and providers?
- Data in Immunocompromised/High-Risk
   Patients: What can be done to support ACIP's calls for clinical trial diversity to better represent and understand the safety and effectiveness

- of vaccines in older, high-risk, and pregnant populations? Given their increased susceptibility to and severity of disease, what evidence can be collected to demonstrate the value of vaccination in these subgroups?
- Passive Immunizations: What criteria will be used to determine which future passive immunizations and mAbs are reviewed by ACIP? What preparation and planning is needed to understand the inclusion or exclusion of such products in federal programs such as Vaccines for Children?
- Complex Recommendations: As vaccine recommendations become more complex, particularly when multiple products are available, what strategies can be deployed to reduce implementation barriers and support patient-provider decision making?
- COVID-19: How will uninsured populations access COVID-19 prevention measures as government-purchased vaccine stockpiles are depleted? What policy and programmatic options exist to support patient access and how will they be implemented? Can a simplified recommendation, harmonized with other seasonal adult vaccines like influenza, be expected for fall 2023?

Since this meeting, ACIP has updated its recommendations to eliminate SCDM for RSV vaccination among older adults, likely due in part to SCDM implementation complexity and potential to impede access. Given the access challenges associated with SCDM, ACIP is likely to continue debating the role of its SCDM recommendations in future meetings.



### Strengthening a Product's Value Proposition for ACIP Review

Avalere helped a vaccine manufacturer prepare for ACIP review of one of its products.

#### Challenge

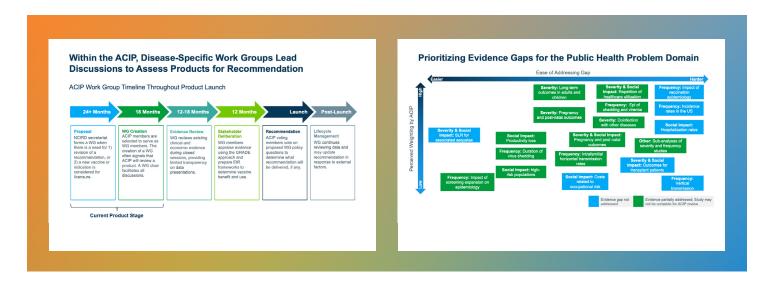
A vaccine manufacturer sought to develop a scientific narrative in support of one of its pipeline vaccines and generate an evidence strategy to strengthen that narrative in anticipation of product review by ACIP.

#### **Solution**

Avalere designed and facilitated a workshop to help the client understand ACIP's Evidence to Recommendation (EtR) framework for product reviews and decision making by indication-specific ACIP work groups, assess the strength of existing evidence in support of the product's value proposition, and identify evidence gaps to drive further research and evidence generation.

#### **Results**

Insights from the workshop helped the client to develop a compelling scientific narrative for its product to drive ACIP engagement and EtR review, and to generate evidence to fill gaps in that narrative.





# Analyzing How ACIP Assesses Equity When Evaluating Vaccines

Avalere analyzed ACIP's use of the EtR framework Equity domain for vaccine recommendation decision making.

#### Challenge

A vaccine manufacturer sought to understand how consistently ACIP work groups have applied the Equity domain to EtR product evaluations.

#### **Solution**

Avalere conducted qualitative analyses of all EtR presentations that included the Equity domain throughout a three-year period. Avalere evaluated all Equity judgments for their level of variability among ACIP work group members and applied statistical techniques to 1) interpret trends in the variability of Equity domain evaluations and 2) compare differences in variability trends between Equity and other EtR domains.

#### **Results**

This study demonstrated variability in how ACIP work groups have used the Equity domain since it was added to the EtR framework in 2020, highlighting the need for ACIP to clarify the meaning and intended use of this domain in the evaluation of vaccines for future recommendations.



#### **Coverage and Reimbursement**

# Guide to Vaccine Coverage Policies

Next Up	

Following Inflation Reduction Act (IRA) passage in 2022, Avalere experts described the federal statutes, regulations, and sub-regulatory guidance governing US vaccine coverage.

Over the past decade, federal policymakers have aimed to standardize and expand immunization coverage across markets. The IRA included <u>two provisions</u> modifying vaccine coverage in Medicaid and Medicare.

- Eliminating Vaccine Cost Sharing in Medicare Part D: Effective January 1, 2023, all Medicare Part D plans are required to cover all ACIP-recommended adult vaccines not covered under Part B with no cost sharing, even if the beneficiary is in the deductible phase of the benefit.
- Mandating Medicaid Coverage of Adult
   Vaccines: Effective October 1, 2023, all
   state Medicaid programs are required to
   cover all ACIP-recommended adult vaccines
   and their administration without cost sharing.
   This policy aligns coverage for traditional
   Medicaid with that of the expansion

population for whom vaccine coverage was already mandated.

As a result of these policy changes, most individuals in the United States now have a pathway to no-cost coverage of all ACIP-recommended vaccines.

While coverage is now required across most markets, variation exists in federal policies governing which immunizations are subject to coverage requirements, the timeline for which coverage requirements must be in effect, and other elements impacting patient access. These variations can limit where and from whom individuals can receive their immunizations. To provide clarity on the vaccine coverage policy landscape, Avalere published a whitepaper summarizing key policies across markets. Although policy landscape evolution expanded the populations for whom coverage without cost sharing is required, remaining policy variations could create barriers to coverage for certain populations, including uninsured and underinsured individuals. Policymakers and other stakeholders will likely consider reforms aimed at populations that continue to face barriers to vaccine access.

Download the white paper: <u>A Guide to Vaccine Coverage Policies</u>
Funding for this research was provided by Pfizer. Avalere retained full editorial control.

#### **Coverage and Reimbursement**

# Payment Barriers Persist for Vaccinating Providers

Next Up	

In 2024, Avalere experts discussed provider vaccination barriers and the potential policy solutions stakeholders are supporting to address them.

Vaccinating providers' ability to offer vaccines to patients is impeded by several financial and administrative barriers, including uncertainty and concern about inadequate payment rates across payer types and sites of care. These providers often invest resources upfront to stock and administer vaccines to patients with the intent of recouping these costs through reimbursement (Figure 1).

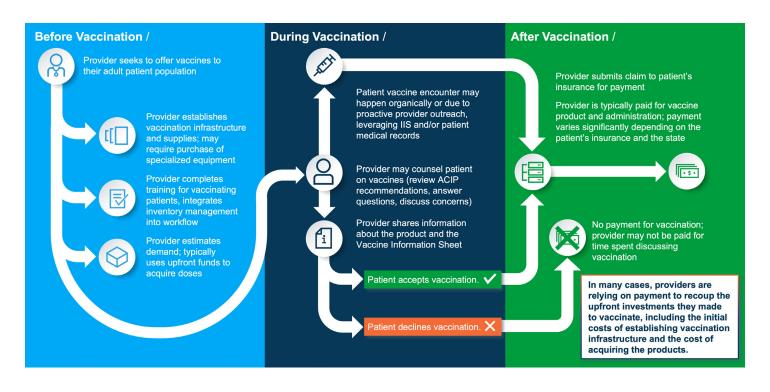
Concerns about varied payment rates may contribute to provider uncertainty about timely reimbursement and could further affect decisions about whether to continue stocking and administering vaccines over the long term.

Policymakers and stakeholder advocates are considering reforms to mitigate these challenges, thereby improving vaccine access across care settings and provider types and ultimately increasing adult vaccination rates.

Payment reform may become increasingly relevant with the launch of new vaccine delivery methods, and advancing certain reforms may require coordinating alignment across partner advocates and generating additional evidence to garner policymaker support.

Download the white paper: Examining Provider-Focused Vaccine Policy Reforms: Considerations for Patient Access Funding for this research was provided by the Adult Vaccine Access Coalition. Avalere retained full editorial control.

Figure 1. Example of a Provider Journey to Vaccinate an Adult Patient





#### **Haley Payne**

#### Consultant II

Haley Payne provides subject matter expertise in vaccines, preventive services, pandemic preparedness and response, and healthcare quality to support clients' above-brand and brand-level policy objectives.

#### Haley's Take

"There are several points in the provider vaccination journey that require upfront costs. Uncertainty among providers about whether they will receive adequate reimbursement can impede patient access to recommended vaccines, and this issue has catalyzed many reimbursement policies being explored in recent years."

**Access and Uptake** 

## Declines in Routine Adult and Teen Vaccinations Continued in 2021

Next Up	

A 2022 Avalere analysis found that routine immunization continued to lag below pre-pandemic levels, highlighting the ongoing effect of the COVID-19 pandemic on routine vaccination.

The COVID-19 pandemic continues to impact healthcare delivery, including the utilization of routine preventive services like vaccines. In February and June 2021, Avalere released a series of analyses that found persistent and sometimes steep declines in vaccination claims for ACIP-recommended adolescent and adult vaccines since the start of the pandemic.

The analyses compared 2019 to 2020 claims submissions for ACIP-recommended vaccines from January–November across commercial, Managed Medicaid, Medicare Advantage, and Medicare Fee-for-Service (FFS) Part B markets. The analyses found that declines in ACIP-recommended adolescent and adult vaccine claims across from 2019 to 2020 translated into an estimated 26 million missed doses of recommended vaccines.

To assess the pandemic's continued impact on routine immunizations, Avalere conducted a follow-up analysis comparing vaccine claims from December 2020–July 2021 to claims from the same months in 2019 (e.g., comparing May 2019 to May 2020). This analysis treats 2019 vaccine claims as representative of baseline prepandemic vaccination levels.

#### Key Findings from 2020–2021

- Extending Avalere's previous findings, this analysis found that from January 2020–July 2021, monthly vaccine claims decreased, on average across markets, by 32% for adults and 36% for adolescents when compared to the same months in 2019.
- Declines in ACIP-recommended adolescent and adult vaccinations persisted across all markets from December 2020–July 2021.
   Across markets, total vaccine claims in this timeframe were between 7%–64% lower than 2019 claims in adolescents and 15%– 62% lower than 2019 claims in adults.
- From December 2020–July 2021, adolescents and adults in the studied

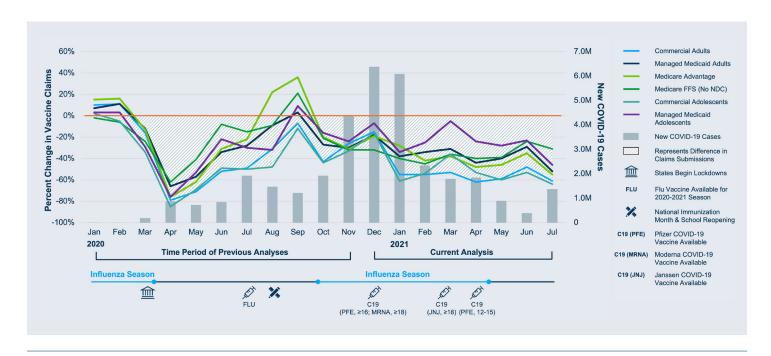
- markets may have missed approximately 11.1 million doses of recommended vaccines compared to 2019.
- Cumulatively, from January 2020–July 2021, adolescents and adults across the studied markets may have missed an estimated 37.1 million doses of recommended vaccines compared to 2019.

## Adolescent and Adult Vaccine Claims Continue to Lag Behind Pre-Pandemic Levels

Across both adolescent and adult populations, total routine vaccine administration and product claims from January 2020–July 2021 were below 2019 levels. At the end of 2020, a surge in early flu vaccinations drove claims above 2019 levels for the same timeframe. This most recent analysis, however, found that the rate of routine vaccinations among adults decreased markedly

in January 2021, ranging from 28%-55% lower than January 2019 rates depending on the source of insurance coverage, with steepest declines occurring among commercially insured adults. Adult vaccination levels throughout the first half of 2021 were relatively stable but remained lower than 2019 levels. Adolescent routine vaccinations similarly remained below 2019 levels from December 2020-July 2021 but increased briefly across both commercial and Managed Medicaid markets around March 2021, with claims in Managed Medicaid rising to 5% below March 2019 levels. This increase coincided with phased school reopenings and the restart of activities such as school sports in some states. These improvements were temporary, however, as vaccination levels fell again in April and continued to decline through July.

Figure 1. Changes in Claims for All ACIP-Recommended Adolescent and Adult Vaccines Across Markets January 2020–July 2021 Compared to the Same Months in 2019



Avalere used national enrollment data to extrapolate the difference between observed monthly vaccine claims from January 2020–July 2021 and monthly claims in 2019 to estimate the potential number of "missed doses" on a national level. The method employed is consistent with the previously reported analysis.

The analysis found that from January 2020–July 2021, adolescents and adults across the included insurance markets missed a potential 37.1 million doses of recommended vaccines,

with an additional 11.1 million missed doses since November 2020. As with the previous analysis, "missed doses" refers to the decrease in doses of recommended adolescent and adult vaccines from 2019 to 2020 and 2019 to 2021. Adults enrolled in commercial plans continue to experience the largest volume of missed doses, followed by adolescents in commercial plans and adults in Medicare FFS. Notably, missed doses in both Medicare FFS and Medicare Advantage markets as of July 2021 more than doubled since November 2020.

Figure 2. Estimated Missed Doses for All Vaccine Claims Across Markets, January 2020–July 2021



#### **Discussion**

As noted in Avalere's <u>previously published</u> <u>analysis</u>, adolescent and adult vaccination rates increased moderately during the second half of 2020, particularly as COVID-19 cases declined temporarily, flu vaccinations became available, and some schools made plans to reopen. These gains plateaued or steadily declined through the end of 2020 and into 2021 as new cases of COVID-19 surged. During this time, COVID-19 vaccines became available, initially for older adolescents and adults and then for younger adolescents. In May 2021, the CDC <u>updated guidance</u> to allow coadministration of COVID-19 vaccines with other routine vaccines, in part to encourage

uptake of other ACIP-recommended vaccines, although the impact of those recommendations remains unclear.

The evolving COVID-19 landscape impacted routine preventive care in the United States, particularly uptake of routine vaccinations, which was sub-optimal even before the pandemic. Some broad cultural shifts associated with the pandemic, such as heightened vaccine hesitancy in some communities, may continue to challenge efforts to surpass pre-pandemic routine vaccine coverage levels to meet <a href="mailto:national">national</a> vaccination goals.



#### Elif Alyanak

**Principal** 

Elif Alyanak supports clients with evidencebased research and analysis that spans a variety of healthcare sectors and stakeholders. With a background in health policy and vaccine research, she applies her skills in comparative effectiveness and recommendation development to a broad range of client projects.

#### Elif's Take

"Although routine immunization rates are catching up to pre-pandemic levels, policy and access pathways for next-generation immunizations remain unclear. Manufacturers, particularly of novel products such as preventive mAbs and therapeutic vaccines, should engage regulators and policymakers proactively to facilitate patient access."



### Synthesizing Evidence to Inform ACIP Engagement Strategy

Avalere investigated the potential benefits of decreasing the ACIP-recommended age for some routine vaccinations.

#### Challenge

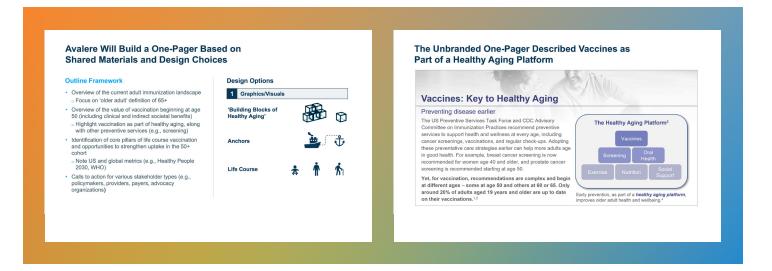
A vaccine manufacturer sought to understand the potential individual health and societal benefits of decreasing the age for routine vaccination from 60 to 50 years of age for some ACIP-recommended vaccines.

#### **Solution**

Avalere conducted a thorough review of existing evidence and synthesized it in a white paper demonstrating that decreasing the age for some routine vaccinations to 50 years of age could help prevent disease and severe health outcomes (including those associated with chronic and infectious disease comorbidities), slow immunosenescence, reduce overall healthcare spending by increasing preventive service use among adults, and enhance harmonization between vaccinations and other preventive services.

#### **Results**

This work provided the client with evidence and business intelligence to guide its stakeholder engagement strategies and ultimately drive reforms to increase the uptake of key preventive services.





# Analyzing the Causes and Effects of Vaccine Hesitancy

Avalere helped a life sciences organization understand and develop plans to mitigate the rise in vaccine hesitancy.

#### Challenge

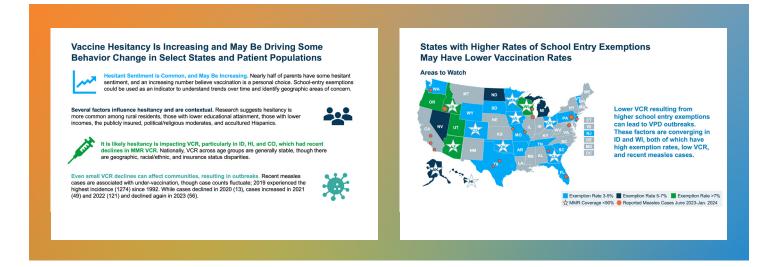
Amid growing reports of vaccine hesitancy, a vaccine manufacturer sought to map trends in, and understand underlying causes of, decreasing vaccine coverage rates and increasing vaccine-preventable disease outbreaks.

#### **Solution**

To map the landscape of vaccine hesitancy and coverage rates, Avalere combined market research on patient and provider vaccine-related attitudes and behaviors with in-depth analysis of news coverage and epidemiological studies. Avalere also mapped recent outbreaks of vaccine-preventable diseases to assess the consequences of increasing vaccine hesitancy and decreasing vaccine coverage rates.

#### **Results**

This work provided the client with a deeper understanding of vaccine hesitancy and its impacts on vaccine coverage rates and outbreaks of vaccine-preventable diseases, and with business intelligence insights to inform strategies for increasing vaccine uptake.



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Our subject matter experts advise throughout the vaccines lifecycle, from strengthening evidence strategies to maximizing public and provider disease and prevention awareness.

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For more information, please contact **info@avalere.com**. You can also visit us at **avalere.com**.

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