



Association of  
Immunization  
Managers

JUNE 2026

# VACCINE IMPLEMENTATION PLAYBOOK

Guidance for Immunization Programs Implementing  
New and Updated Vaccine Recommendations



# Purpose and Audience

The Vaccine Implementation Playbook is designed to help immunization programs anticipate and prepare to implement new or revised vaccine recommendations. It provides practical considerations across key stages of the vaccine development and recommendation process, from regulatory review through early rollout and ongoing implementation.

This playbook focuses on planning for the implementation of recommended vaccines. It does not address the process for determining whether a vaccine should be recommended.

This playbook is intended as a planning resource. Each immunization program will need to evaluate activities based on its jurisdictional authority, program structure, and available resources.

The activities included in this playbook reflect insights from immunization program managers, national partners, and subject matter experts involved in vaccine implementation. The Association of Immunization Managers (AIM) is grateful to the many individuals who shared their experiences and feedback to help inform this resource.

## **Primary Audience:**

State, local, and territorial immunization program managers and staff.

# How to Use This Playbook

The playbook is organized around key milestones in the vaccine development and implementation process, beginning with submission of a Biologics License Application (BLA) to the U.S. Food and Drug Administration (FDA) and continuing through early vaccine rollout and ongoing immunization program activities.

**Each stage of the playbook follows a consistent structure.**

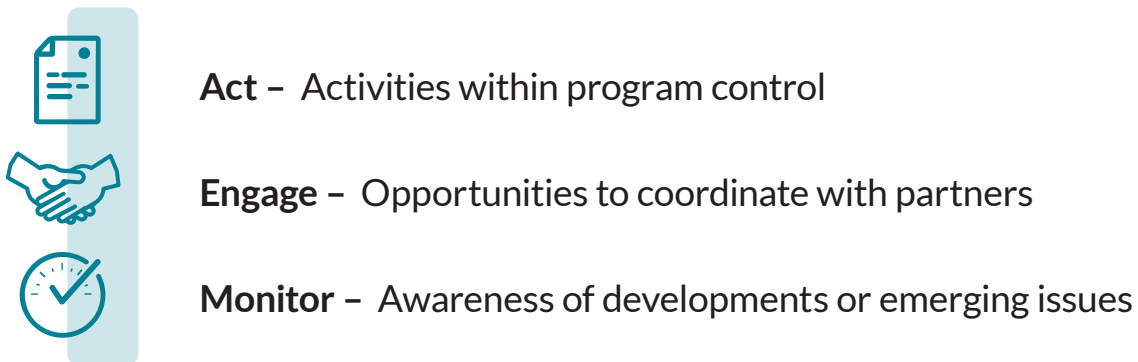
## What's Happening Nationally

Key regulatory, policy, and operational developments that may influence vaccine implementation.

## What Immunization Programs Can Do

Practical activities immunization programs can do to prepare for the implementation of a new or revised vaccine recommendation.

Activities are organized using the following framework to help programs quickly identify the type of action involved:



**Within each category, activities are further divided into:**

-  **Recommended** Essential activities commonly undertaken by immunization programs
-  **Consider** Activities that may depend on program capacity, jurisdictional authority, or vaccine characteristics

Each section also includes a **Resources** subsection highlighting tools and references that support implementation activities.

Key terms and acronyms used throughout the playbook are defined in the **Glossary** at the end of the document.

# Overview of Playbook Timeline

The following table provides a high-level overview of the stages included in the playbook, and the types of activities immunization programs may consider at each stage\*.

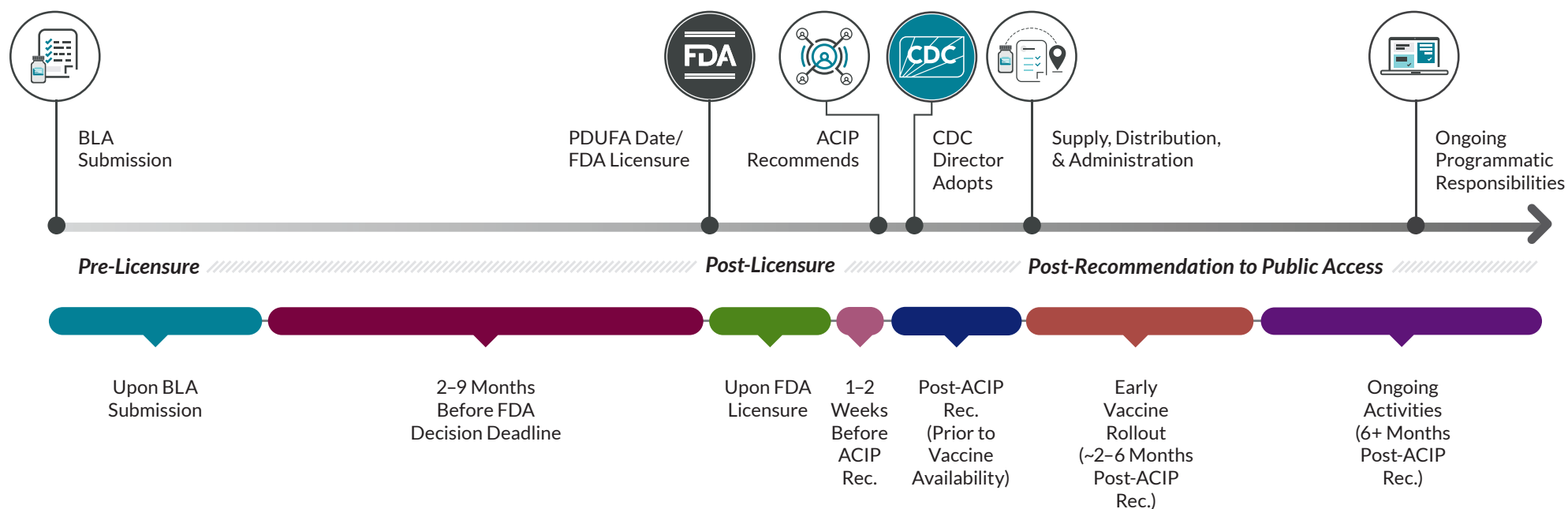
| STAGE |                                                                                     | FOCUS                                                                                                                                                                                                           |
|-------|-------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 1     | Upon BLA Submission                                                                 | <b>Initiate early planning:</b> Assess priority populations, identify provider types, initiate immunization information system (IIS) considerations, and begin early disease awareness education with partners. |
| 2     | 2–9 Months Before FDA Decision Deadline                                             | <b>Strengthen operational readiness:</b> Advance IIS onboarding and vendor coordination, engage payers and partners, and develop provider and public communication materials.                                   |
| 3     | Upon FDA Licensure                                                                  | <b>Translate licensure details into operational readiness:</b> Determine funding pathways, clinical protocols, communication updates, and IIS system preparation.                                               |
| 4     | 1–2 Weeks Before Advisory Committee on Immunization Practices (ACIP) Recommendation | <b>Finalize readiness:</b> Confirm communication readiness and prepare to respond quickly following the ACIP vote.                                                                                              |
| 5     | Post-ACIP Recommendation (Prior to Vaccine Availability)                            | <b>Activate implementation plans:</b> Update materials, prepare ordering and distribution systems, finalize standing orders and protocols, and prepare providers for rollout.                                   |
| 6     | Early Vaccine Rollout (~2–6 Months Post-ACIP Recommendation)                        | <b>Support early implementation:</b> Monitor provider participation, address operational challenges, coordinate with partners, and promote access through providers and community settings.                     |
| 7     | Ongoing Activities (6+ Months Post-ACIP Recommendation)                             | <b>Monitor access and uptake:</b> Analyze IIS data to address barriers to vaccination, support quality improvement, and share lessons learned.                                                                  |

**\*NOTE:** The timing of vaccine availability and implementation activities may vary depending on product characteristics, supply conditions, and operational factors. The stages in this playbook are intended to support planning and may not always occur within the same timeframe for every vaccine.

# Playbook Timeline

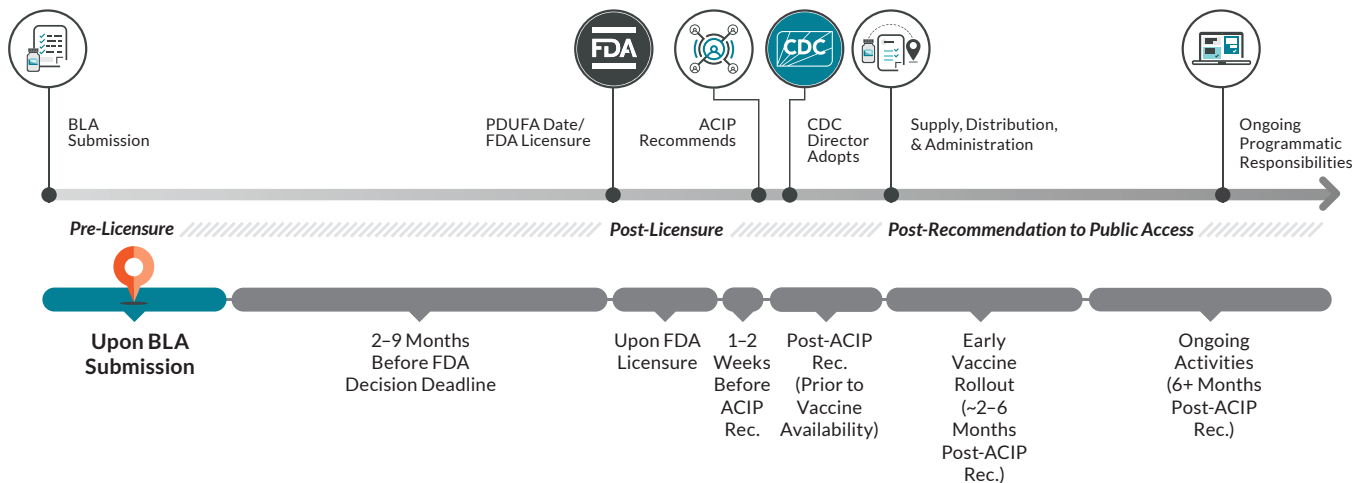
The following timeline illustrates the major milestones that structure the stages of this playbook. Earlier pre-licensure stages (e.g., research and development and clinical trials) are not shown.

## TIMELINE AND ACTIVITIES



Marks placement in the process

# TIMELINE AND ACTIVITIES



## STAGE 1

## Upon Biologics License Application (BLA) Submission

Following completion of clinical trials assessing vaccine safety and efficacy, the manufacturer submits the research and clinical trial data to the FDA through a BLA, seeking licensure of the vaccine.

### What's Happening Nationally

- FDA sets the BLA decision deadline (the Prescription Drug User Fee Act (PDUFA) date).
- The manufacturer may begin conducting pre-approval information exchange (PIE) presentations with healthcare decision-makers.
- Historically, ACIP workgroups may have begun meeting during earlier clinical trial phases and continued reviewing Phase 3 data in parallel with the FDA's review.

### What Immunization Programs Can Do

At this stage, the manufacturer believes that the product has met regulatory requirements for licensure and has submitted the necessary data to the FDA. While FDA licensure is not guaranteed, immunization programs should begin preparing for a potential new product. Many details about a potential vaccine (e.g., dosing schedules or operational guidance) may not yet be finalized. This section is intended to help programs think about implementation of a new vaccine, recognizing that information will continue to evolve.

# STAGE 1

## Upon BLA Submission

### What Immunization Programs Can Do



#### Act – Within Program Control

##### ✓ Recommended

- Assess the anticipated product and populations likely to be affected (e.g., high-risk groups, adults, children) and identify internal staff roles needed to support early planning.
- Determine which provider groups may administer the vaccine and identify any IIS onboarding needs.
- Enroll new, specialty, and/or adult vaccine providers, as needed.
- Determine how vaccines administered during clinical trials appear in the IIS to avoid downstream challenges (e.g., school vaccine requirements or future changes to indications).

##### 💡 Consider

- Begin early provider and public education about the disease to help establish the importance of prevention. Include community-based organizations and trusted messengers.
- Determine if the target infection(s)/disease(s) are state reportable conditions.



#### Engage – Coordinate With Partners

##### ✓ Recommended

- Identify new or specialty Vaccines for Children (VFC) and/or adult providers and/or related partner organizations, as needed.
- Use existing touchpoints with the Centers for Disease Control and Prevention (CDC) to emphasize the value of early operational or VFC guidance for future rollouts.

# STAGE 1

## Upon BLA Submission



### Consider

- Participate in manufacturer PIE presentations, if available, to better understand anticipated product characteristics (e.g., cost, distribution, packaging, storage, administration).
- Coordinate with legislative liaisons or other partners to identify any jurisdiction-specific laws, regulations, or policies that may need attention once an ACIP recommendation is or is not issued.
- Connect with Medicaid and other payers to understand any anticipated coverage or billing considerations for the vaccine.

Collaborate with local health jurisdictions (LHJs) to:

- Connect with partners and providers serving populations most likely to be prioritized for vaccine administration to help identify early considerations.
- Partner with appropriate organizations (e.g., coalitions, health care professional organizations) to support early disease-specific provider education, as needed, to demonstrate the importance of prevention.



## Monitor – Awareness Only



### Recommended

- Follow AIM's vaccine implementation updates.
- Watch for the formation of ACIP workgroups and for opportunities to suggest participants or follow discussions.



### Consider

- Follow major conference updates (e.g., [IDWeek](#)), manufacturer press releases, and other public information on this and other products in development.
- Monitor community attitudes toward the disease(s) associated with the vaccine in development and, if feasible, gather local feedback to inform future planning.

# STAGE 1

## Upon BLA Submission

### Resources

- [Advisory Committee on Immunization Practices \(ACIP\) meeting and workgroup information](#) | CDC
- [VFC Operations Guide](#) | CDC
- [Resource Repository](#) | American Immunization Registry Association (AIRA)
- [Guidance on Indicating Clinical Trial Vaccines](#) | AIRA
- [Program Practices Database](#) | AIM

#### Communications

- [Public Health Communications Collaborative Communications Planning Guide for Local Health Departments](#) | National Association of County and City Health Officials (NACCHO)
- [Center for Health Communication Resources](#) | Harvard T.H. Chan School of Public Health
- [Checklist to Build Trust, Improve Public Health Communication, and Anticipate Misinformation During Public Health Emergencies](#) | Johns Hopkins Bloomberg School of Public Health

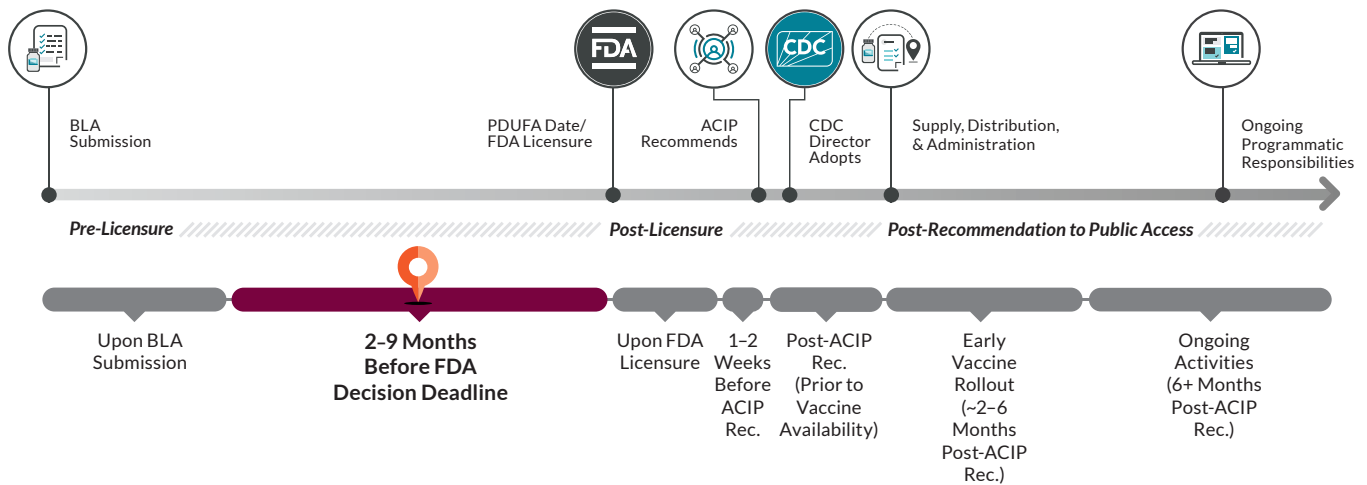
#### Legislative Partnerships

- [Immunization Program Policy Toolkit](#) | AIM
- [Connecting the Dots: Legislative Sessions](#) | AIM
- For individual support, [contact AIM Chief Policy and Government Relations Officer Brent Ewig](#) | AIM

#### Medicaid Partnerships

- [Communicating the Value of IIS: A Toolkit for Program Managers](#) | AIM
- [Medicaid and Immunization Programs Collaboration Toolkit](#) | AIM

# TIMELINE AND ACTIVITIES



## STAGE 2

## 2–9 Months Before FDA Decision Deadline

The FDA is actively reviewing the submitted BLA in advance of the anticipated decision deadline (PDUFA date). ACIP workgroup discussions may also be underway.

### What's Happening Nationally

- Typically, the ACIP workgroup continues meeting to discuss the product.
- The American Medical Association (AMA) determines the new Current Procedural Terminology (CPT) product code and publishes as “early release” in April, July, or October. If AMA rejects the CPT application, the manufacturer will apply for a Healthcare Common Procedure Coding System (HCPCS) II code from the Centers for Medicare and Medicaid Services (CMS) instead.
- The manufacturer establishes product pricing and may submit pricing information to private pricing compendia in preparation for launch.
- The FDA’s Vaccines and Related Biologic Products Advisory Committee (VRBPAC<sup>1</sup>) may review and vote on the product.

<sup>1</sup> Or the FDA Antimicrobial Drugs Advisory Committee (AMDAC) in the case of non-traditional immunization technology

## 2–9 Months Before FDA Decision Deadline

### What Immunization Programs Can Do



#### Act – Within Program Control

##### Recommended

- Continue IIS onboarding for identified provider groups, including testing and transition to production for bidirectional data exchange.
- Revisit IIS vendor conversations to identify plans to handle potential challenges.
- Brief jurisdiction leadership on pending vaccine products, as needed.
- Notify Medicaid and Children's Health Insurance Program (CHIP) about the potential inclusion of a new vaccine in the VFC and/or adult program, as needed.
- In universal purchase states, begin internal process to ensure adequate non-VFC funding, as applicable.
- Begin outlining communication considerations and potential resource needs for providers, pharmacists, and the public, aligning with national messaging when possible.

##### Consider

- Prepare providers for any known storage considerations, as needed.
- Develop high-level educational materials for internal review, recognizing that final content may depend on licensure and recommendation details.
- Develop materials to brief legislators and their staff on the disease, as appropriate according to jurisdictional policy.

## 2–9 Months Before FDA Decision Deadline



### Engage – Coordinate With Partners

#### ✓ Recommended

- Coordinate with other jurisdictions using the same IIS vendor (e.g., through vendor consortiums or regional public health collaboratives) to share information and align approaches to potential systems challenges.
- Use touchpoints with CDC staff to inquire about vaccine supply or operational considerations.

#### 💡 Consider

- Connect with regional payers, as feasible, to understand their internal review processes (e.g., status of Pharmacy and Therapeutics (P&T) Committees) and strengthen relationships with appropriate points of contact.
- Flag upcoming electronic health records (EHR) implementation considerations with EHR partners (e.g., Healthcare Information and Management Systems Society (HIMSS), American Immunization Registry Association (AIRA)) to raise awareness ahead of formal guidance.
- Engage state pharmacy associations to identify potential implementation challenges and support needs.
- Collaborate with LHJs to coordinate with immunization coalitions, medical associations, and other partners on messaging development, including disease education and supporting partner communication with policymakers and other audiences.

# STAGE 2

## 2–9 Months Before FDA Decision Deadline



### Monitor – Awareness Only

#### ✓ Recommended

- Follow AIM's vaccine implementation updates.
- Monitor the release of new CPT codes.
- Follow ACIP workgroup discussions and data, as publicly available.
- Monitor scheduled VRBPAC meetings and review publicly available briefing materials and presentations.

#### 💡 Consider

- Follow and/or sign up for new manufacturer press releases and other public information.
- Track updates from professional medical associations (e.g., American Academy of Pediatrics (AAP), American College of Obstetricians and Gynecologists (ACOG)).

## Resources

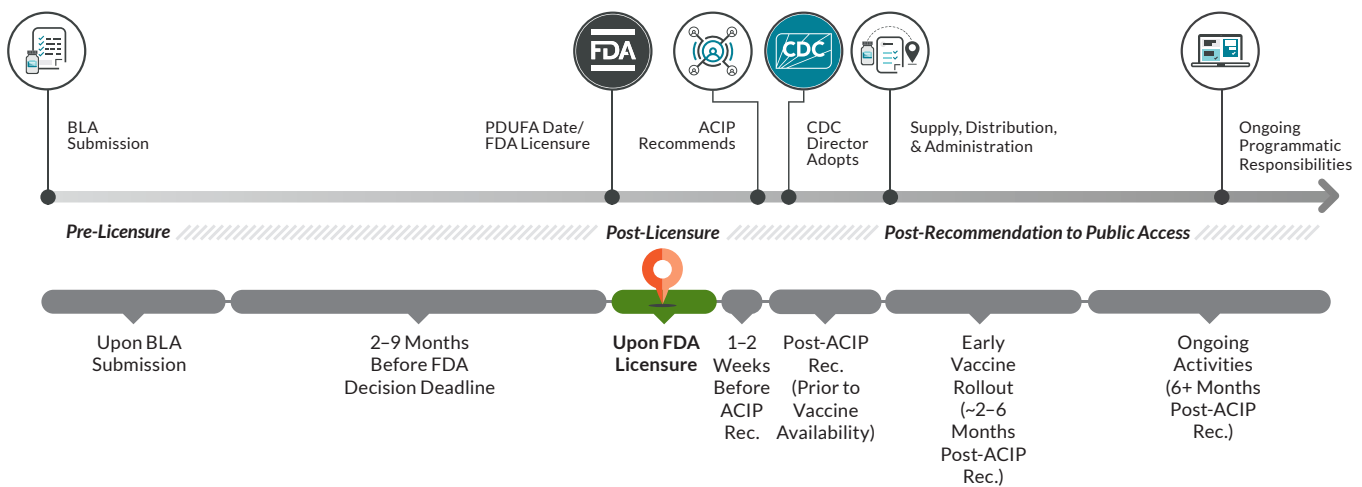
- [Connecting the Dots: Universal Purchase](#) | AIM
- [IIS Orientation to Provider Onboarding: Resources Checklist](#) | AIRA
- [State Pharmacy Association Directory](#) | National Alliance of State Pharmacy Associations (NASPA)

See previously listed [communications](#), [legislative partnerships](#), and [Medicaid](#) resources.

### Monitoring

- [CPT Codes](#) | AMA
- [VRBPAC Meetings](#) | FDA
- [ACIP Workgroups](#) | CDC

# TIMELINE AND ACTIVITIES



## STAGE 3

### Upon FDA Licensure

The FDA has licensed the vaccine and approved its prescribing information (package insert), authorizing the product for use according to its labeled indications, but ACIP has not yet voted on a recommendation. Draft ACIP workgroup recommendation options may be available.

#### What's Happening Nationally

- FDA issues approval for the vaccine.
- FDA assigns and registers national drug code (NDC). Manufacturer updates DailyMed to assign NDC to the vaccine and begins large-scale manufacturing.
- CDC publishes vaccine administered code set (CVX), if needed, and updates NDC crosswalk table.
- Payers use pricing benchmarks to establish pricing files and fee schedules and may begin preparing systems and coding logic.

# STAGE 3

## Upon FDA Licensure

### What Immunization Programs Can Do



#### Act – Within Program Control

##### ✓ Recommended

- Review the vaccine package insert and update existing implementation plans as necessary.
- Identify fact sheets and webpages that will need to be updated if recommendations are issued.
- Schedule convening of jurisdiction-specific committees or advisory boards, if required by state law.
- Determine how the vaccine may be covered across funding streams (Section 317 and VFC programs, etc.) and anticipate any funding needs if medical associations' (e.g., AAP, ACOG) recommendations differ from the ACIP recommendation, as applicable.
- Consider whether the vaccine may affect use of existing products (e.g., implications for brand choice policies or formulary limitations).
- Determine if state-level standing orders will be needed to align with anticipated recommendations. Immunize.org will publish draft standing orders following a recommendation.
- Assess whether any delegation-of-authority mechanisms (e.g., for underinsured children at federally qualified health centers (FQHCs)/rural health clinics (RHCs)) may need to be established or updated.
- Identify any additional resources needed to maintain mobile clinics or non-traditional service settings, as applicable. Solicit input from LHJs.
- Plan for data displays, dashboards, and metrics to support early monitoring and communication (e.g., product availability, uptake, or school-related measures, as applicable).
- Begin considering contingency plans in the event that federal vaccine contracts are not available for the populations or schedules adopted in your jurisdiction.

# STAGE 3

## Upon FDA Licensure



### Consider

- Meet with clinical services leadership to discuss the vaccine and potential inclusion in LHJ formularies.
- Coordinate with clinical services to draft or update LHJ nursing protocols.



### Recommended

## Engage – Coordinate With Partners

- Work with IIS vendor to incorporate new code sets (CVX, MVX, NDC, CPT<sup>2</sup>) and begin planning for forecasting updates (e.g., Clinical Decision Support for Immunization).
- Distribute talking points and communication materials to LHJs.



### Consider

- Brief legislators and their staff on the disease and vaccine, using AIM- and/or partner-developed materials, as available and appropriate according to jurisdictional policy.
- Refer media and legislators to informational webinars or fact sheets, as available, to support accurate reporting and preparedness for rollout messaging.

### Collaborate with LHJs to:

- Initiate expectation-setting communications for providers, pharmacists, legislators, including clarity on product availability, timing, and next steps.
- Update and finalize coordinated messaging with immunization coalitions and partners, including public education about the disease and the importance of prevention.
- Consider promoting available EHR implementation guidance when communicating with healthcare organizations, as feasible.

# STAGE 3

## Upon FDA Licensure



### Monitor – Awareness Only

#### ✓ Recommended

- Continue following ACIP workgroup discussions and national updates relevant to the pending recommendation.
- Monitor the political landscape, coordinating with your legislative liaison or other appropriate partners, to anticipate any potential legislation or policy responses related to the new vaccine.

#### 💡 Consider

- Understand the jurisdictional pathways for consideration of adding vaccines to school, daycare, or workplace requirements (e.g., legislation versus health department rulemaking).
- Stay aware of any employer mandate or work policy considerations that may affect public perception or controversy.

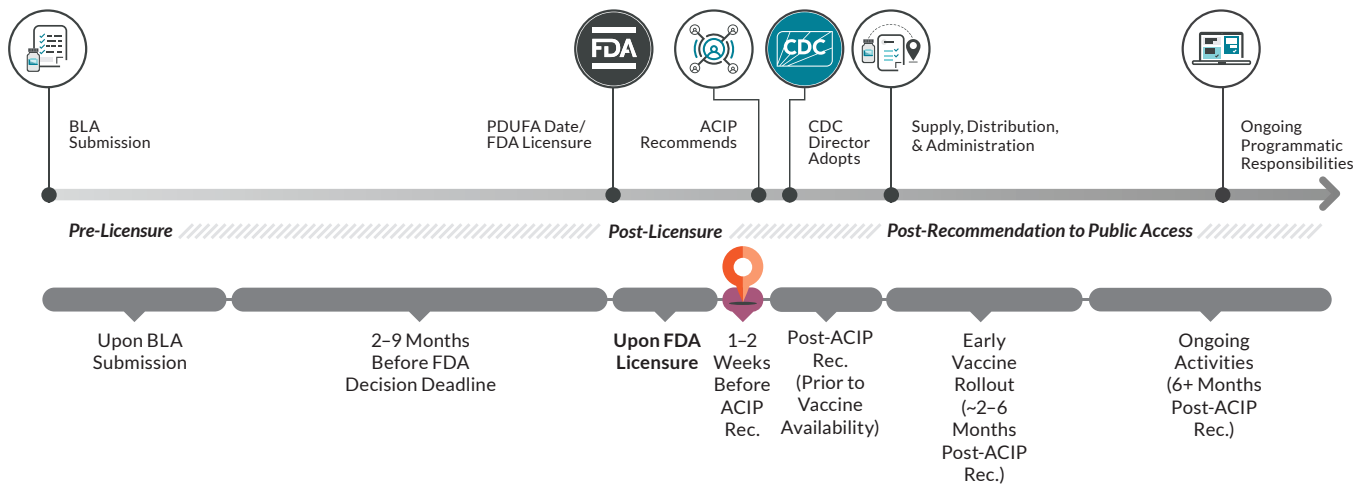
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<sup>2</sup> CVX – Vaccine Administered Code – records vaccine administration  
MVX – Manufacturer Vaccine Code – identifies vaccine manufacturer  
NDC – National Drug Code – used for inventory management, ordering, billing, tracking  
CPT – Current Procedural Terminology – code used for vaccine administration, billing and payment

## Resources

See previously listed [communications](#), [legislative partnerships](#), and [Medicaid](#) resources.

# TIMELINE AND ACTIVITIES



## STAGE 4

## 1-2 Weeks Before ACIP Recommendation

ACIP is expected to vote in 1-2 weeks on the vaccine recommendation, and jurisdictions should prepare for potential implementation decisions following the vote. Draft ACIP workgroup recommendation options may be available.

### What's Happening Nationally

- Historically, ACIP workgroups have reviewed all relevant data and proposed policy language and voting options months in advance of a vote. Related data and draft workgroup recommendations may be discussed in ACIP meetings leading up to licensure and recommendation votes.
- Historically, CDC has published information about the upcoming ACIP meeting approximately 60 days prior.<sup>3</sup>

<sup>3</sup> Prior to 2025, meeting slides were typically posted about one week in advance; since 2025, this has not occurred.

# STAGE 4

## 1–2 Weeks Before ACIP Recommendation

### What Immunization Programs Can Do



#### Act – Within Program Control

##### ✓ Recommended

- Confirm final operational readiness across internal teams, data systems, provider support functions, and partner coordination pathways in anticipation of an ACIP vote.
- Prepare, refine, and test communication plans and resources to support potential recommendations and broader rollout.
- Prepare to react to media interest in alignment with jurisdiction policies.
- Confirm funding, coverage, and procurement assumptions and identify any issues requiring rapid follow-up after the ACIP vote.
- Develop a high-level vaccine allocation approach in case of early supply limitations.

##### 💡 Consider

- Register for oral public comments and add comments to the Federal Register, as jurisdiction rules allow.



#### Engage – Coordinate With Partners

##### 💡 Consider

Collaborate with LHJs to:

- Share ACIP public comment opportunities.
- Amplify and share disease awareness and expectation-setting communications for local providers, pharmacists, legislators, and the public.

# STAGE 4

## 1–2 Weeks Before ACIP Recommendation



### Monitor – Awareness Only

#### ✓ Recommended

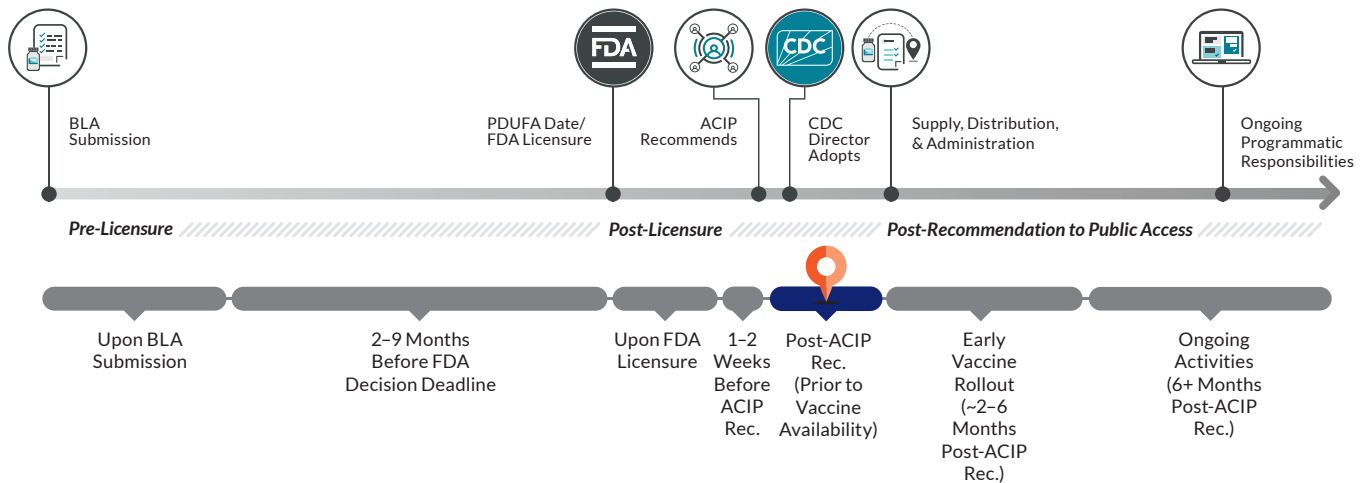
- Follow AIM’s vaccine implementation updates.
- Review anticipated ACIP voting language and slide decks, as available.
- Monitor proposed or existing legislation that may relate to the vaccine and coordinate internally as needed to address potential implementation impacts.

### Resources

See previously listed [communications](#), [legislative partnerships](#), and [Medicaid](#) resources.

- [ACIP Meeting Information and Registration](#) | CDC

# TIMELINE AND ACTIVITIES



## STAGE 5

## Post-ACIP Recommendation (Prior to Vaccine Availability)

This stage occurs immediately following ACIP recommendation and includes the process of CDC adoption.

**Note:** The timing of vaccine availability and contracting can vary. In some situations (e.g., seasonal or urgent products), these processes may move quickly; in others, they may take longer. Ideally, vaccine supply is ready to ship upon recommendation.

### What's Happening Nationally

- The CDC director reviews and adopts the ACIP recommendation within this time frame. CDC then adds to the age-appropriate vaccine schedule and VFC program, as appropriate, and publishes the recommendation in the Morbidity and Mortality Weekly Report (MMWR).
- CDC negotiates prices with manufacturers and finalizes the federal contract.
- CDC updates Clinical Decision Support for Immunization (CDSi) supporting tools to include vaccine recommendation.
- IIS vendors add the vaccine and related code sets to the list of available vaccines that jurisdictions are able to add to the IIS.

## Post-ACIP Recommendation (Prior to Vaccine Availability)

### What Immunization Programs Can Do



#### Act – Within Program Control

##### ✓ Recommended

- Update fact sheets, webpages, and publicly available materials to reflect the new recommendation.
- Disseminate prepared communications to providers, pharmacists, and the public.
- Coordinate with vaccine manager to incorporate the vaccine into the spend plan and IIS ordering systems (e.g., VTrckS). Adhere to CDC guidance and requirements.
- Refine the vaccine distribution plan to ensure equitable distribution across geographies, demographics, and provider types within any thresholds or allocation limits imposed by CDC. Use provider ordering history for other vaccines for a comparable population to help predict provider demand.
- Obtain jurisdiction-specific recommendations or approvals from state committees or advisory boards, as required by state law.
- Adjust internal systems to manage ordering, inventory, and distribution and to monitor provider compliance with the requirements of the VFC and/or adult program.

This may include, but is not limited to:

- Updating vaccine planning documents, VFC program/317 program eligibility charts, billing code tables, and health plan documentation
- Modifying public and private vaccine order options
- Monitoring provider ordering and reporting
- Overseeing VFC and/or adult program accountability
- Issue or activate state-level standing orders, if previously identified as needed.
- Implement or update delegation-of-authority mechanisms, if applicable.

# STAGE 5

## Post-ACIP Recommendation (Prior to Vaccine Availability)



- Revise plan for how the vaccine may be covered across funding streams (Section 317 and VFC programs, etc.), if needed.
- Initiate procurement contracts, as needed, if federal contract pathways do not support your jurisdiction's adopted schedule or coverage decisions.
- Share updated recommended vaccination schedules, once published.
- Test and prepare CDSi and related IIS/EHR forecasting systems to anticipate and navigate potential complexity in immunization schedules.



### Engage – Coordinate With Partners



#### Consider

- Participate in AIRA's Standards and Interoperability Steering Committee to obtain further support in preparing for CDSi complexity.

Collaborate with LHJs to:

- Engage coalitions, advisory groups, and community partners to support rollout activities.
- Coordinate with partners servicing resource-constrained settings (e.g., rural areas) to help ensure awareness and access, as feasible.



### Monitor – Awareness Only



#### Recommended

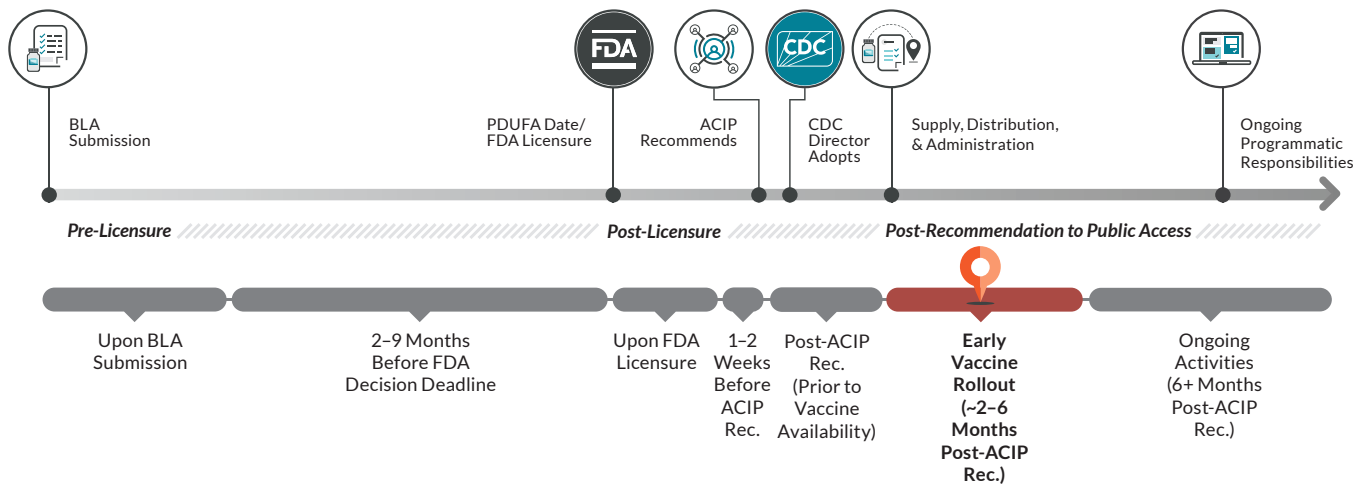
- Review ACIP meeting recordings and/or AIM summaries.
- Monitor insurance coverage updates for the vaccine.
- Track recommendations or guidance by professional medical associations (e.g., AAP, ACOG).
- Monitor for CDC director adoption of ACIP recommendations and inclusion of the vaccine into CDC-recommended schedules.

## Post-ACIP Recommendation (Prior to Vaccine Availability)

### Resources

- [Standards and Interoperability Steering Committee \(SISC\)](#) | AIRA
- [Promising Practices to Improve Pediatric COVID-19 Immunization Rates Toolkit](#) | AIM
  - Includes resources on targeted outreach, mobile clinics, at-home vaccination support, etc., that can be repurposed for any immunization campaign.
- [Program Practices Database](#) | AIM

# TIMELINE AND ACTIVITIES



## STAGE 6

## Early Vaccine Rollout (~2–6 Months Post-ACIP Recommendation)

This stage represents the early months of vaccine rollout following an ACIP recommendation.

**Note:** Clinical guidance and support materials (e.g., MMWR publications, clinical considerations, FAQs) may not yet be finalized. Programs should anticipate variability in timing and be prepared to respond to questions with available information, recognizing that the sense of urgency may differ depending on the product and timing (e.g., seasonal considerations).

### What's Happening Nationally

- CDC may set jurisdiction-specific ordering allocations/ thresholds for publicly funded vaccines if supply is inadequate.
- In early rollout, CDC publishes preliminary vaccine information statement (VIS).
- Ongoing safety monitoring systems continue to track the safety of the vaccine.

## Early Vaccine Rollout (~2–6 Months Post-ACIP Recommendation)

### What Immunization Programs Can Do



#### Act – Within Program Control

##### ✓ Recommended

- Continue provider, pharmacy, and public communications throughout early rollout (e.g., considering seasonality where relevant).
- Provide responsive technical assistance and updated operational guidance to providers, pharmacists, and partners as implementation questions emerge.
- Analyze IIS data to identify reporting gaps, data quality issues, and provider participation concerns, and implement necessary system adjustments and outreach to address them.

##### 💡 Consider

- Monitor providers' ordering patterns and identify where additional support or outreach may help optimize uptake.
- Support vaccination in mobile clinics and other non-traditional settings, when applicable, using identified resources and partnerships.
- Anticipate emerging challenges and notify partners when coordinated talking points may be helpful.
- Share observations from early rollout with AIM and/or other national partners to support broader efforts to improve implementation.

## Early Vaccine Rollout (~2–6 Months Post-ACIP Recommendation)



### Engage – Coordinate With Partners



#### Consider

- Report any payment challenges to [AAP's Hassle Form](#) (pediatrics) or National Adult and Influenza Immunization Summit ([NAIIS](#)) [Billing and Payment Workgroup](#) (adults or influenza).
- Report relevant implementation challenges to AIM and to manufacturer, via your regional account manager.
- Follow up with state pharmacy associations to assess rollout progress, identify emerging implementation challenges, and gather insight from independent pharmacies.

Collaborate with LHJs to:

- Partner with community organizations to ensure vaccines are promoted and available in appropriate settings.
- Work with partners to address logistical access barriers (e.g., transportation, childcare, internet access) as resources allow.
- Support creative vaccine access solutions (e.g., mobile clinics and non-traditional settings, such as food banks and libraries), as resources allow.
- Continue engaging coalitions and advisory groups to identify emerging needs during rollout.
- Identify barriers by population subgroup and connect with providers and partners serving these populations.

# STAGE 6

## Early Vaccine Rollout (~2–6 Months Post-ACIP Recommendation)



### Monitor – Awareness Only

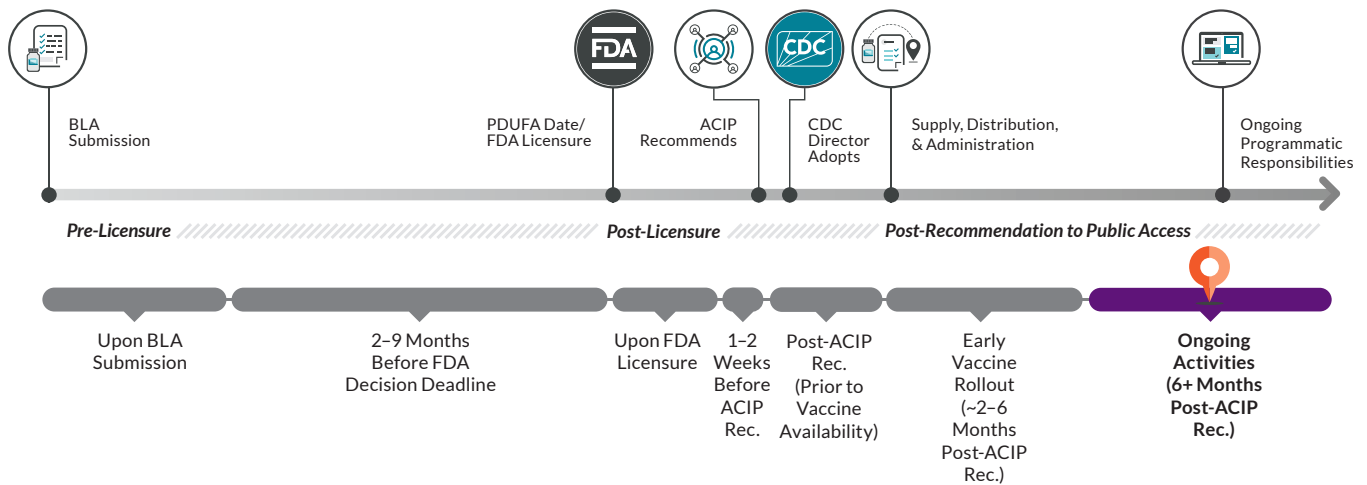
#### ✓ Recommended

- Monitor barriers or changes to insurance coverage and relevant payer policies.
- Stay current on ACIP recommendations, VIS updates, and coding changes.
- Follow AIM vaccine implementation updates.
- Follow updates from partners including Immunize.org Ask the Experts and AIRA Technical Advisory Bulletin.

### Resources

- [VISs](#) | CDC
- For IIS: [Data at Rest Initiative](#) | AIRA
- Lessons learned from [NACCHO's virtual community database](#) (may require collaboration with your LHJ to access)
- [Program Practices Database](#) | AIM
- [Hassle Form \(pediatrics\)](#) | AAP
- [Billing and Payment Workgroup \(adults or influenza\)](#) | NAIIS

# TIMELINE AND ACTIVITIES



## STAGE 7

## Ongoing Activities (6+ Months Post-ACIP Recommendation)

This stage focuses on ongoing implementation and monitoring responsibilities following the early months of vaccine rollout.

### What's Happening Nationally

- Payers cover the vaccine within one insurance plan year of the MMWR publication as required by the Affordable Care Act (ACA) and the Inflation Reduction Act (IRA).
- Final VIS is published.

## Ongoing Activities (6+ Months Post-ACIP Recommendation)

### What Immunization Programs Can Do



#### Act – Within Program Control

##### ✓ Recommended

- Continue provider, pharmacy, and public communications as needed through at least the first year of rollout.
- Monitor provider ordering patterns and identify areas where additional support may improve uptake.
- Monitor and address IIS data quality and bidirectional exchange performance to ensure accurate reporting and forecasting of vaccine eligibility. Reach out to AIRA for resources, as needed.
- Monitor vaccine coverage rates, identify corresponding vaccine deserts, and partner with FQHCs and/or pharmacies to close gaps.
- Identify and troubleshoot ongoing barriers to vaccination.
- Refine communication, access, and provider support strategies based on uptake data, implementation challenges, and community feedback.

##### 💡 Consider

- Plan for sharing available vaccination data with providers to support quality improvement efforts (e.g., through provider-run reports or existing quality improvement programs, such as Immunization Quality Improvement for Providers (IQIP) or other quality assurance (QA) activities).
- Share vaccination coverage data publicly through dashboards or reports once sufficient data exist.
- Update state committees or advisory boards with information about barriers to vaccination and uptake data.

# STAGE 7

## Ongoing Activities (6+ Months Post-ACIP Recommendation)

- Participate in efforts to document lessons learned to strengthen future vaccine introductions.
- Begin identifying and documenting future policy activities (e.g., potential school-entry requirements) that may need consideration in later years.



### Engage – Coordinate With Partner



#### Consider

- Share lessons learned with national partners (e.g., AIM) to support broader immunization community learning.
  - Continue to report any payment challenges to [AAP's Hassle Form](#) (pediatrics) or [NAIIS Billing and Payment Workgroup](#) (adults or influenza).
  - Continue to report relevant implementation challenges to manufacturer, via your regional account manager, and/or AIM.
- Contribute to publications or summaries, as resources allow, to help capture institutional knowledge.
- Share details of ongoing barriers to vaccination with CDC and/or other invested partners.



### Monitor – Awareness Only



#### Recommended

- Stay up to date on insurance coverage changes, VIS updates in different languages, and any other changes.

## Resources

- [VISs Translations](#) | Immunize.org
- [Program Practices Database](#) | AIM's
- [Hassle Form \(pediatrics\)](#) | AAP
- [Billing and Payment Workgroup \(adults or influenza\)](#) | NAIIS

# APPENDICES

## **APPENDIX A:**

The Routine Vaccine Implementation Process — A Flowchart

## **APPENDIX B:**

Cytomegalovirus (CMV) Vaccine Rollout Tabletop Exercise

## **APPENDIX C:**

Glossary

## APPENDIX A:

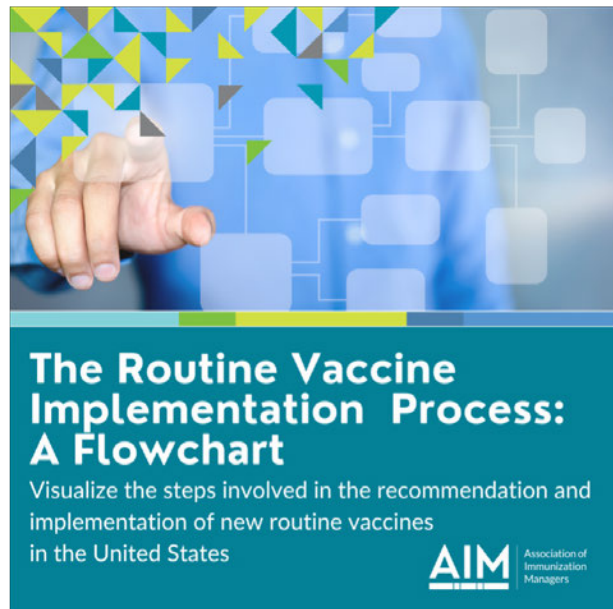
### The Routine Vaccine Implementation Process — A Flowchart

AIM's [Routine Vaccine Implementation Process: A Flowchart](#) outlines the usual steps involved in the recommendation and implementation of new vaccines and immunization technologies in the U.S. It is intended as a tool to help visualize the most routine aspects of this process (as they were in March 2025) and remains a working draft.

The flowchart reflects the most generalized steps, but AIM acknowledges that many variables, such as product type, target population, and current environment, can significantly influence the process.

The flowchart also reflects a generalized view of immunization programs. Jurisdictions' processes vary significantly based on policies, capacity, priorities, and health department structure. This chart aims to capture common experiences while recognizing those differences.

Please review the introduction at the top of the flowchart for background on how to interpret it.



## APPENDIX B:

### Cytomegalovirus (CMV) Vaccine Rollout Tabletop Exercise

This [tabletop exercise](#) was demonstrated at the 2025 AIM Leadership in Action conference in Palm Springs, CA. The exercise is designed to explore and enhance a jurisdiction's plan for the rollout of a newly licensed Cytomegalovirus (CMV) vaccine. It focuses on the unique challenges associated with CMV, including its impact on congenital infection (cCMV) and immunocompromised individuals, communication strategies, and logistical considerations, particularly for reaching specific target populations like women of childbearing age and transplant recipients.



An AIM member website login is required to access this document.

## APPENDIX C:

### Glossary

| TERM                               | DESCRIPTION                                                                                                                                                                                                                                                                                                                                  |
|------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| AAP                                | American Academy of Pediatrics                                                                                                                                                                                                                                                                                                               |
| ACIP                               | Advisory Committee on Immunization Practices                                                                                                                                                                                                                                                                                                 |
| AIM                                | Association of Immunization Managers                                                                                                                                                                                                                                                                                                         |
| AIRA                               | American Immunization Registry Association                                                                                                                                                                                                                                                                                                   |
| AMA                                | American Medical Association                                                                                                                                                                                                                                                                                                                 |
| <b>Bidirectional data exchange</b> | The ability for an IIS and an EHR to both send vaccination data to each other and receive updated information automatically.                                                                                                                                                                                                                 |
| BLA                                | Biologics License Application – the submission a manufacturer provides to the FDA requesting licensure of a biological product, including vaccines.                                                                                                                                                                                          |
| CBER                               | Center for Biologics Evaluation and Research – the FDA center responsible for ensuring vaccines are safe and effective.                                                                                                                                                                                                                      |
| CDC                                | Centers for Disease Control and Prevention                                                                                                                                                                                                                                                                                                   |
| CDSi                               | Clinical Decision Support for Immunization – logic used by IIS and EHRs to determine which vaccines are due based on vaccination history and current recommendations.                                                                                                                                                                        |
| CMS                                | Centers for Medicare and Medicaid Services                                                                                                                                                                                                                                                                                                   |
| CPT                                | Current Procedural Terminology – a coding system maintained by the American Medical Association used to report medical procedures and services.                                                                                                                                                                                              |
| CVX                                | Vaccine Administered Codes – standardized codes used to record vaccine administration.                                                                                                                                                                                                                                                       |
| EHR                                | Electronic Health Record                                                                                                                                                                                                                                                                                                                     |
| FDA                                | U.S. Food and Drug Administration                                                                                                                                                                                                                                                                                                            |
| FQHC                               | Federally Qualified Health Center                                                                                                                                                                                                                                                                                                            |
| HCPCS                              | Healthcare Common Procedure Coding System – a coding system overseen by CMS which allows payers to process claims consistently. There are two levels of HCPCS codes. Level I are comprised of CPT codes (see above). Level II are maintained by CMS and are used to identify products, supplies, and services not included in the CPT codes. |

|                       |                                                                                                                                                                                                     |
|-----------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>HIMSS</b>          | Healthcare Information and Management Systems Society                                                                                                                                               |
| <b>IIS</b>            | Immunization Information System                                                                                                                                                                     |
| <b>IQIP</b>           | Immunization Quality Improvement for Providers                                                                                                                                                      |
| <b>LHJ</b>            | Local Health Jurisdiction                                                                                                                                                                           |
| <b>MMWR</b>           | Morbidity and Mortality Weekly Report                                                                                                                                                               |
| <b>MXV</b>            | Manufacturer of Vaccine – codes used to identify the manufacturer of a vaccine.                                                                                                                     |
| <b>NAIIS</b>          | National Adult and Influenza Immunization Summit                                                                                                                                                    |
| <b>NDC</b>            | National Drug Code – a universal product identifier for human drugs which indicates the product, manufacturer or packager, and the packaging configuration.                                         |
| <b>PDUFA</b>          | Prescription Drug User Fee Act – legislation establishing timelines for FDA review of drug and biologic license applications.                                                                       |
| <b>PIE</b>            | Pre-Approval Information Exchange – a regulatory pathway allowing manufacturers to share certain product information with healthcare decision-makers before FDA approval.                           |
| <b>QA</b>             | Quality Assurance                                                                                                                                                                                   |
| <b>Standing Order</b> | A written protocol that authorizes qualified healthcare professionals (e.g., nurses or pharmacists) to administer vaccines according to an approved schedule without an individual physician order. |
| <b>VFC</b>            | Vaccines for Children Program – a federally funded program providing vaccines at no cost to eligible children through enrolled providers.                                                           |
| <b>VIS</b>            | Vaccine Information Statement – a federal document explaining vaccine benefits and risks that must be provided before vaccination.                                                                  |
| <b>VRBPAC</b>         | Vaccines and Related Biological Products Advisory Committee – an FDA committee which reviews and evaluates data concerning the safety, effectiveness, and appropriate use of vaccines.              |
| <b>VTrckS</b>         | Vaccine Tracking System – CDC’s vaccine management application used by jurisdictions to order and manage publicly funded vaccines.                                                                  |



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