COVID-19 Vaccine Distribution Update

Presented by Aon
Issue Date: December 21st, 2020

(Note: Aon is updating this information regularly. This update replaces all prior dated and undated versions.)
Today’s Discussion

- Status of Vaccine Development—Approvals and Safety
- Vaccine Availability and Distribution—Employer Considerations
- Support for Employee Vaccinations—Employer Options
- Sources of Information
- Next Steps
# Status of Vaccine Development— Approvals and Safety (as of Dec. 21)

## Vaccines in Development/Approval Process

<table>
<thead>
<tr>
<th>Manufacturer</th>
<th>Status</th>
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<tbody>
<tr>
<td>Pfizer-BioNTech</td>
<td>Authorized by FDA for emergency use</td>
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<tr>
<td>Moderna</td>
<td>Authorized by FDA for emergency use</td>
</tr>
<tr>
<td>AstraZeneca</td>
<td>Phase 3 clinical trials</td>
</tr>
<tr>
<td>Janssen (J&amp;J)</td>
<td>Phase 3 clinical trials</td>
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* J&J and AstraZeneca are using a non-replicating viral vector vaccine; not mRNA

## FDA EUA vs. FDA Approval

- **FDA EUA**
  - A mechanism to facilitate the availability during public health emergencies
  - In an emergency, the FDA makes a product available to the public based on the best available evidence, without waiting for all the evidence that would be needed for FDA approval
  - FDA must determine that the known and potential benefits outweigh the known and potential risks

- **FDA Approval**
  - Data on the drug’s effects have been reviewed by CDER (Center for Drug Evaluation Research)
  - Extended data retrieval period

## COVID-19 mRNA Vaccines Will Be Rigorously Evaluated for Safety

- mRNA vaccines are being held to the same rigorous safety standards as all other types of vaccines in the U.S.
- There are currently no licensed mRNA vaccines in the U.S. However, researchers have been studying and working with them for decades.

Source:
1. [https://www.jhsph.edu/covid-19/articles/what-is-emergency-use-authorization.html](https://www.jhsph.edu/covid-19/articles/what-is-emergency-use-authorization.html)
Vaccine Availability and Distribution—Employer Considerations

What we know now…

The WHO and CDC have provided guidelines for a phased approach for distribution. In the U.S., CDC provided suggested guidance to the states who, in turn customize for their jurisdiction.

CDC suggested guidance for U.S. states:

- **Phase 1a**: health care personnel and, in some states, long-term care facility residents
- **Phase 1b and 1c**: Essential workers, people age 65 and older, and those with high risk medical conditions
- **Phase 2**: Larger supplies available—pharmacies and public health venues become vaccine administrators
- **Phase 3**: Shift to routine strategies—open access to vaccination

Key employer considerations…

What business is my organization in?

*Can segments of the workforce be considered essential?*

Where is my workforce located?

*Definitions and distribution will vary by country, and by state.*

How can or will the vaccine costs be covered?

*In many countries, national governments will cover vaccine costs. In the U.S., the federal government will cover vaccine costs, and administration charges must be covered by U.S. health plans for plan participants.*

How can my organization support access?

*Understanding the rules and process in each state is crucial, as is making connections with state and local public health departments.*

What uncertainties should we consider?

*Risks exist, and working with support of counsel to understand and manage the risks of the strategy pursued should begin now.*

- Federal government will coordinate with states on phases of distribution of limited vaccine supplies, focusing on front-line health care workers and populations at significant risk such as those in nursing facilities. Although allocation guidance will be provided by CDC/ACIP, ultimate decision making authority is retained by state and local health departments.
- Segmenting/prioritizing the workforce based on roles will be needed, as will connection to each state’s and local department of health.
Support for Employee Vaccinations—Employer Options

- **Mandate**
  - Will require significant education to support
  - Consider workplace discrimination laws
  - EEOC considers a vaccine an “examination” and as such must either be voluntary or job-related/business necessity
  - Consider need for exceptions
  - What possible business liabilities exist if a negative reaction occurs?
  - What constitutes proof of vaccination—HIPAA issue?
  - Is this consistent with desired culture?

- **Incentivize**
  - Will require significant education to support
  - Similar to an incentive for a flu vaccine
  - Tax/legal considerations of incentivizing dependents vs. employees and those enrolled in the health plan vs. not enrolled
  - Guidance under ADA and GINA is outstanding for wellness programs
  - Reasonable accommodation may be needed
  - What constitutes proof of vaccination—HIPAA issue?
  - Is this consistent with desired culture?

- **Educate**
  - What sources of information will be available?
  - How will materials be updated based on emerging evidence?
  - Will the education be factual only or meant to drive behavior?
  - If mandate or incentive exists, communication should include availability, payment, timelines, consequences
  - Expect significant difference of opinion from employees on the issue of vaccination
  - Are there legal risks if available information turns out to be incorrect?

- **No Action**
  - Position as a personal decision for employees
  - What business risks exist if some significant percentage of employees choose to not receive a vaccination?
  - If employees are required to come to work, will they expect support from the employer for vaccination?
  - Is this consistent with desired culture?

Decisions should be made in concert with legal counsel and adjusted as new information becomes available
**Provider Delivery Considerations and Pricing – US**

**Who pays for the vaccine?**

<table>
<thead>
<tr>
<th>U.S. Government*</th>
<th>Employer**</th>
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<tbody>
<tr>
<td><strong>Vaccine Doses</strong></td>
<td><strong>Administration of Vaccine</strong></td>
</tr>
<tr>
<td><strong>Other Costs (transport, vendor fees, etc.)</strong></td>
<td></td>
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</tbody>
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Vaccine doses purchased with U.S. taxpayer dollars will be given to the American people at **no cost**. However, vaccination providers will be able to charge an administration fee for administering the shot. Vaccine providers can get this fee reimbursed by the patient’s public or private insurance company or, for uninsured patients, by the Health Resources and Services Administration’s Provider Relief Fund. (per CDC 2020^4)

**Initial Cost of Vaccine to US Government**

Prices exclude cost of administering vaccine, which may be borne by employers and health plans

- Pfizer/BioNTech- $19.50 a dose (two doses necessary)^1
- Moderna- $35 a dose (two doses necessary)^2
- Janssen- $10 a dose^3

**Cost of Vaccine Administration**

In order to administer the vaccine, a provider will need to get the vaccine to the site, store it, ensure there are licensed healthcare providers available to vaccinate, and provide necessary equipment (syringes, dry ice, PPE). The extent of this cost is still unclear as is the party who will be responsible to pay such costs. That said, it is clear that individual patients will not be charged to receive vaccination.

Source:
COVID Vaccine Injury Program – US
Addressing the concern of potential COVID-19 vaccine injury

Occasionally, a pandemic, epidemic, or security danger threatens the US. To combat these threats, the government supports the development of countermeasures such as vaccines. The Countermeasures Injury Compensation Program (CICP) was created so that in the unlikely event a person experiences a serious injury from a covered countermeasure, the person may be considered for benefits. COVID-19 vaccine is such a countermeasure. See: https://www.hrsa.gov/cicp

Countermeasures Injury Compensation Program (CICP):
- Program run by Health and Human Services (HHS)
- Covers harm resulting from vaccine used in a pandemic, epidemic, security danger
- High threshold for proving a relationship between an injury and the vaccine
- No-fault system

Employers:
- Vaccine Sponsor
- Vaccine Campaigns
- Required or Voluntary
- Injury claims already emerging

Vaccine Court:
- Orders payouts for claims
- Mandated to pay awards quickly and easily

Source: https://www.hrsa.gov/cicp

Note: The above description of CICP only applies to US. COVAX Facility has its own approach to addressing vaccine injury for COVAX member countries; we will include discussion of COVAX Facility in our next update.
Likely U.S. Vaccine Distribution Timeline - The Next Six Months

**Phase 1a**
- Pfizer vaccine gains FDA EUA approval on December 11th
- First vaccination on December 14th
- Healthcare workers begin getting immunized, critical populations prioritized by state
- Moderna gains FDA EUA approval, increasing U.S. supply of vaccines

**Phase 1b**
- Continue to immunize critical populations
- Additional guidance provided by states on prioritizing and allocating vaccine to essential employees
- Essential workers prioritized based on State definitions
- Employers will have to meet requirements on a state by state basis
- Clarity around distribution of vaccines to general public
- Employers may need to seek partners for distribution

**Phase 1c**
- Vaccine becomes available to public based on risk
- Mass immunizers are expected to gain access to vaccine for general public availability

[Diagram showing timeline with phases and key events]
Expected Employer Timeline

December 2020 ➔ January 2021 ➔ February/March 2021 ➔ 2nd Quarter 2021

**Critical**

Receive Vaccine

**Essential**

Planning ➔ Receive Vaccine

**Other Employees**

Planning ➔ Receive Vaccine

- Employers will be required to identify which employees are essential and begin planning for vaccine in early 2021
- Vaccine availability may vary by state
- Planning should include policy, distribution, partnerships, and campaigns
Sources of Information
Topics from CDC website (December 16, 2020)

1. The CDC Website
2. State and Local Government Vaccine Distribution Plans
3. Aon FAQ Document
4. CDC Interim Playbook for States
Next Steps

▪ Confirm preferred employer approach to supporting employee vaccinations
  – Determine business preference regarding mandates, incentives, education
  – Consult with legal counsel
  – Build administration and communication action plans accordingly

▪ Take action to support access to vaccine (business classification permitting):
  – Classify employee populations based on roles consistent with state definitions of “essential workers”
  – Focus on states with populations of “essential workers”, and establish connections with the state health departments—most often facilitated via existing state public relations resources
  – Confirm availability/access for each group of the population
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