



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

Manufacturer	Status
Pfizer-BioNTech	Authorized by FDA for emergency use
Moderna	Authorized by FDA for emergency use
AstraZeneca	Phase 3 clinical trials
Janssen (J&J)	Phase 3 clinical trials

* J&J and AstraZeneca are using a non-replicating viral vector vaccine; not mRNA

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>
2. <https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization>
3. <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/different-vaccines/mrna.html>

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

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.
- National Conference of State Legislators: <https://www.ncsl.org/research/labor-and-employment/covid-19-essential-workers-in-the-states.aspx> has provided an interactive map showing state definitions of "essential workers", which may be informative regarding the vaccine distribution priorities.

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

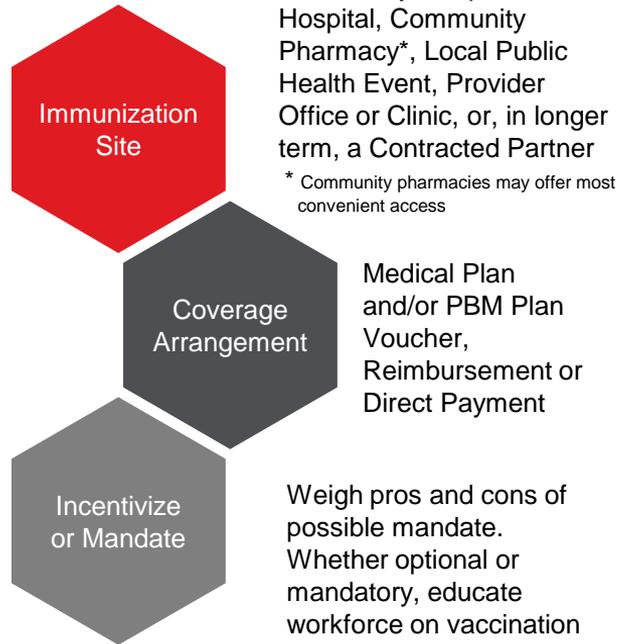
- What sources of information will be available?
- How will materials be updated based on emerging evidence?
- Will the education be factual only or meant to drive behavior?
- If mandate or incentive exists, communication should include availability, payment, timelines, consequences
- Expect significant 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?

U.S. Government*



Vaccine Doses

Employer**



Administration of Vaccine



Other Costs (transport, vendor fees, etc.)

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 2020⁴)

*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 dose³

**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:

1. <https://www.barrons.com/articles/covid-19-vaccine-makers-could-be-heroes-but-not-if-the-price-tag-is-too-high-51595623222>¹
2. <https://www.obsnews.com/news/coronavirus-vaccine-moderna-charging-more-rival-treatments/>²
3. <https://scrip.pharmaintelligence.informa.com/SC141970/COVID19-Vaccine-Could-Cost-As-Little-As-10-A-Dose-Says-Janssen>³
4. <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/faq.html>⁴

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

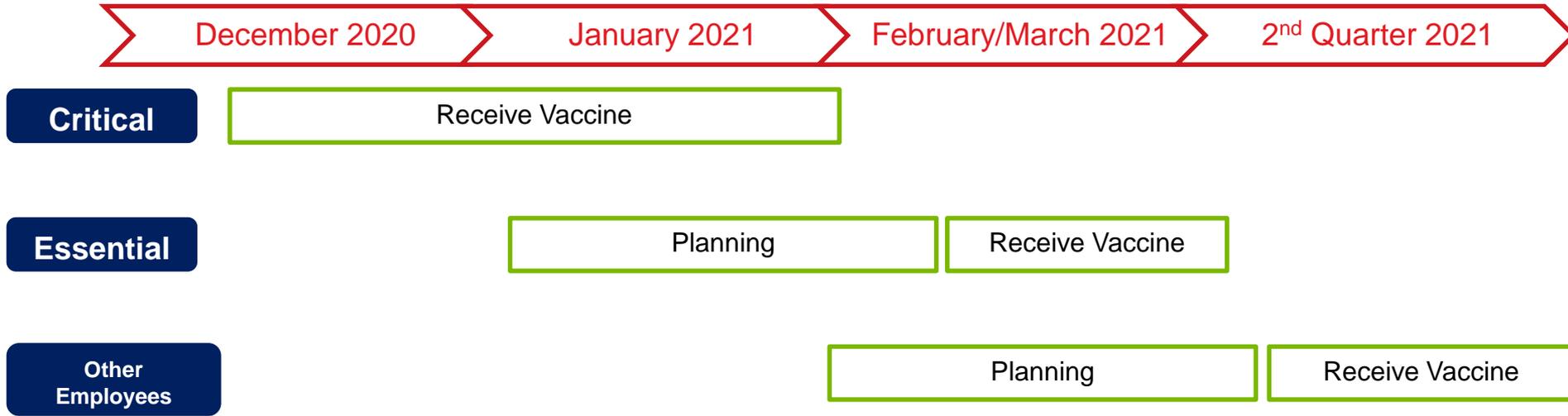
Note: The above description of CICP only applies to US. COVAX Facility has its own approach to addressing vaccine injury for COVAX member countries; we will include discussion of COVAX Facility in our next update.

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

Likely U.S. Vaccine Distribution Timeline- The Next Six Months



Expected Employer Timeline



- **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](#)

Vaccine Information for You and Your Family

8 Things to Know about the U.S. COVID-19 Vaccination Program >

Different COVID-19 Vaccines >

When Vaccine Supply is Limited, Who Gets Vaccinated First? >

Ensuring Safety of COVID-19 Vaccines >

What to Expect at Your COVID-19 Vaccination Visit >

Ensuring COVID-19 Vaccines Work >

Frequently Asked Questions about COVID-19 Vaccination >

Benefits of Getting a COVID-19 Vaccine >



For Healthcare Professionals

Resources for the planning, allocation, distribution, administration, storage & handling, patient education, and more for COVID-19 vaccine.

[Vaccine Information for Healthcare Professionals](#)

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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