### **Policy Question**

Should vaccination with Pfizer-BioNTech COVID-19 vaccine (2-doses, IM) be recommended for persons 16 years of age and older under an emergency use authorization?

# **Evidence to Recommendations Framework**Summary: Work Group Interpretations

Balance of consequences

Undesirable consequences clearly outweigh desirable consequences in most settings

Undesirable consequences probably outweigh desirable consequences in most settings

The balance between desirable and undesirable consequences is closely balanced or uncertain

Desirable
consequences
probably
outweigh
undesirable
consequences
in most
settings

Desirable consequences clearly outweigh undesirable consequences in most settings

There is insufficient evidence to determine the balance of consequences

Type of recommendation

We do not recommend the intervention

We recommend the intervention for individuals based on shared clinical decision-making

We recommend the intervention

### **ACIP Vote – Interim Recommendation**

The Pfizer-BioNTech COVID-19 vaccine is recommended for persons 16 years of age and older in the U.S. population under the FDA's Emergency Use Authorization.

For purposes of ACIP's role under the Affordable Care Act, ACIP recommends vaccination with COVID-19 vaccines within the scope of the Emergency Use Authorization or Biologics License Application for the particular vaccine.

## ACIP Vote – Interim Recommendation Amendment to 2021 Adult and Child/Adolescent Immunization Schedule

Recommend the proposed amendment to the 2021 Adult and Child/Adolescent immunization Schedules

## **ACIP Vote – Interim Recommendation**Amendment to 2021 Adult Immunization Schedule

#### **Notes**

#### Recommended Adult Immunization Schedule, United States, 2021

For vaccine recommendations for persons 18 years of age or younger, see the Recommended Child/Adolescent Immunization Schedule.

#### Additional Information

#### COVID-19 Vaccination

ACIP recommends use of COVID-19 vaccines within the scope of the Emergency Use Authorization or Biologics License Application for the particular vaccine. Interim ACIP recommendations for the use of COVID-19 vaccines can be found at <a href="https://www.cdc.gov/vaccines/hcp/acip-">https://www.cdc.gov/vaccines/hcp/acip-</a>

recs/vacc-specific/covid-19.html

- At risk for hepatitis A virus infection: 2-dose series HepAor3-dose series HepA-HepB as above
- Chronic liver disease (e.g., persons with hepatitis B, hepatitis C, cirrhosis, fatty liver disease, alcoholic liver disease, autoimmune hepatitis, alanine aminotransferase [ALT] or aspartate aminotransferase [AST] level greater than twice the upper limit of normal)
- HIV infection
- Menwhohavesexwithmen
- Injection or noninjection drug use
- Persons experiencing homelessness
- Work with hepatitis A virus in research laboratory or with nonhuman primates with hepatitis A virus infection
- Travelin countries with high or intermediate endemic hepatitis A (HepA-HepB [Twinrix] may be administered on an accelerated

weeksapart]or3-dose seriesEngerix-Bor RecombivaxHB at 0,1,6months [minimum intervals:dose1to dose2: 4 weeks / dose2 to dose 3: 8 weeks / dose 1 to dose 3: 16 weeks])or3-dose seriesHepA-HepB (Twinrix at 0, 1,6 months [minimumintervals:dose1 to dose 2: 4 weeks / 5 dose2 to dose3: 5 months])

#### Special situations

 At risk for hepatitis B virus infection: 2-dose (Heplisay-B) or 3-dose (Engerix-B, Recombivax HB) series or 3-dose series HepA-HepB (Twinrix) as above

**Chronic liver disease** (e.g., persons with hepatitis C, cirrhosis, fatty liver disease, alcoholic liver disease, autoimmune hepatitis, alanine aminotransferase [ALT] or aspartate aminotransferase [AST] level greater than twice upper limit of normal)

- HIV infection

## ACIP Vote – Interim Recommendation Amendment to 2021 Child and Adolescent Immunization Schedule

Notes Recommended Child and Adolescent Immunization Schedule for ages 18 years or younger, United States, 2021

For vaccine recommendations for persons 19 years of age or older, see the Recommended Adult Immunization Schedule.

#### Additional information

#### COVID-19 Vaccination

ACIP recommends use of COVID-19 vaccines within the scope of the Emergency Use Authorization or Biologics
License Application for the particular vaccine. Interim
ACIP recommendations for the use of COVID-19 vaccines
can be found at

https://www.cdc.gov/vaccines/hcp/acip-recs/vacc-

 Consult relevant ACIP statements for detailed recommendations at www.cdc.gov/vaccines/hcp/acip-recs/index.html. The repeat dose should be spaced after the invalid dose by the recommended minimum interval. For further details, see Table 3-1, Recommended and minimum ages and intervals between vaccine doses, in *General Best Practice Guidelines for Immunization* at www.cdc.gov/vaccines/hcp/acip-recs/general-recs/timing.html.

- Information on travel vaccine requirements and recommendations is available at http://www.cdc.gov/travel/.
- For vaccination of persons with immunodeficiencies, see Table 8-1, Vaccination of persons with primary and secondary immunodeficiencies, in *General Best Practice Guidelines for Immunization* at <a href="https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/immunocompetence.html">https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/immunocompetence.html</a>, and "Immunization in Special Clinical Circumstances" (In: Kimberlin DW, Brady MT, Jackson MA, Long SS, eds. *Red Book: 2018 Report of the Committee*