Advisory Commission on Childhood Vaccines (ACCV) update

(December 2021 to May 2022)

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Pfizer BioNTech COVID-19 Vaccine

- 9 Dec 2021 - Authorized the use of a single booster dose of Pfizer-BioNTech COVID-19 Vaccine for individuals 16 and 17 years of age at least six months after completion of a primary series with the Pfizer-BioNTech COVID-19 Vaccine.

Janssen COVID-19 Vaccine

- 14 Dec 2021 - FDA announced revisions to the Janssen COVID-19 Vaccine Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) and the Fact Sheet for Recipients and Caregivers.
  - Contraindication to the administration of the Janssen COVID-19 Vaccine to individuals with a history of thrombosis with thrombocytopenia syndrome (TTS) following the Janssen COVID-19 Vaccine or any other adenovirus-vectored COVID-19 vaccine and updated the information about the risk of TTS following vaccination.

Pfizer BioNTech COVID-19 Vaccine

- 3 Jan 2022 - amended the emergency use authorization (EUA) for the Pfizer-BioNTech COVID-19 Vaccine to:
  - Expand the use of a single booster dose to include use in individuals 12 through 15 years of age.
  - Shorten the time between the completion of a primary series of the Pfizer-BioNTech COVID-19 Vaccine and a booster dose to at least five months.
  - Allow for a third primary series dose for certain immunocompromised children 5 through 11 years of age.

Moderna COVID-19 Vaccine

- 7 Jan 2022 - Amended the EUA to shorten the time between the completion of a primary series of the vaccine and a booster dose to at least five months for individuals 18 years of age and older.

Janssen COVID-19 Vaccine

- 11 Jan 2022 - FDA announced revisions to the Janssen COVID-19 Vaccine Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) and the Fact Sheet for Recipients and Caregivers.
- The Fact Sheet for Healthcare Providers includes information about reports of adverse events following use of the vaccine which suggest an increased risk of ITP during the 42 days following vaccination, and that individuals with a history of ITP should discuss the risk and the potential need for platelet monitoring following vaccination with their healthcare provider.
- The Fact Sheet for Recipients and Caregivers has been revised to inform about ITP and instructs individuals who have ever had a diagnosis of ITP to talk to their vaccination provider.

Moderna COVID-19 Vaccine

- 31 Jan 2022 - Approval of Spikevax to prevent coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 18 years of age and older. Spikevax has the same formulation as the EUA Moderna COVID-19 Vaccine and is administered as a primary series of two doses, one month apart.

Pfizer BioNTech and Moderna COVID-19 Vaccines

- 29 Mar 2022 - Authorized a second booster dose of either the Pfizer-BioNTech or the Moderna COVID-19 vaccine for older people and certain immunocompromised individuals. Specifically:
  - A second booster dose of the Pfizer-BioNTech COVID-19 Vaccine or Moderna COVID-19 Vaccine may be administered to individuals 50 years of age and older at least 4 months after receipt of a first booster dose of any authorized or approved COVID-19 vaccine.
  - A second booster dose of the Pfizer-BioNTech COVID-19 Vaccine may be administered to individuals 12 years of age and older with certain kinds of immunocompromise at least 4 months after receipt of a first booster dose of any authorized or approved COVID-19 vaccine.
  - A second booster dose of the Moderna COVID-19 Vaccine may be administered at least 4 months after the first booster dose of any authorized or approved COVID-19 vaccine to individuals 18 years of age and older with certain kinds of immunocompromise.

Janssen COVID-19 Vaccine

- 5 May 2022 - Limited the authorized use of the Janssen COVID-19 Vaccine to individuals 18 years of age and older for whom other authorized or approved COVID-19 vaccines are not accessible or clinically appropriate, and to individuals 18 years of age and older who elect to receive the Janssen COVID-19 Vaccine because they would otherwise not receive a COVID-19 vaccine for the following reasons:
  - There is a risk of thrombosis with thrombocytopenia syndrome (TTS), a syndrome of rare and potentially life-threatening blood clots in combination with low levels of blood platelets with onset of symptoms approximately one to two weeks following administration of the Janssen COVID-19 Vaccine.
  - After conducting an updated analysis, evaluation and investigation of reported cases of TTS, the FDA determined the risk of TTS following administration of the Janssen COVID-19 Vaccine, warrants limiting the authorized use of the vaccine.
  - The FDA considered that individuals with TTS may rapidly deteriorate, despite prompt diagnosis and treatment, that TTS can lead to long-term and debilitating health consequences and that TTS has a high death rate. FDA also considered the availability of alternative authorized and approved COVID-19 vaccines which provide protection from COVID-19 and have not been shown to present a risk for TTS.
  - The FDA determined the known and potential benefits of the vaccine for the prevention of COVID-19 outweigh the known and potential risks for individuals 18 years of age and older for whom other authorized or approved COVID-19 vaccines are not accessible or clinically appropriate, and for individuals 18 years of age and older who elect to receive the Janssen COVID-19 Vaccine because they would otherwise not receive a COVID-19 vaccine.

Janssen COVID-19 Vaccine

- 5 May 2022 - The Fact Sheet for Healthcare Providers Administering Vaccine was revised to reflect the authorized use of the Janssen COVID-19 Vaccine and includes a warning statement at the beginning of the fact sheet for prominence, summarizing information on the risk for TTS. Additionally, information on the revision to the authorized use of the vaccine and updated information on this risk of blood clots with low levels of blood platelets has been added to the Fact Sheet for Recipients and Caregivers.

Pfizer BioNTech COVID-19 Vaccine

- 17 May 2022 - Authorized the use of a single booster dose of Pfizer-BioNTech COVID-19 Vaccine for individuals 5 through 11 years of age at least five months after completion of a primary series with the Pfizer-BioNTech COVID-19 Vaccine.

VRBPAC meetings this month

- 7 Jun 2022 - to discuss an EUA request for a COVID-19 vaccine manufactured by Novavax to prevent COVID-19 in individuals 18 years of age and older.
- 14 Jun 2022 - to discuss Moderna's EUA request for their COVID-19 vaccine for individuals 6 years through 17 years of age.
- 15 Jun 2022 - to discuss Moderna EUA request for their COVID-19 vaccine for children 6 months through 5 years of age and Pfizer's EUA request for the Pfizer-BioNTech COVID-19 Vaccine for children 6 months through 4 years of age.
- 28 Jun 2022 - to discuss whether the SARS-CoV-2 strain composition of COVID-19 vaccines should be modified, and if so, which strain(s) should be selected for Fall 2022.

FDA COVID-19 Website

- FDA has a website dedicated to its COVID-19 activities, including FDA's pandemic response activities pertaining to vaccines, testing, therapeutics, and devices. The website is frequently updated and is a resource for the public, including healthcare providers and industry. https://www.fda.gov/emergency-preparedness-and-response/counterterrorism-and-emerging-threats/coronavirus-disease-2019-covid-19

Thank you!