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State Health Advisory Supplement

Johnson & Johnson Vaccine and Bamlanivimab

Coronavirus Disease 2019 Supplemental Advisory #12.8

Wyoming Department of Health

April 24, 2021

SITUATION SUMMARY

Following CDC's decision on April 23, 2021, to resume use of the Johnson & Johnson (Janssen) COVID-19 vaccine, all Wyoming providers may resume administration of the Johnson & Johnson vaccine, effective immediately.

This advisory also contains information about the revocation of the emergency use authorization for bamlanivimab when used alone to treat mild to moderate COVID-19 in patients at high risk for severe disease.

JOHNSON & JOHNSON (JANSSEN) VACCINE

Following a thorough safety review, including two meetings of the CDC's Advisory Committee on Immunization Practices (ACIP), the U.S. Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC) have determined that the recommended pause regarding the use of the Johnson & Johnson (Janssen) COVID-19 vaccine in the U.S. should be lifted and use of the vaccine should resume. **All Wyoming providers may resume administration of the Johnson & Johnson vaccine, effective immediately.**

Additional analyses through April 21, 2021, found that among 7.98 million doses of Johnson & Johnson vaccine administered, 15 individuals developed thrombocytopenia (platelets < 150,000 per microliter of blood) and thrombosis or thromboembolism, a syndrome that has been named thrombosis with thrombocytopenia syndrome (TTS). Of these 15 individuals, 12 had cerebral venous sinus thrombosis (CVST). All cases of TTS occurred among females aged 18-59 years with a median age of 37 years and median time to symptom onset of 8 days (range 6-15 days). The highest incidence of TTS was among women aged 18-49 years. The pathogenesis of TTS appears similar to heparin-induced thrombocytopenia with thrombosis (HITT).

There is no association between the COVID-19 mRNA vaccines (Pfizer and Moderna) and TTS.

Given that the occurrence of TTS associated with the Johnson & Johnson vaccine is very rare, the ACIP determined that the overall benefits of Janssen COVID-19 vaccine in preventing COVID-19 outweigh the risks of side effects. Additional details of this review will be published in CDC's Morbidity and Mortality Weekly Report (MMWR) in the upcoming days. The slide deck from ACIP's meetings on April 13, 2021 and April 24, 2021, can be found here: <https://www.cdc.gov/vaccines/acip/meetings/index.html>.

The FDA has updated the Johnson & Johnson vaccine fact sheets for providers and for clinicians to include information about TTS. Please find the updated patient fact sheet here: <https://www.fda.gov/media/146305/download>. Please find the updated provider fact sheet here: <https://www.fda.gov/media/146304/download>.

Recommendations for Clinicians

1. Providers may resume the use of the Johnson & Johnson COVID-19 vaccine, effective immediately.
2. Maintain a high index of suspicion for symptoms that may represent serious thrombotic events or thrombocytopenia in patients who have received the Johnson & Johnson COVID-19 vaccine within the previous 3 weeks, including severe headache, backache, new neurologic symptoms, severe abdominal pain, shortness of breath, leg swelling, petechiae, or new or easy bruising. Obtain platelet counts and screen for evidence of immune thrombotic thrombocytopenia.
3. In patients with a thrombotic event and thrombocytopenia after the Johnson & Johnson COVID-19 vaccine, evaluate initially with a screening PF4 enzyme-linked immunosorbent assay (ELISA) as would be performed for autoimmune heparin-induced thrombocytopenia (HIT). Consultation with a hematologist is strongly recommended.
4. Do not treat patients with thrombotic events and thrombocytopenia following receipt of Johnson & Johnson COVID-19 vaccine with heparin, unless HIT testing is negative.
5. If HIT testing is positive or unable to be performed in a patient with thrombotic events and thrombocytopenia following receipt of Johnson & Johnson COVID-19 vaccine, non-heparin anticoagulants and high-dose intravenous immune globulin should be strongly considered.
6. Report adverse events to VAERS, including serious and life-threatening adverse events and deaths in patients following receipt of COVID-19 vaccines as required under the Emergency Use Authorizations for COVID-19 vaccines.

The American Society of Hematology has also released clinical guidance for the diagnosis and treatment of thrombosis with thrombocytopenia following administration of the Johnson & Johnson vaccine. The American Society of Hematology guidelines can be found here: <https://www.hematology.org/covid-19/vaccine-induced-immune-thrombotic-thrombocytopenia>

Recommendations for the Public

WDH asks providers to share the following information with their patients:

1. If you have received the Johnson & Johnson COVID-19 vaccine and develop severe abdominal pain, leg pain, or shortness of breath within three weeks of vaccination, contact your healthcare provider or seek medical care.

2. Report adverse events following receipt of any COVID-19 vaccine to VAERS

REVOCATION OF EMERGENCY USE AUTHORIZATION FOR BAMLANIVIMAB ALONE

On April 16, 2021, the U.S. Food and Drug Administration (FDA) revoked the emergency use authorization (EUA) of bamlanivimab **alone** for the treatment of mild to moderate COVID-19 in patients at high risk for severe disease. Because of the sustained increase of SARS-CoV-2 variants that are resistant to bamlanivimab alone, resulting in the increased risk for treatment failure, the FDA has determined that the known and potential benefits of bamlanivimab, when administered alone, no longer outweigh the known and potential risks for its authorized use. This revocation is not due to any safety concerns.

Bamlanivimab can still be used in combination with etesevimab for the treatment of mild to moderate COVID-19 in patients at high risk for severe disease (<https://www.fda.gov/media/145802/download>). Etesevimab can be ordered alone to pair with any existing bamlanivimab stores. The combination of casirivimab and imdevimab (Regen-Cov, formerly known as Regeneron) can also be used (<https://www.fda.gov/media/143892/download>).

The Wyoming Department of Health (WDH) no longer receives allocations of COVID-19 monoclonal antibody therapies for distribution. Providers and facilities can order COVID-19 monoclonal antibody therapies directly from the distributor, AmerisourceBergen. Information about the direct order process can be found here: <https://www.phe.gov/emergency/events/COVID19/investigation-MCM/Pages/direct-order-process-covid19-mAb.aspx>.

The order form can be found here: <https://app.smartsheet.com/b/form/255d164d67834793b4ab549e160941e8>

CONTACT INFORMATION

Wyoming healthcare providers and facilities are reminded to check COVID-19 resources available from WDH and CDC. Healthcare providers or facilities can contact WDH through the following channels:

- Please email questions about preparedness, PPE, infection control, or other non-urgent topics to wdh.covid19@wyo.gov. This email address is monitored 7 days a week and replies will come within 24 hours.
- Please contact WPHL with questions about specimen collection, storage, or shipping at 307-777-7431 or WPHL@wyo.gov.
- **Please use the WDH Public Health Emergency Line (1-888-996-9104) for urgent questions. This line is intended ONLY for healthcare providers. Do not share this number with the public.**

For specific questions about the Johnson & Johnson vaccine or COVID-19 monoclonal antibodies, healthcare providers may contact Dr. Alexia Harrist at 307-777-7716.

Please refer questions from the general public to 211 or to the WDH email box (wdh.covid19@wyo.gov).