

**Email from Tribal Self-Governance Communication & Education Tribal Consortium
April 16, 2021**

Subject: Indian Health Service Update: Johnson & Johnson/Janssen Vaccine Update

We wanted to notify you that at the recommendation of the Food and Drug Administration and the Centers for Disease Control and Prevention the Indian Health Service (IHS) **has lifted its pause** of Johnson & Johnson/Janssen COVID-19 vaccine administration. The pause was lifted this evening, April 23. Indian Health Service facilities will resume administering the Johnson & Johnson/Janssen COVID-19 vaccine.

IHS originally paused administration of the Johnson & Johnson/Janssen COVID-19 vaccine to allow the FDA and CDC to review data involving six reported U.S. cases of a rare and severe type of blood clot in individuals receiving the vaccine. IHS has vaccine safety monitoring systems in place. To date, there have been no cases reported through IHS of the rare and severe type of blood clot seen in some individuals who have received the Johnson & Johnson/Janssen COVID-19 vaccine.

The pause did not have a significant impact on the IHS vaccination plan: Johnson & Johnson/Janssen COVID-19 vaccine makes up approximately 1.6% percent of our recorded shots in arms to date and less than 5% across the entire U.S. IHS does not believe the brief pause affected its goal of fully vaccinating 44 percent of its active adult patients by the end of April.

The FDA and CDC have determined the following:

- Use of the Janssen COVID-19 Vaccine should be resumed in the United States.
- The FDA and CDC have confidence that this vaccine is safe and effective in preventing COVID-19.
- The FDA has determined that the available data show that the vaccine's known and potential benefits outweigh its known and potential risks in individuals 18 years of age and older.
- At this time, the available data suggest that the chance of TTS occurring is very low, but the FDA and CDC will remain vigilant in continuing to investigate this risk.
- Health care providers administering the vaccine and vaccine recipients or caregivers should review the [Janssen COVID-19 Vaccine Fact Sheet for Healthcare Providers Administering Vaccine \(Vaccination Providers\)](#) and [Fact Sheet for Recipients and Caregivers](#), which have been revised to include information about the risk of this syndrome, which has occurred in a very small number of people who have received the Janssen COVID-19 Vaccine.

Additional Resources:

- [Fact Sheet for Healthcare Providers Administering Vaccine](#)
- [Fact Sheet for Recipients and Caregivers](#)
- [CDC Health Alert for Health Care Providers](#)
- [Johnson & Johnson Granting EUA Amendment \(April 23, 2021\)](#)