

Janssen Scientific Affairs, LLC

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April 09, 2021

Kristina Gregory
3025 Chemical Road
Plymouth Meeting, PA 19462
USA

Dear Ms. Gregory,

Please consider the following information.

Response(s):

- Janssen COVID-19 Vaccine - NCCN Cancer and COVID-19 Vaccination - April 2021

I look forward to working with you as you consider the enclosed information. The information provided is not intended as an endorsement of any usage not contained in the Prescribing Information. For complete information, please refer to the full Prescribing Information, including the following sections: INDICATIONS AND USAGE, DOSAGE AND ADMINISTRATION, CONTRAINDICATIONS, WARNINGS AND PRECAUTIONS, and ADVERSE REACTIONS.

If you require further information, please feel free to contact me via the Janssen Medical Information Center at 1-800-JANSSEN (1-800-526-7736).

Sincerely,

A handwritten signature in black ink, which appears to read "Neeti Trivedi". The signature is written in a cursive, flowing style.

Neeti Trivedi, PharmD





ASSOCIATE DIRECTOR
PAYER AND HEALTH SYSTEMS

Inquiry #:02096867

Enclosure(s)/Electronic Link(s):

- Janssen COVID-19 Vaccine - EUA Fact Sheet for HCPs including the Full EUA Prescribing Information
- Janssen COVID-19 Vaccine - Emergency Use Authorization (EUA) Letter
- Janssen COVID-19 Vaccine - EUA Fact Sheet for Recipients and Caregivers

Need Help? If you have any additional questions, please contact us via:

 1-800-JANSSEN Monday - Friday, 9 am - 8 pm EST	 24x7 Access to Medical Information www.janssenmd.com
 Email Medical Information	 Locate Medical Science Liaison www.janssenmsl.com

To report a possible adverse event or product quality complaint, please call the Medical Information Center immediately, at 1-800-JANSSEN (1-800-526-7736).

**Janssen COVID-19 Vaccine
Compendia Communication – Recommendations of the NCCN® COVID-19
Vaccination Advisory Committee – April 2021**

SUMMARY

- The Janssen COVID-19 Vaccine has been granted an Emergency Use Authorization (EUA) by the U.S. Food and Drug Administration (FDA). The Janssen COVID-19 Vaccine has not been approved or licensed by FDA, but has been authorized for emergency use by FDA, under an EUA for active immunization to prevent Coronavirus Disease 2019 (COVID-19) in individuals 18 years of age and older. The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of the medical product under Section 564(b)(1) of the Federal Food, Drug, and Cosmetic Act unless the declaration is terminated or authorization revoked sooner.^{1, 2}
- Janssen Scientific Affairs, LLC conducted a recent review of the NCCN® Cancer and COVID-19 Vaccination recommendations titled: [Recommendations of the NCCN COVID-19 Vaccination Advisory Committee](#).³
- Please find below suggested changes to the NCCN: Cancer and COVID-19 Vaccination recommendations that correspond to the most current Janssen COVID-19 Vaccine Full Emergency Use Authorization (EUA) Fact Sheets for Healthcare Providers Administering Vaccine (Vaccination Providers) and for Recipients and Caregivers.^{1, 4}
- Please ensure alignment with the current Janssen COVID-19 Vaccine Full Emergency Use Authorization (EUA) Fact Sheets for Healthcare Providers Administering Vaccine (Vaccination Providers) and for Recipients and Caregivers dated March 19, 2021.^{1, 4}

COMMENTS FOR CONSIDERATION

Section	Subsection	Comments	Suggested Change	Documentation
Table 1. COVID-19 Vaccination Recommendations for Cancer Patients	Caregivers and Household/Close Contacts (≥16 years of age)	Janssen COVID-19 vaccine is authorized for use under an Emergency Use Authorization (EUA) for active immunization 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.	Please add a footnote/text to note only the Pfizer-BioNTech COVID-19 Vaccine is indicated for use in individuals 16 years of age and older.	Janssen COVID-19 Vaccine. Emergency Use Authorization (EUA) Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) and Full Prescribing Information. PFIZER-BIONTECH COVID-19 VACCINE (COVID-19 mRNA Vaccine) [Product Monograph]. Pfizer Inc.; https://www.pfizer.ca/pfizer-biontech-covid-19-vaccine-covid-19-mrna-vaccine . ⁵
VACCINE SAFETY AND EFFICACY	"The available single dose SARS-CoV-2 viral vector (Adenovirus 23	The Janssen COVID-19 Vaccine is composed of a recombinant, replication-incompetent human adenovirus type	Please revise "Adenovirus 23 [Adv]" to "adenovirus type	Janssen COVID-19 Vaccine. Emergency Use Authorization (EUA) Fact Sheet for Healthcare

IN CANCER PATIENTS	[Adv] vaccine (Janssen/Johnson & Johnson) is..."	26 vector that, after entering human cells, expresses the SARS-CoV-2 spike (S) antigen without virus propagation. An immune response elicited to the S antigen protects against COVID-19.	26 (Ad26) vector"	Providers Administering Vaccine (Vaccination Providers) and Full Prescribing Information.
VACCINE SAFETY AND EFFICACY IN CANCER PATIENTS:	Post-vaccine lymphadenopathy and Imaging Studies in Cancer Patients: "...this side effect has not been reported to date with the Adv vector vaccine (Janssen/Johnson & Johnson)."	The Janssen COVID-19 Vaccine is composed of a recombinant, replication-incompetent human adenovirus type 26 vector that, after entering human cells, expresses the SARS-CoV-2 spike (S) antigen without virus propagation. An immune response elicited to the S antigen protects against COVID-19. As such, please revise to "Adv vector" to "adenovirus type 26 vector".	Please revise "Adv vector" to "adenovirus type 26 vector".	Janssen COVID-19 Vaccine. Emergency Use Authorization (EUA) Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) and Full Prescribing Information.
VACCINE SAFETY AND EFFICACY IN CANCER PATIENTS	"Anaphylaxis has been reported with both mRNA vaccines, although incidence is very low, ranging from 2.5-4.9 cases per million doses administered."	Severe allergic reactions, including one case of anaphylaxis in an ongoing open-label study in South Africa, have been reported following the Janssen COVID-19 vaccine administered in clinical studies.		Janssen COVID-19 Vaccine. Emergency Use Authorization (EUA) Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) and Full Prescribing Information.

REFERENCES

1. Janssen COVID-19 Vaccine. Emergency Use Authorization (EUA) Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) and Full Prescribing Information. Janssen Biotech, Inc; <https://www.janssenlabels.com/emergency-use-authorization/Janssen+COVID-19+Vaccine-HCP-fact-sheet.pdf>.
2. United States Food and Drug Administration. Janssen COVID-19 Vaccine. FDA Emergency Use Authorization Letter. Available from: <https://www.janssenlabels.com/emergency-use-authorization/Janssen+COVID-19+Vaccine-EUA.pdf>.
3. (NCCN) National Comprehensive Cancer Center. Recommendations of the NCCN COVID-19 Vaccination Advisory Committee. Available at: https://www.nccn.org/covid-19/pdf/COVID-19_Vaccination_Guidance_V2.0.pdf. Accessed March 17, 2021.
4. Janssen COVID-19 Vaccine. Emergency Use Authorization (EUA) Fact Sheet for Recipients and Caregivers. Janssen Biotech, Inc.

<https://www.janssenlabels.com/emergency-use-authorization/Janssen+COVID-19+Vaccine-Recipient-fact-sheet.pdf>.

5. PFIZER-BIONTECH COVID-19 VACCINE (COVID-19 mRNA Vaccine) [Product Monograph]. Pfizer Inc.; <https://www.pfizer.ca/pfizer-biontech-covid-19-vaccine-covid-19-mrna-vaccine>.