National Vaccine Information Center

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August 2, 2023

VIA REGULATIONS.GOV

ACIP Meeting
Centers for Disease Control and Prevention
1600 Clifton Road NE
Mailstop H24–8
Atlanta, Georgia 30329–4027

Re: Docket No. CDC–2023–0063 – NVIC Written Public Comment

Dear ACIP Committee Members,

In response to the above docket and the draft agenda on the committee's website dated July 17, 2023,[1] the committee appears to be holding a vote on Vaccines for Children (VFC) funding for the RSV monoclonal antibody Nirsevimab.

Should this be the case, the National Vaccine Information Center takes this opportunity to point out the following potential conflicts relating to such a vote:

- Nirsevimab is not a vaccine, and was approved by the FDA as a drug;[2][3]
- The FDA's Antimicrobial Drugs Advisory Committee (AMDAC) evaluates the data on drug products for use in the treatment of infectious diseases and disorders. AMDAC was provided with briefing documents on Nirsevimab and voted on recommendations during the committee's June 8, 2023 meeting.[4] [5] [6] The FDA's Vaccines and Related Biological Products Advisory Committee, which evaluates vaccine safety data and makes recommendations on vaccine use to the FDA has made no such recommendation;[7] [8] [9]
- The FDA approved label for Nirsevimab states that it is a monoclonal antibody;[10]
- Similar to other monoclonal antibodies, such as the existing RSV monoclonal antibody Synagis,[11] Nirsevimab is classified by the World Health Organization as an antiviral monoclonal antibody within the Anatomical Therapeutic Chemical (ATC) Classification of antiviral monoclonal antibodies[12] and does not fall into the ATC's vaccine classification.[13]

The above points clearly demonstrate that Nirsevimab is not a vaccine. While the ACIP's charter allows for their review and recommendations of Nirsevimab as an antibody product,[14] Section 1928 of the Social Security Act noted in the ACIP's charter appears to limit VFC funding to pediatric vaccines, as stated below:

"(1) In general.—In order to meet the requirement of section 1902(a)(62), each State shall establish a pediatric vaccine distribution program (which may be administered by the State department of health), consistent with the requirements of this section, under which—

(A) each vaccine-eligible child (as defined in subsection (b)), in receiving an immunization with a qualified pediatric vaccine (as defined in subsection (h)(8)) from a program-registered provider (as defined in subsection (c)) on or after October 1, 1994, is entitled to receive the immunization without charge for the cost of such vaccine;

(e) Use of Pediatric Vaccines List.—The Secretary shall use, for the purpose of the purchase, delivery, and administration of pediatric vaccines under this section, the list established (and periodically reviewed and as appropriate revised) by the Advisory Committee on Immunization Practices (an advisory committee established by the Secretary, acting through the Director of the Centers for Disease Control and Prevention).

(h) Definitions.—For purposes of this section:

(6) The term "pediatric vaccine" means a vaccine included on the list under subsection (e)."[15]

Given the above, NVIC calls on the ACIP to table the VFC vote on Nirsevimab, as it is not a vaccine and does not appear to meet VFC funding requirements under the authorizing statute in committee's charter.

Sincerely,

Theresa Wrangham

Theresa Wrangham,
Executive Director

References

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[1] Advisory Committee on Immunization Practices. Draft Agenda - July 17, 2023. *U.S. Centers for Disease Control and Prevention* Accessed Aug. 2, 2023.
[2] U.S. Food & Drug Administration. FDA NEWS RELEASE - FDA Approves New Drug to Prevent RSV in Babies and Toddlers. July 17, 2023.
[3] U.S. Food & Drug Administration.
[4] AstraZeneca. Nirsevimab BLA 761328 - Briefing Document for June 8, 2023 Antimicrobial Drugs Advisory Committee Meeting. *U.S. Food & Drug Administration* May 17. 2023.
[5] U.S. Food & Drug Administration. Antimicrobial Drugs Advisory Committee (formerly known as the Anti-Infective Drugs Advisory Committee). Accessed: Aug. 2, 2023.
[6] U.S. Food & Drug Administration. Charge to the Committee - Antimicrobial Drugs Advisory Committee. June 8, 2023.
[7] U.S. Food & Drug Administration. 2023 Meeting Materials, Vaccines and Related Biological Products Advisory Committee. Accessed: Aug. 2, 2023.
[8] U.S. Food & Drug Administration. 182 nd Meeting of the Vaccines and Related Biological Products Advisory Committee (VRBPAC) Transcript. June 15, 2023.
[9] U.S. Food & Drug Administration. Food and Drug Administration Center for Biologics Evaluation and Research SUMMARY MINUTES 181st VACCINES AND RELATED BIOLOGICAL PRODUCTS ADVISORY COMMITTEE. May 18, 2023.

[10] Beyfortus. HIGHLIGHTS OF PRESCRIBING INFORMATION. *U.S. Food & Drug Administration.*
[11] MedImmune. Synagis - HIGHLIGHTS OF PRESCRIBING INFORMATION. *U.S. Food & Drug Administration.* Accessed: July 31, 2023.
[12] WHO Collaborating Centre for Drug Statistics Methodology. J06BD Antiviral monoclonal antibodies. Jan. 23, 2023.
[13] WHO Collaborating Centre for Drug Statistics Methodology. J07B VIRAL VACCINES. Jan. 23, 2023.
[14] U.S. Centers for Disease Control and Prevention. CHARTER of the ADVISORY COMMITTEE ON IMMUNIZATION PRACTICES. Mar. 28, 2022.
[15] Social Security. Sec. 1928. [42 U.S.C. 1396s] - PROGRAM FOR DISTRIBUTION OF PEDIATRIC VACCINES. In: Compilation of the Social Security Laws. Accessed: Aug. 2, 2023.