CALIFORNIA DEPARTMENT OF HEALTH CARE SERVICES
Michelle Baass | Director

DATE: October 18, 2023

CCS Information Notice: 23-04

TO: All County California Children's Services Program Administrators

SUBJECT: Use of Nirsevimab and Palivizumab for the Prevention of Respiratory Syncytial Virus (RSV) Disease in Infants and Children During 2023-2024

Background: California Children's Services (CCS) issued guidance for use of palivizumab (trade name Synagis) in Numbered Letter (N.L.) 13-0914, most recently updated in CCS Information Notice (I.N.) 22-04.[1, 2] Providers should refer to these two previous documents along with the present I.N.

Nirsevimab (trade name Beyfortus), is a long-acting monoclonal antibody product to reduce risk of both hospitalizations and healthcare visits for RSV. The U.S. Food and Drug Administration (FDA) approved this agent on July 17, 2023. On August 3, 2023, the Advisory Committee on Immunization Practices (ACIP) of the Centers for Disease Control (CDC) voted unanimously in favor of recommending use of nirsevimab as indicated in its FDA package insert, and to include nirsevimab in the Vaccines for Children (VFC) program. On August 15, 2023, the American Academy of Pediatrics (AAP) released recommendations for the use of nirsevimab for prevention of RSV disease.[3]

Birth hospitals providing care to Medi-Cal, uninsured, American Indian/Alaskan Native, or underinsured newborns may benefit from enrollment in the California Vaccines for Children (VFC) Program. VFC would provide access to the monoclonal antibody nirsevimab as soon as it becomes available for ordering this fall. To obtain more information about VFC or to submit an enrollment application, please visit www.eziz.org or call the VFC Program Customer Service Center at (877) 243-8832.

Guidance for RSV Prevention within the CCS Program: Use of nirsevimab and palivizumab for prevention of RSV disease in infants and children should conform with

[1] https://www.dhcs.ca.gov/services/ccs/Documents/ccsnl130914.pdf
[2] https://www.dhcs.ca.gov/services/ccs/Documents/CCS-Information-Notice-22-04.pdf
[3] Redbook Online. ACIP and AAP Recommendations for Nirsevimab. American Academy of Pediatrics. Accessed August 15, 2023.

existing CCS guidance and ACIP, CDC, and AAP recommendations, largely quoted below.[1-3, 4, 5, 6]

1. If nirsevimab is unavailable or not feasible to administer, infants at high risk for RSV disease (as specified in CCS N.L.13-0914) should receive palivizumab, **as specified in this N.L**., until nirsevimab becomes available.

    a. Additionally, a new group has been identified for whom second-season prophylaxis is recommended, *differing from the existing palivizumab recommendations*: American Indian and Alaska Native children.

    b. If palivizumab was administered initially for the season and <5 doses were administered, the infant should receive 1 dose of nirsevimab. No further palivizumab should be administered.

2. If an infant receives nirsevimab, then palivizumab should not be administered later that season.

3. If palivizumab was administered in season 1 and the child is eligible for RSV prophylaxis in season 2, the child should receive nirsevimab in season 2, if available. If nirsevimab is not available, palivizumab should be administered as recommended in this guidance.

4. Timing of nirsevimab administration:

    a. Providers should aim for nirsevimab administration in the first week of life for infants born shortly before and during the RSV season. Administration can occur during the birth hospitalization or in the outpatient setting.

        i. Infants with prolonged birth hospitalizations because of prematurity or other causes should receive nirsevimab shortly before or promptly after discharge.

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[4] Redbook Online. ACIP and AAP Recommendations for Nirsevimab. American Academy of Pediatrics. Accessed August 15, 2023. https://publications.aap.org/redbook/resources/25379/?utm_source=MagnetMail

[5] Proposed clinical considerations for maternal RSVPreF vaccine and nirsevimab (Centers for Disease Control and Prevention) (2023). https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2023-09-22/07-Mat-Peds-Jones-508.pdf

[6] CDC recommends new vaccine to help protect babies against severe respiratory syncytial virus (RSV) illness after birth. Centers for Disease Control and Prevention; 2023. https://www.cdc.gov/media/releases/2023/p0922-RSV-maternal-vaccine.html

b. Nirsevimab should be administered shortly before the start of the RSV season for infants younger than 8 months.

c. Nirsevimab should be administered shortly before the start of the RSV season for infants and children 8 through 19 months of age who are at increased risk of severe RSV disease as specified in item 1 above.

d. Nirsevimab may be given to age-eligible infants and children who have not yet received a dose at any time during the season.

e. Only children who meet high-risk criteria should receive more than one dose of nirsevimab – one dose in their first RSV season and one dose in their second RSV season. Healthy newborns born at the end of RSV season who received nirsevimab around the time of delivery (first RSV season) should not receive a second dose entering their second season even if they are <8 months of age; conversely, healthy infants born at the end of their first RSV season who did NOT receive nirsevimab and are <8 months of age entering their second RSV season may receive one dose of nirsevimab.

f. On the basis of pre-pandemic RSV infection patterns, nirsevimab may be administered from October through the end of March. Because timing of the onset, peak, and decline of RSV activity may vary, providers can adjust administration schedules on the basis of local RSV activity in the community.

5. Maternal vaccination against RSV

   a. The CDC recommends recently approved maternal RSV vaccine (Pfizer's bivalent RSVpreF vaccine – trade name Abrysvo ^{TM}) for pregnant people during 32 through 36 weeks gestation, using seasonal administration, to prevent RSV lower respiratory tract infection in infants. They also voted to approve Pfizer's bivalent RSVpreF vaccine for the Vaccines for Children Program (applying to pregnant people under 19 years of age).

      i. Most infants whose mother receives Pfizer's RSVpreF vaccine will not need nirsevimab

   b. To maximize protection for babies after birth, CDC recommends seasonal administration of one dose of RSV vaccine for pregnant people during weeks 32 through 36 of pregnancy.

   c. 14 days or more from time of maternal vaccination are likely needed for development and transplacental transfer of maternal antibodies to protect the

infant; therefore, nirsevimab is recommended for infants born within 14 days of vaccination.

d. Thus, the earliest an infant can be born and have maternal vaccine induced protection is at 34 weeks gestation.

e. Infants born at <34 weeks gestation should receive nirsevimab.

f. Protection from maternal vaccination may begin to wane after 3 or more months.

   i. However, because maternal RSV vaccine administration is recommended during September through January, most infants of vaccinated mothers will be born during RSV season (i.e., born during October–March).

g. Mothers of most infants born outside of RSV season (i.e., born during April through September) will not have been vaccinated, and nirsevimab is recommended for these infants.

6. Coadministration with routine childhood vaccines:

   a. In accordance with the CDC's general best practices for immunizations, simultaneous administration of nirsevimab with age-appropriate vaccines is recommended.

If you have any questions regarding this I.N., please contact DHCS ISCD Medical Policy, at ISCD-MedicalPolicy@dhcs.ca.gov.

Sincerely,

ORIGINAL SIGNED BY

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