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July 31, 2023

Mandy K. Cohen, MD, MPH
Director
Centers for Disease Control and Prevention
1600 Clifton Road
Atlanta, GA 30329

Chiquita Brooks-LaSure
Administrator
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Dear Dr. Cohen and Ms. Brooks-LaSure:

On behalf of the American Academy of Pediatrics (AAP), a non-profit professional organization of more than 67,000 primary care pediatricians, pediatric medical subspecialists, and pediatric surgical specialists dedicated to the health, safety, and well-being of all infants, children, adolescents, and young adults, I write to ask for your urgent help with the implementation of nirsevimab-alip (Beyfortus) for the prevention of respiratory syncytial virus (RSV). While this product has the potential to significantly reduce severe RSV cases and hospitalizations in young children, its promise will not be realized without effective and equitable administration. Our members will face severe financial pressures and challenging administrative burdens associated with delivering this expensive product, and as such we need the federal government to take urgent and decisive action to ensure the success of this roll out and to protect the long-term success and viability of the Vaccines for Children (VFC) program.

We understand that the Advisory Committee on Immunization Practices (ACIP) will meet on August 3 to consider recommendations for the use of nirsevimab-alip. In the event that ACIP recommends universal use of nirsevimab-alip consistent with the FDA approval, it is vital that the administration provide the necessary infrastructure supports to ensure equitable distribution and access. This infrastructure does not currently exist, and pediatricians and other providers face the prospect of moral injury resulting from having an available product without the ability to administer it given financial and administrative barriers and burdens. Families living in lower-income and under-resourced communities, as well as those with infants at greatest risk for severe RSV illness, may face challenges accessing nirsevimab-alip in the absence of additional infrastructure support. Consequently, we encourage the CDC and CMS to adopt the following recommendations to better support pediatricians and other providers in protecting infants from severe RSV illness this fall/winter:

- 1. Develop a comprehensive strategy to ensure equitable access to nirsevimab-alip in hospitals, birthing centers, and ambulatory practice settings.**
- 2. Assuming that ACIP votes to recommend that nirsevimab-alip be included in VFC, enhance VFC payment policies and minimize VFC administrative burden to encourage VFC participation.**
- 3. Support the continued use of palivizumab as an option for the prevention of RSV disease in high-risk infants for the upcoming season given the likely implementation challenges with nirsevimab-alip.**

Develop a comprehensive strategy to ensure equitable access to nirsevimab-alip in hospitals, birthing centers, and ambulatory practice settings

Equitable access to nirsevimab-alip will require strategic support across the health system to ensure that infants are able to access the product in a variety of settings from hospitals to birthing centers to ambulatory practices. Each of these settings have unique challenges to implementation of nirsevimab-alip administration. Hospital barriers may include the newborn bundle payment, which does not account for the cost of nirsevimab-alip; the effort to ensure nirsevimab-alip is included in hospital formularies; and the fact that very few hospitals participate in Vaccines for Children (VFC) (assuming that ACIP votes to recommend that nirsevimab-alip be included in VFC).

Ambulatory setting barriers include implementation of this new product at the same time as COVID vaccine commercialization, financial and administrative burdens for an expensive new product, anticipated delayed appropriate payment for both product payment and administration by payers, delays related to the need for unique administration codes, and potential confusion about how to communicate with families about the new product. Historically under-resourced hospitals and ambulatory settings will be most impacted by these challenges, and particular attention needs to be given to further support infrastructure in these areas, particularly in Indian Health Service facilities and in rural settings.

A comprehensive strategy should include:

- **Increasing bundled payment for normal newborn and specialty hospital care to account for the cost of nirsevimab-alip:** Ideally, all babies born during the RSV season would receive nirsevimab-alip prior to discharge from their birthing hospital. Increasing the payment for the newborn bundle to account for the cost of nirsevimab-alip would help to support administration to commercially insured patients by hospitals, as well as inclusion in hospital formularies.
- **Proactively support birthing institutions to be able to participate in the VFC program** (assuming that ACIP votes to recommend that nirsevimab-alip be included in VFC): Increasing the number of birthing institutions that provide nirsevimab-alip will help to increase equitable access. Hospitals may have unique circumstances to participate in VFC, and we urge innovation with the goal to create equitable access.
- **Supporting expedited consideration of a new immune globulin administration code for nirsevimab-alip:** Of particular importance to clinicians in ambulatory settings is the creation of an appropriate administration code for providing nirsevimab-alip to their patients. Because nirsevimab-alip is a monoclonal antibody, it is categorized as an immune globulin for administrative coding purposes. A new CPT code for nirsevimab-alip was approved during the May 2023 AMA CPT Coding meeting; however, an appropriate administration code does not exist. The work to administer nirsevimab-alip is anticipated to be greater than that for routine immunization administration or that of usual immune globulin administration. The AAP proposes a new administration code be approved to better reflect and to support the actual work involved. We urge the CDC and CMS to support this effort so that clinicians are able to be paid fairly as quickly as possible.
- **Encourage private insurance companies to expedite the addition of the new nirsevimab-alip product code and administration code (once available) in their payment systems:** Past experience suggests that payers can take up to 6-12 months to update their payment systems with the

implementation of new immunization products. Prompt updates to payer systems would reduce financial and administrative burdens on those administering nirsevimab-alip.

Assuming that ACIP votes to recommend that nirsevimab-alip be included in VFC, enhance VFC payment policies and minimize VFC administration burden to encourage VFC participation

In addition to increasing the opportunities for nirsevimab-alip to be administered in hospitals, birthing centers and ambulatory settings, the AAP also encourages CDC and CMS to ensure that the VFC program can properly pay for administration of nirsevimab-alip and that participating VFC providers have the flexibility needed to continue to participate in the program. To ensure robust provider participation in VFC, we encourage CDC and CMS to take the following steps:

- **Allow “stand-alone” immunization counseling payment—for both passive and active immunizations—in VFC:** We urge the federal government to ensure payment for “stand-alone” immunization counseling for both nirsevimab-alip and routine immunizations in the VFC program for all VFC eligible children, including those not enrolled in Medicaid. With declining immunization rates and an epidemic of vaccine misinformation and disinformation, pediatricians are trusted messengers and well-positioned to have conversations about immunizations with families – conversations that may be even more complicated with nirsevimab-alip. The AAP continues to applaud the December 2021 CMS announcement that the Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) benefit is interpreted to include Medicaid coverage of “stand-alone” immunization counseling for Medicaid-eligible individuals for COVID-19 vaccine and all routine childhood immunizations to age 21. We expect that this EPSDT coverage of stand-alone immunization counseling will be extended to nirsevimab-alip, should it be adopted for recommendation by the ACIP. However, this will not address such “stand-alone” counseling for children eligible for VFC, but not enrolled in Medicaid. We encourage review of all funding opportunities to ensure appropriate and equitable access to conversations with trusted pediatricians about the importance of all childhood immunizations, for all VFC eligible children.
- **Raise the VFC maximum regional charges to appropriately account for immunization administration costs and include passive immunization products:** VFC maximum regional charges have long served as a ceiling for what pediatricians can bill for the cost of administering VFC vaccine. Most state Medicaid programs, as the insurers of most children who receive VFC vaccine, pay well below these state-by-state caps, which were most recently revalued in 2012. The AAP strongly believes that instead of a cap on payment, the VFC program should establish a minimum floor for which Medicaid must pay for vaccine administration, to better capture the actual practice costs of immunizing children and counseling families. The AAP recognizes that creation of a minimum floor would likely require a statutory change. In the interim, we call on CMS and CDC to update the 2012 VFC maximum regional charges to reflect the current costs of administering immunizations to children. Further, we call for the maximum regional charge structure to properly accommodate new product types like nirsevimab-alip.
- **Assist pediatric practices with the financial impact of purchasing nirsevimab-alip for privately insured children by allowing flexible borrowing and storage policies:** The Academy encourages the CDC to allow bidirectional borrowing between public and private stock for nirsevimab-alip in all states and to clearly communicate this policy to all jurisdictions. With the uncertainty of demand for nirsevimab-alip, large upfront costs of purchasing commercial stock, and probable delays in VFC delivery, participating VFC providers should be able to borrow from one stock to another to efficiently

respond to ebb and flow in demand. We urge the CDC to allow practices to order excess VFC stock during a six-month ramp up period, which is anticipated to correspond with the traditional October through March RSV season, so that practices may borrow VFC stock for private-pay patients, with borrowed nirsevimab-alip to be returned by the end of this period. We would also urge CDC to permit VFC providers to swap from either public or private stock when good faith efforts are made to determine a child's insurance status, but an inadvertent error was made in classification. This flexibility will also allow time for insurer payment systems to be updated so there is less financial risk to practices.

In addition, the AAP urges CDC to clarify that public and private nirsevimab-alip stock may be stored in the same refrigerator as long as they are clearly labeled and not mixed together, particularly during the RSV season. With the addition of nirsevimab-alip and COVID-19 immunizations, it is essential that there are flexible storage requirements to assist pediatricians and other providers in accommodating these additional products in their already crowded refrigerators. It is our hope that CDC will encourage its state and local grantee programs to exercise flexibility with respect to compliance and program integrity during this period of transition, and that state and local programs engage with participating clinics in a collaborative manner.

Support the continued use of palivizumab as an option for prevention of RSV disease in high risk infants for the upcoming season given the likely implementation challenges with nirsevimab-alip

Due to anticipated implementation challenges and the limited time to fully address these challenges prior to the 2023-2024 RSV season, the AAP believes it is important for palivizumab to remain available as an option to protect infants who are at highest risk for severe RSV illness.

FDA's approval of nirsevimab-alip indicates that the product has the potential to reduce the number of neonates and infants who are hospitalized for medically attended RSV lower respiratory tract illness. Pediatricians need the federal government to take urgent and decisive action to ensure the success of this roll out and to protect the long-term success and viability of the Vaccines for Children (VFC) program. We respectfully request a meeting with CDC and CMS leadership to discuss these recommendations to ensure successful, equitable access to nirsevimab-alip. As always, the AAP stands ready to partner with the CDC and CMS to further the uptake of immunizations through the VFC and keep children and their families safe.

Sincerely,

A handwritten signature in black ink, appearing to read 'S. Chung', written in a cursive style.

Sandy L. Chung, MD, FAAP
President