

# AREXVY



## (RESPIRATORY SYNCYTIAL VIRUS VACCINE RECOMBINANT, ADJUVANTED)

Arexvy (GSK)

- RSV vaccine for adults 60+ years
- Medicare part D
- 1 dose: 0.5 mL IM
- Requires reconstitution
- Storage: fridge



## Abrysvo

- Adults 60 years and older
- Medicare Part D
- 1 dose: 0.5 mL IM
- Requires reconstitution
- Storage: fridge
- Tentative schedule for maternal indication
  - Pfizer RSV vaccine for use in pregnancy  $\geq 24$  weeks and  $\leq 36$  weeks
  - ACIP discussed policy question in February 2023
  - Plan for ACIP approval October 2023

# ACIP Meeting Votes

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PCV 20 in peds

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RSV vaccine for adults 60+ years

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Polio for adults

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Flu

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RSV monoclonal (*tentative*)



# Nirsevimab by Sanofi

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- Monoclonal antibody engineered to provide **passive** immunity.
  - Active immunity results from infection or vaccination, which triggers an immune response
  - Passive immunity is when a person receives antibodies from an external
  - source
    - From mother to baby through transplacental or breastmilk transfer
    - Direct administration of antibodies, such as IVIG or monoclonal antibodies





## Timing and location of nirsevimab administration

- For infants born during Oct–Mar, shortly after birth or as soon as possible
  - Administration in hospital prior to discharge would be optimal to ensure early protection
  - If not given prior to discharge, administration at first visit to primary care provider, ideally within 1 week of discharge
- For infants born Apr–Sep
  - Nirsevimab administration recommended during Oct–Nov (e.g., during regularly scheduled 2-, 4-, or 6-month well child visits)

## Administration and storage

- Administered as intramuscular injection using pre-filled, single-use syringe available in the following doses for infants born during or entering 1st RSV season:
  - 50mg (0.5mL) for infants weighing <5 kg or
  - 100mg (1.0 mL) for infants ≥5 kg
- For high-risk infants and children entering 2<sup>nd</sup> RSV season, dosing is 200mg (two 100 mg doses administered at the same time)
- One dose of nirsevimab per season
- Storage at refrigerator temperatures (2°C - 8°C)
- May be kept at room temperature (20°C - 25°C) when protected from light for a maximum of 8 hours

## Equity and payment

- Nirsevimab inclusion in Vaccines For Children (VFC) program undetermined
- If not included in VFC, state Medicaid, Medicaid expansion (Children's Health Insurance Programs), and private insurance would likely cover nirsevimab
  - Underinsured and uninsured would likely have reduced access

# ACIP Workgroup Summary (February 2023)

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## 1st RSV season

- The WG recommends nirsevimab a) at birth for all infants born during October to March and b) when entering first RSV season and <8 months of age for all infants born during April through September?
- Many expressed concerns about feasibility and equity, particularly because inclusion in VFC is unknown
- Some WG expressed concern that at higher prices, nirsevimab may not be a reasonable and efficient allocation of resources



# ACIP Workgroup Summary (February 2023)

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## 2nd RSV season

- WG would like more time to consider which infants and children would be sufficiently high risk to warrant nirsevimab in their 2<sup>nd</sup> RSV season
  - Limited efficacy and safety data
  - Limited data to measure the risk of severe disease in the 2<sup>nd</sup> RSV season
  - At this time, WG recommended nirsevimab for those who are eligible for palivizumab in their 2<sup>nd</sup> RSV season, since assumed to be cost effective
  - WG will continue to evaluate other conditions