



دائرة الصحة
DEPARTMENT OF HEALTH

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To: Healthcare Facilities
The Health Insurance Companies and Third-Party Administrators

إلى: منشآت الرعاية الصحية
شركات الضمان الصحي وشركات إدارة المطالبات

Subject: Introduction of Long-Acting Monoclonal Antibodies (mAbs) for Respiratory Syncytial Virus (RSV) at birth in the Immunization Program

الموضوع: إدراج الأجسام المضادة أحادية النسيلة طويلة المفعول للفيروس التنفسي المخلوي ضمن برنامج التحصين للأطفال عند الولادة

Greetings,

تحية طيبة وبعد ،،،

We extend our greetings and best wishes for your continued success.

بدايةً، يسرنا أن نتقدم لكم بخالص التحية والتقدير متمنين لكم دوام التوفيق والسداد.

In line with the latest scientific evidence-based practices and recommendations from the Higher National Immunization Committee and the National Immunization Technical Advisory Group, Abu Dhabi Public Health Centre (ADPHC) is updating the immunization program. Accordingly, kindly be informed of the following updates:

استناداً إلى الممارسات القائمة على الأدلة العلمية والتوصيات المقدمة من اللجنة الوطنية العليا للتحصين والمجموعة الوطنية الفنية الاستشارية للتحصين، يقوم مركز أبوظبي للصحة العامة بتحديث برنامج التحصين. وعليه، نود إحاطة الجميع بالتحديثات التالية:

First: Inclusion of (RSV) Long-Acting Monoclonal Antibodies (mAbs) in the Childhood Immunization Program, to be administered at birth during the RSV season; from 1st September to 1st March; starting from the 2025-2026 season onward, as follows:

أولاً: إدراج الأجسام المضادة أحادية النسيلة طويلة المفعول للفيروس التنفسي المخلوي (RSV mAbs) ضمن برنامج التحصين للأطفال، وتُعطى عند الولادة خلال موسم الفيروس التنفسي المخلوي، في الفترة ما بين 1 سبتمبر إلى 1 مارس من كل عام، وذلك اعتباراً من موسم 2025 - 2026، وفقاً لما يلي:

- A single dose of RSV Long-Acting Monoclonal Antibody shall be administered to all newborns born during the RSV season, concurrently with the Hepatitis B and BCG vaccines.

- إعطاء جرعة واحدة من الجسم المضاد أحادي النسيلة طويل المفعول للفيروس التنفسي المخلوي لجميع الأطفال حديثي الولادة (المولودين خلال الموسم) بالتزامن مع لقاحي التهاب الكبد (ب) والدرن.

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- Administration of RSV Long-Acting Monoclonal Antibody at birth is indicated in any of the following cases:

- If the mother did not receive the RSV vaccine during pregnancy.
- If the infant was born within 14 days of maternal RSV vaccination.
- If the maternal RSV vaccination status during pregnancy is unknown.

- High-Risk Children:

- A single dose of Nirsevimab shall be administered to children at increased risk of severe RSV disease, aged 8 to 19 months, entering their second RSV season.

- The administration of Clesrovimab shall be restricted to newborn infants only, provided that the child's age does not exceed 8 months.

- **Second:** Compliance with the approved technical and regulatory guidelines is mandatory, including adherence to the target age group, recommended doses, approved concentrations, and method of administration, in accordance with what is approved for Nirsevimab and Clesrovimab, as detailed in Appendix (1) and Appendix (2).

- يُعطى الجسم المضاد أحادي النسيلة طويل المفعول للفيروس التنفسي المخلوي عند الولادة في أي من الحالات التالية:

- إذا لم تكن الأم قد تلقت لقاح الفيروس التنفسي المخلوي خلال فترة الحمل.
- في حال تمت ولادة الطفل خلال 14 يوم من تلقي الأم لقاح الفيروس التنفسي المخلوي خلال فترة الحمل.
- في حال كانت الحالة التطعيمية للأم بلقاح الفيروس التنفسي المخلوي خلال فترة الحمل غير معروفة.

- الأطفال الأكثر عرضة لخطر الإصابة:
 - إعطاء جرعة واحدة من الجسم المضاد أحادي النسيلة طويل المفعول للفيروس التنفسي المخلوي (Nirsevimab) للأطفال المعرضين لخطر متزايد للإصابة بمرض الفيروس المخلوي التنفسي الحاد، والذين تتراوح أعمارهم ما بين 8 أشهر و19 شهراً، عند دخولهم موسم الفيروس المخلوي التنفسي الثاني.

- يُقتصر إعطاء الجسم المضاد أحادي النسيلة طويل المفعول للفيروس التنفسي المخلوي (Clesrovimab) على الأطفال حديثي الولادة، وبعمر لا يتجاوز 8 أشهر.

- ثانياً: يجب التقيد بالإرشادات الفنية والتنظيمية المعتمدة، والالتزام بالفئة العمرية المستهدفة، والجرعات الموصى بها، والتركيزات المعتمدة، وآلية الإعطاء، وفقاً لما هو معتمد لكل من Nirsevimab و Clesrovimab كما هو مبين بالمرفق (1) والمرفق (2).





- **Third:** The costs of administration at birth shall be covered for children in healthcare facilities where long-acting monoclonal antibodies are provided free of charge. For other categories and healthcare facilities that procure any of the approved RSV long-acting monoclonal antibodies, the costs shall be covered in accordance with the health insurance program for beneficiaries.
- **Fourth:** Healthcare providers shall continue to administer and use the monoclonal antibody (Palivizumab) for the targeted groups of children at higher risk of severe RSV disease, in accordance with the DOH standards and guidelines for those groups, until the existing stock is depleted.
- **Fifth:** Review and update of children's vaccination status based on the child's age and the immunization schedule in the Emirate of Abu Dhabi, including follow-up of children who are delayed in receiving the required vaccines.
- **Sixth:** Document all vaccinations given through online e-notification system: Immunization Information System (IIS) available under the following link:
<https://bpmweb.doh.gov.ae/UserManagement/Login.aspx>
- **Seventh:** Submitting incidents of suspected vaccine adverse events through the e-notification system: Adverse Event Following Immunization (AEFI) via the following link:
<https://bpmweb.doh.gov.ae/UserManagement/Login.aspx>

• ثالثاً: سيتم تغطية تكاليف إعطاء الأطفال عند الولادة في المنشآت الصحية التي يتم فيها توفير الأجسام المضادة أحادية النسيلة طويلة المفعول بشكل مجاني. أما الفئات الأخرى والمنشآت الصحية التي تقوم بشراء أي من الأنواع المعتمدة من الأجسام المضادة أحادية النسيلة طويلة المفعول، فسيتم تغطية التكاليف وفقاً لبرنامج التأمين الصحي المعتمد للمستفيدين.

• رابعاً: على مقدمي الرعاية الصحية الاستمرار في إعطاء واستخدام الجسم المضاد أحادي النسيلة (Palivizumab) للفئات المستهدفة من الأطفال الأكثر عرضة لخطر الإصابة بمرض الفيروس المخلوي التنفسي الحاد، وذلك وفقاً للمعايير والإرشادات الصادرة من دائرة الصحة - أبوظبي لهذه الفئات، إلى حين استنفاد المخزون الحالي.

• خامساً: مراجعة وتحديث تطعيمات الأطفال بناءً على عمر الطفل وجدول التحصين في إمارة أبوظبي، مع متابعة الأطفال المتأخرين عن التطعيمات.

• سادساً: تسجيل جميع التطعيمات التي تم إعطاؤها عبر النظام الإلكتروني الخاص بالتطعيمات المتوفر على الرابط التالي:

<https://bpmweb.doh.gov.ae/UserManagement/Login.aspx>

• سابعاً: التبليغ في حال الاشتباه بحالات لآثار جانبية للتطعيم عبر النظام الإلكتروني الخاص بالآثار الجانبية الناتجة عن التطعيم (AEFI) على الرابط التالي:

<https://bpmweb.doh.gov.ae/UserManagement/Login.aspx>





دائرة الصحة
DEPARTMENT OF HEALTH

For further information and inquiries in this regard, kindly contact the vaccination section via email: vaccine@adphc.gov.ae

للمزيد من المعلومات والاستفسارات بهذا الشأن، يرجى التواصل مع قسم التطعيمات عبر البريد الإلكتروني: vaccine@adphc.gov.ae

This circular is effective from its date of issuance.

يدخل هذا التعميم حيز التنفيذ اعتباراً من تاريخ صدوره.

We hope that all will adhere to the above, for the best interest of the health sector in the Emirate.

أملين من الجميع الالتزام بما ورد أعلاه، لما فيه مصلحة القطاع الصحي في الإمارة.

Thank you for your cooperation,

شاكرين لكم حسن تعاونكم معنا،

This circular is designed for regulatory procedures and should not be used as content for media publication.

هذا التعميم للإجراءات التنظيمية وغير مخصص كمحتوى للنشر الإعلامي.

Appendices:

المرفقات:

Appendix (1): RSV Long-Acting Monoclonal Antibodies Information

المرفق (1): معلومات عن الأجسام المضادة أحادية النسيلة طويلة المفعول للفيروس التنفسي المخلوي.

Appendix (2): RSV Long-Acting Monoclonal Antibodies Guidelines for Healthcare Professionals.

المرفق (2): إرشادات الأجسام المضادة أحادية النسيلة طويلة المفعول للفيروس التنفسي المخلوي للمهنيين الصحيين

د. نورة خميس الغيثي
وكيل دائرة الصحة



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Appendix 1

المرفق 1

RSV Long-Acting Monoclonal Antibodies Information

Nirsevimab-alip	Clesrovimab-cfor
Brand Name	Brand Name
BEYFORTUS™	ENFLONSIA™
Description and Indication	Description and Indication
A respiratory syncytial virus (RSV) F protein-directed fusion inhibitor indicated for the prevention of RSV lower respiratory tract disease - Neonates and infants are born during or entering their first RSV season. - Children aged 8 to 19 months remain at increased risk of severe disease and are entering their second RSV season, (see table) *	A respiratory syncytial virus (RSV) F protein-directed fusion inhibitor indicated for the prevention of RSV lower respiratory tract disease. - Neonates and infants are born during or entering their first RSV season.
Note: DOH / ADPHC introduces RSV Long-Acting Antibodies at birth for newborns born from 1st September to 1st March.	
Dosage Form and Strength	Dosage Form and Strength
- 50 mg/0.5 mL in a single-dose pre-filled syringe. - 100 mg/mL in a single-dose pre-filled syringe	- 105 mg/0.7 mL in a single-dose prefilled syringe.
Dosage and Administration	Dosage and Administration
Neonates and Infants Born During or Entering Their First RSV Season - 50 mg if less than 5 kg in body weight as a single intramuscular (IM) injection. - 100 mg if greater than or equal to 5 kg in body weight as a single intramuscular (IM) injection. Children aged 8 to 19 months who remain vulnerable through their second RSV season - A single 200 mg dose administered as two IM injections (2 x 100 mg). NOTE: IM preferably in the anterolateral aspect of the thigh.	- 105 mg administered as a single intramuscular (IM) injection. NOTE: IM preferably in the anterolateral aspect of the thigh.

Adverse Events	Adverse Events
Most common adverse reactions: Injection site reactions and rash.	Most common adverse reactions: Injection-site erythema, injection-site swelling and rash.
Contraindication and Precaution	
- Contraindicated in infants and children with a history of serious hypersensitivity reactions, including anaphylaxis, to the active substance or to any of the excipients. - Serious adverse events are rare; however, despite their rarity, preparedness for the possibility of anaphylaxis is essential. - Severe hypersensitivity reactions, including anaphylaxis, may occur, similar to reactions reported with other human IgG1 monoclonal antibodies. - It is recommended that all infants and children be observed for at least 15 minutes following administration of RSV monoclonal antibodies to detect any changes or sensitivity reaction that may occur.	
Children at Increased Risk of Severe Disease and are Entering their Second RSV Season *	
Infants and children aged 8 to 19 months, who are at increased risk for severe RSV disease and are entering their second RSV season. High-risk criteria include the following: - Chronic lung disease of prematurity requires medical support (chronic corticosteroid therapy, diuretic therapy, or supplemental oxygen). - Children with cystic fibrosis have either: - Manifestations of severe lung disease (previous hospitalization for pulmonary exacerbation in the first year of life or abnormalities on chest imaging that persist when stable, or - Weight-for-length <10th percentile - Sever immunocompromised children - Other high-risk conditions, based on treating physician evaluation.	



RSV Long-Acting Monoclonal Antibodies

Guidelines for Healthcare Professionals

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A. Introduction

This document aims to provide guidance for Healthcare Professionals (HCPs) involved in the administration of long-acting monoclonal antibodies (mAbs), specifically Nirsevimab and Clesrovimab, for the prevention of respiratory syncytial virus (RSV) infection in infants. It presents practical recommendations related to eligibility criteria, administration procedures, and safety monitoring requirements.

The introduction of monoclonal antibody-based prevention is aligned with the issued ministerial decree and supports ADPHC efforts to reduce RSV-related morbidity, mortality, and the overall burden on the healthcare system.

B. Respiratory Syncytial Virus infection (RSV) in infants and associated complications

Respiratory syncytial virus (RSV) is a leading cause of acute lower respiratory tract infection in infants and young children worldwide, with the highest incidence and severity in those under 2 years of age.

RSV accounts for >3.6 million hospitalizations and an estimated 26,000–100,000 deaths annually among children under 5 years of age worldwide. Approximately half of RSV-related deaths among children occur in infants under the age of 6 months.

Most infants experience mild upper respiratory symptoms; however, a significant proportion develop bronchiolitis or pneumonia, often requiring emergency visits and hospital admission, especially among preterm infants and those with underlying cardiac, pulmonary, neuromuscular, or immunocompromising conditions.

Severe RSV disease in infants can lead to respiratory distress, apnoea (particularly in young or preterm infants), hypoxaemia, dehydration, and, in rare cases, respiratory failure requiring intensive care support. Early identification of at-risk infants and timely implementation of preventive strategies, including long-acting monoclonal antibodies, are therefore critical to reduce morbidity and protect this vulnerable population.

C. About The RSV Long-Acting Monoclonal Antibodies

Infant RSV long-acting monoclonal antibodies products are injectable preparations that provide passive protection against severe RSV disease in infants and some young children. Unlike infection or vaccination, they do not stimulate the child's own immune response (no active immunization); instead, the administered antibodies directly neutralize the virus.

Because they do not activate the immune system, their protection is most effective in the weeks following administration and gradually decreases over time, offering coverage for about 5 months—when infants are at highest risk of severe RSV—after which older children are less likely to develop severe disease.

D. Respiratory Syncytial Virus (RSV) Immunization for Infants

1. Long-acting Monoclonal Antibodies (mAbs)

There are two approved and registered long-acting monoclonal antibodies that are available for RSV prevention in infants:

- Nirsevimab (Beyfortus®) – single intramuscular (IM) dose:
 - 50 mg IM once for infants weighing <5 kg
 - 100 mg IM once for infants weighing ≥5 kg
- Clesrovimab (ENFLONSIA™) – single IM dose of
 - 105 mg once for all infants, regardless of weight.

RSV monoclonal antibodies are used as a single dose for infants born during 1st September to 1st March.

No preference is given for one monoclonal antibody over the other; both are administered as a single dose in line with Department of Health (DOH) and Abu Dhabi Public Health Centre (ADPHC) recommendations for eligible infants. The details of each monoclonal antibody are highlighted in this document.

2. Short-acting Monoclonal Antibody (mAb)

Palivizumab, a short-acting RSV monoclonal antibody, used for prevention of severe RSV disease in high-risk infants and young children.

Palivizumab is a humanized IgG1 monoclonal antibody directed against the RSV fusion (F) protein, blocking viral entry into respiratory epithelial cells and thereby providing passive immunity. Because of its shorter half-life, it requires monthly intramuscular dosing during the RSV season to maintain protective serum antibody levels.

The dose for palivizumab should be calculated based on the baby weight as 15mg/kg/dose to be given as an intramuscular injection monthly during the season for up to 5 doses for high risk during the RSV season as per DOH standards.

Palivizumab manufacturing will be discontinued and no longer available; therefore, healthcare providers are advised to use the available stock until it is depleted and to transition eligible infants to the recommended long-acting RSV monoclonal antibodies products in line with current guidelines.

E. RSV Long-Acting Monoclonal Antibodies Products

Nirsevimab-alip

a.	Brand Name	BEYFORTUS™
b.	Generic Name	Nirsevimab-alip
c.	Manufacturer	Manufactured by: AstraZeneca AB, Södertälje Sweden. Distributed by: Sanofi Pasteur, Inc., USA
d.	Type	Long-acting Monoclonal antibodies (mAbs)
e.	Dosage Forms and Strength	Sterile, preservative-free, clear to opalescent, colorless to yellow solution available as follows: - 50 mg/0.5 mL in a single-dose in a Prefilled Syringe with a Purple plunger rod for infant's weigh < 5kg - 100 mg/mL in a single-dose Prefilled Syringe with a Light Blue plunger rod, for infants' weigh 5kg
f.	Route	Intramuscular (IM) injection, preferably in the anterolateral aspect of the thigh.
g.	Ingredients	Each 0.5 mL contains: 50 mg nirsevimab-alip, arginine hydrochloride (8 mg), histidine (1.1 mg), L-histidine hydrochloride monohydrate (1.6 mg), polysorbate 80 (0.1 mg), sucrose (21 mg), and water for injection (USP). The pH is 6.0. Each 1 mL contains: 100 mg nirsevimab-alip, arginine hydrochloride (17 mg), histidine (2.2 mg), L-histidine hydrochloride monohydrate (3.3 mg), polysorbate 80 (0.2 mg), sucrose (41 mg), and water for injection (USP). The pH is 6.0
h.	Indication and Uses	Nirsevimab is a respiratory syncytial virus (RSV) F protein-directed fusion inhibitor indicated for the prevention of RSV lower respiratory tract disease - Neonates and infants are born during or entering their first RSV season < 8 months. - Children aged 8 to 19 months remain at increased risk of severe disease and are entering their second RSV season.

i.	Timing of Administration	Respiratory Syncytial Virus (RSV) season starting from 1 st September until 1 st of March of each year, in accordance with the issued ministerial decree and the defined RSV activity period In the United Arab Emirates (UAE).
j.	Immunization Schedule	Neonates and Infants Born During or Entering Their First RSV Season - 50 mg if less than 5 kg in body weight as a single intramuscular (IM) injection. Prefilled with a Purple plunger, - 100 mg if greater than or equal to 5 kg in body weight as a single intramuscular (IM) injection. Prefilled with a Light Blue plunger Children aged 8 to 19 months who remain vulnerable through their second RSV season - A single 200 mg dose administered as two IM injections (2 x 100 mg).

1. Preparation, Administration and Instructions for Use

1.1. Before Use

- 1.1.1. Nirsevimab-alip is supplied in prefilled syringes containing 50 mg with a purple plunger and 100 mg with a light blue plunger.
- 1.1.2. The solution should be visually inspected before administration to ensure it is free from particles or discoloration. It should appear clear to slightly opalescent and colorless to pale yellow.
- 1.1.3. The PFS must not be used if the liquid is cloudy, discolored, or it contains large particles or foreign particulate matter.
- 1.1.4. Do not use the PFS if it has been dropped or damaged, the security seal on the carton has been broken, or the expiration date has passed.

1.2. Administration Instructions

- 1.2.1. Make sure to select the correct 50 mg or 100 mg presentation as required (figure 1). Figure 2 shows the components of the pre-filled syringe.

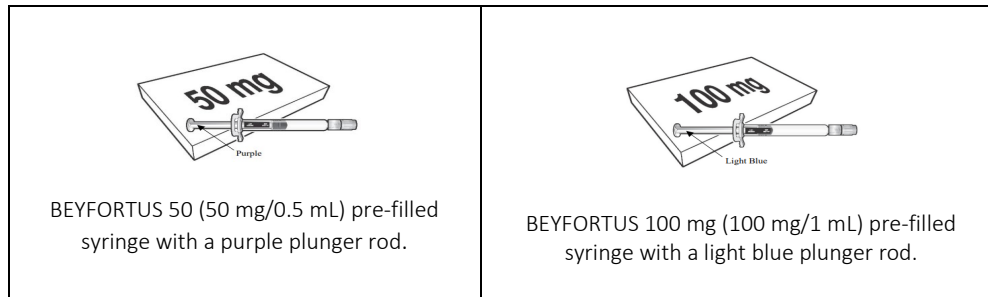


Figure 1: BEYFORTUS 50 mg and a 100 mg pre-filled syringe.

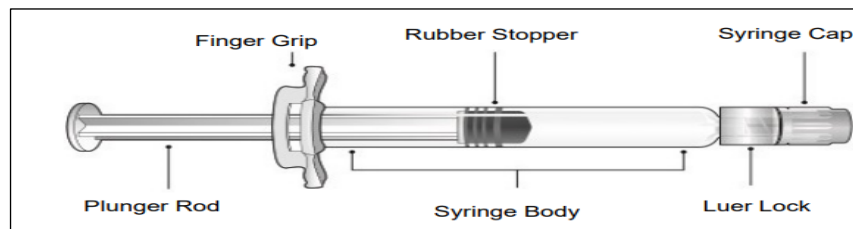


Figure 2: Luer Lock Syringe Components

- 1.2.2. Hold the Luer lock in one hand (avoid holding the plunger rod or syringe body), unscrew the syringe cap by twisting it counterclockwise with the other hand.
- 1.2.3. Attach a Luer lock needle to the pre-filled syringe by gently twisting the needle clockwise onto the prefilled syringe until slight resistance is felt.
- 1.2.4. Hold the syringe body with one hand and carefully pull the needle cover straight off with the other hand.
 - Do not hold the plunger rod while removing the needle cover or the rubber stopper may move.
 - Do not touch the needle or let it touch any surface.
 - Do not recap the needle or detach it from the syringe.
- 1.2.5. Administer the entire contents of the prefilled syringe as an IM injection, preferably in the anterolateral aspect of the thigh. The gluteal muscle should not be used as an injection site because of the risk of damage to the sciatic nerve.
- 1.2.6. Discard syringe into a sharp's container.

2. Storage and Handling

- 2.1. It should be stored in a refrigerator at a temperature between 2°C and 8°C and must never be frozen.
- 2.2. Nirsevimab must be stored in its original packaging to protect it from light.
- 2.3. Do not freeze. Do not shake. Do not expose to heat.

Clesrovimab-cfor

k.	Brand Name	ENFLONIA™
l.	Generic Name	Clesrovimab-cfor
m.	Manufacturer	MSD LLC , USA
n.	Type	Long-acting Monoclonal antibodies (mAbs)
o.	Dosage Forms and Strength	Sterile, preservative-free, clear to slightly opalescent, colorless to slightly yellow solution in a single-dose prefilled syringe as follows: - 105 mg/0.7 mL in a single-dose Prefilled Syringe.
p.	Route	Intramuscular (IM) injection, preferably in the anterolateral aspect of the thigh.
q.	Ingredients	Each 0.7 mL contains: 105 mg of clesrovimab-cfor, arginine hydrochloride (10.33 mg), histidine (0.55 mg), L-histidine monohydrochloride monohydrate (0.74 mg), polysorbate 80 (0.14 mg), sucrose (35 mg) and water for injection (USP). The pH is 6.0. sterile, preservative-free
r.	Indication and Uses	Clesrovimab-cfor is a respiratory syncytial virus (RSV) F protein-directed fusion inhibitor indicated for the prevention of RSV lower respiratory tract disease. - Neonates and infants are born during or entering their first RSV season and younger than < 8 months.
s.	Timing of Administration	Respiratory Syncytial Virus (RSV) season starting from 1 st September until 1 st of March of each year, in accordance with the issued ministerial decree and the defined RSV activity period in the In the United Arab Emirates (UAE).
t.	Immunization Schedule	Neonates and Infants Born During or Entering their First RSV Season - 105 mg administered as a single intramuscular (IM) injection.

1. Preparation, Administration and Instructions for Use

1.1. Before Use

- 1.1.1. Remove the Clesrovimab PFS from the refrigerator and allow to come to room temperature for approximately 15 minutes.
- 1.1.2. The solution should be visually inspected before administration to ensure it is free of particles or discoloration. It should be clear to slightly opalescent, colorless to slightly yellow solution.
- 1.1.3. The PFS must not be used if the liquid is cloudy, discolored, or it contains large particles or foreign particulate matter.
- 1.1.4. Do not use the PFS if it has been dropped or damaged, the security seal on the carton has been broken, or the expiration date has passed.

1.2. Administration Instructions

- 1.2.1. Hold the syringe barrel in one hand and unscrew the tip cap by twisting it counter-clockwise with the other hand. Do not remove the Luer Lock adaptor and the finger flange extender, figure (1)

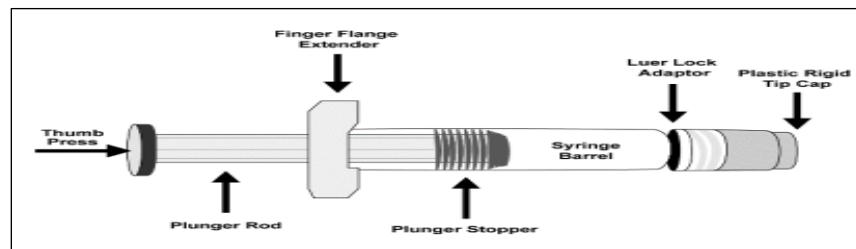


Figure 1: Prefilled Syringe Components

- 1.2.2. Attach a sterile Luer Lock needle by twisting in a clockwise direction until the needle fits securely on the syringe. Due to the viscosity of the product, use a 22- to 25-gauge needle.
 - Do not touch the needle or let it touch any surface.
 - Do not recap the needle or detach it from the syringe.
- 1.2.3. Administer the entire contents of the clesrovimab prefilled syringe intramuscularly in the anterolateral aspect of the thigh. Clesrovimab should not be injected in the gluteal area or areas where there may be a major nerve trunk and/or blood vessel.

2. Storage and Handling

- 1.3. It should be stored in a refrigerator at a temperature between 2°C and 8°C and must never be frozen.
- 1.4. Clesrovimab must be stored in its original packaging to protect it from light.
- 1.5. After removal from the refrigerator, allow the PFS to come to room temperature for approximately 15 minutes before administration.
- 1.6. Do not freeze. Do not shake. Do not expose to heat.

F. Eligible Group

The respiratory syncytial virus (RSV) long-acting monoclonal antibodies immunization is recommended for:

- Neonates and infants younger than < 8 months who are born during or entering their first RSV season (1st September – 1st March) if:
 - The mother did not receive RSV preF vaccine during pregnancy or
 - The mother's RSV preF vaccination status is unknown, or
 - The infant was born within 14 days of maternal RSV vaccination.
- Infants and children aged 8 to 19 months who are at increased risk for severe RSV disease and are entering their second RSV season*. High-risk criteria include the following:
 - Chronic lung disease of prematurity requires medical support (chronic corticosteroid therapy, diuretic therapy, or supplemental oxygen)
 - Children with cystic fibrosis have either:
 - Manifestations of severe lung disease (previous hospitalization for pulmonary exacerbation in the first year of life or abnormalities on chest imaging that persist when stable, or
 - Weight-for-length <10th percentile
 - Sever immunocompromised children
 - Other high-risk conditions based on treating physician evaluation.
- For children undergoing cardiac surgery with cardiopulmonary bypass, an additional dose is required as soon as the child is clinically stable following the surgery. The dose and timing of administration may vary depending on the product used.

G. RSV long-acting monoclonal antibodies Safety

I. Adverse Events

- Most common: Injection-site erythema, injection-site swelling and rash.
- Hypersensitivity reactions are uncommon but have been reported with similar to human IgG1 mAbs products.

II. Contraindications

- RSV long acting mAbs are contraindicated in infants and children with a history of serious hypersensitivity reactions, including anaphylaxis, to the active substance or to any of the excipients.

III. Warning and Precautions

- Serious adverse events are rare; however, despite their rarity, preparation for the possibility of anaphylaxis is essential.
- Severe hypersensitivity reactions, including anaphylaxis, may occur, similar to reactions reported with other human IgG1 monoclonal antibodies. Appropriate medications and/or supportive therapy should be initiated if signs or symptoms occur.
- As with any other IM injections, administer with caution in infants and children with thrombocytopenia, any coagulation disorder, as well as those receiving anticoagulation therapy.

H. Immunization Safety Monitoring

I. Post-Immunization Observation Period

It is recommended that all infants and children be observed for at least 15 minutes following administration of RSV monoclonal antibodies to detect any changes or sensitivity reaction that may occur.

II. Immunization Safety Monitoring

- If an adverse event occurs, provide prompt management according to AEFI and anaphylaxis protocols for the recipient.
- Immediate access to appropriate medications and supportive care must be ensured in the event of hypersensitivity or anaphylactic reaction.
- Report all suspected AEFIs to DOH using Adverse Event Following Immunization (AEFI) form on the e-notification web portal.

III. Appropriate medical treatment and supervision

- Healthcare facilities must be equipped and prepared, in line with immunization standards, to manage severe allergic reactions and anaphylaxis.
- Healthcare providers should be familiar with identifying hypersensitivity or anaphylactic events that might arise and be competent in treating these events at the time of RSV monoclonal antibodies administration and provide supportive care.

IV. Drug Interactions

- a) Clesrovimab: May interfere with some RSV rapid antigen/immunologic assays and cause false-negative results; if rapid test is negative but RSV is still suspected, confirm with an RT-PCR assay.
- b) Nirsevimab: Does not interfere with RSV RT-PCR or commonly used rapid antigen assays; however, if any immunologic assay is negative despite strong clinical suspicion of RSV, confirmation with RT-PCR is recommended.

I. Co-Administration with Childhood Vaccines

Co-administration with Childhood Vaccines and Immunoglobulin Products

- The RSV long-acting monoclonal antibodies; Clesrovimab and Nirsevimab; to be given concomitantly with childhood vaccines, to be administered at birth with BCG and Hepatitis B vaccines.
- When administered concomitantly with other childhood vaccines, should be given using a separate syringe, at a different injection site.
- Long acting mABs should Not be mixed with any vaccines or medications in the same syringe or vial.

J. Duration of Protection

Based on clinical and pharmacokinetic data, long-acting RSV monoclonal antibodies (mAbs) provide protection for at least 5 months after administration, when infants are most at risk of getting severe RSV disease.

Clinical Use Considerations in Preterm and Very Low Birth Weight Infants

K. Data Limitations and Use Considerations in Preterm and Low Birth Weight Infants

- **Very Low Birth Weight infants:**
Dosing in infants with a body weight from 1.0 kg to <1.6 kg is based on extrapolation, and no clinical data is available.
- **Extremely Preterm Infants:**
There is limited data available in extremely preterm infants (Gestational Age [GA] <29 weeks) less than 8 weeks of age, with no available clinical data for those with postmenstrual age (gestational age at birth plus chronological age) of <32 weeks.