PURPOSE:

- To provide instruction on the safe and preparation and administration of Vyjuvek (beremagene geperpavec-svdt).

POLICY:

- Vyjuvek will be administered by a trained registered nurse in accordance with a physician's order, any available / provided pharmacy or manufacturer instructions, and Agency policy.

GENERAL INFORMATION:

- Vyjuvek is a topical gel indicated for the treatment of wounds in patients 6 months of age and older with Dystrophic Epidermolysis Bullosa (DEB) with mutation(s) in the collagen type VII (COL7A1) gene.

- The most common adverse reactions are itching, chills, redness, rash, cough, and runny nose.

SPECIAL CONSIDERATIONS:

- Vyjuvek is administered weekly by a trained registered nurse to skin wounds until they are closed.

- The volume of gel applied each week may vary, up to the maximum weekly dose, as wound size decreases or increases. Prioritize weekly treatment to previously treated wounds until closure before starting treatment of new wounds.

- Healthcare providers and close contacts should avoid direct contact with treated wounds and dressings for the first 24 hours following treatment. Dispose of all materials (i.e., vial, syringe, needle, cleaning materials) that may have come in contact with the medication suspension or gel into a biohazard bag or container. In the event of accidental exposure, flush with clean water for at least 15 minutes.

- Prior to application, Vyjuvek suspension must be mixed with excipient gel.

- For patients 6 months to 3 years of age the weekly maximum dose is 1.6×10^9 plaque-forming units (PFU) of Vyjuvek, prepared with excipient gel (total volume of 0.8ml). For patients 3 years of age and older the weekly maximum dose is up to 3.2×10^9 plaque-forming units (PFU) of Vyjuvek, prepared with excipient gel (total of 1.6ml).

PREPARATION

Supplies Needed for Preparation:

- One (1) carton containing (1) Vyjuvek biological suspension vial and (1) excipient gel vial
- Two (2) 18-guage needles
- Two (2) to four (4) 1ml administration syringes
- One (1) 3ml preparation syringe
- Two (2) to four (4) syringe caps
- Protection gloves
- 70% isopropyl alcohol pads
- Biohazard waste container
- Labels for administration syringes
- Virucidal agent – such as 70% isopropyl alcohol, 6% hydrogen peroxide, or <0.4% ammonium chloride for clean-up
- Absorbent materials (i.e. paper towels)

1. Obtain and verify physician's orders pre-medication orders, concentration/dose, and any emergency protocols. If you notice any discrepancies in the orders, contact the Agency before proceeding.

2. Explain procedure and purpose to patient/caregiver.

3. Perform initial Hand Hygiene and maintain throughout the procedure.

4. Assemble supplies on a clean, dry surface. Ensure all supplies needed to complete the infusion from beginning to end are available. If any supplies are missing, notify the Agency immediately, and prior to starting the infusion process.

5. Assess and record patient's vital signs to establish a baseline and ensure vital signs are not contraindicative to starting the infusion.

Prepare the Preparation Syringe:

1. Wash your hands and don clean gloves.

2. Allow Vjuvek biological suspension and excipient gel vials to thaw and reach room temperature. Visually inspect both vials to ensure they are in liquid form and completely thawed. The excipient gel is more viscous and may take longer to thaw and warm than the suspension. Once the suspension and/or excipient gel is thawed, DO NOT refreeze.

3. Invert the biological suspension vial 4 – 5 times. DO NOT invert the excipient gel vial.

4. Remove the caps from the vials. Clean each vial stopper with a fresh 70% isopropyl alcohol pad. Allow them to dry.

5. Aseptically an 18-guage needle to the 3 ml preparation syringe.

6. Puncture the Vjjuvek biological suspension vial stopper and withdraw 1 ml of the biological suspension. Hold the suspension at a 45° to 90° angle, while pulling the plunger away from the vial.

7. Puncture the excipient gel vial and transfer 1 ml of Vyjuvek biological suspension into the excipient gel vial.

8. Without removing the needle from the excipient gel vial, lift the bevel of the needle above the liquid and pull the plunger back to the 1 ml mark to remove the excess air.

9. Remove the preparation syringe with 1 ml of air and engage the safety lock.

10. Place a 70% isopropyl alcohol pad on top of the excipient gel stopper and hold it tightly in place. Hold the excipient gel vial with the alcohol pad between index finger and thumb, and shake he vial vigorously for 10 seconds.

Prepare the Administration Syringes:

Supplies Needed for Administration:

- Administration syringes (prepared in the steps above)
- Non-adherent hydrophobic dressing
- Scissors
- Standard dressing
- Protective gloves
- Biohazard waste container
- Virucidal agent for clean-up
- Absorbent materials (i.e., paper towels)

1. Aseptically connect an 18-guage needle to the first 1 ml administration syringe and remove the needle cap.

2. Insert the 18-guage needle into the excipient vial containing Vjuvek gel. Tilt the vial to a 45° to 90° angle and withdraw 0.4 ml of Vyjuvek gel.

3. **DO NOT remove the needle from the excipient gel vial stopper.** Lift the bevel of the needle above the Vyjuvek gel and disconnect the administration syringe, leaving the needle in the excipient gel vial stopper.

4. Remove any air pockets from the administration syringe by manipulating the plunger up and down, until all air pockets have been removed. DO NOT flick the syringe to remove air pockets.

5. Put a cap on the administration syringe. Once capped, label the administration syringe, and set it aside. Administration syringes are labeled as #1, #2, #3, and #4.

6. Connect a new administration syringe to the needle remaining in the excipient gel vial containing Vyjuvek. Repeat steps 2 – 5 until the appropriate number of administration syringes have been prepared based on age of patient. **NOTE:** Vyjuvek administration syringes may be stored at room temperature for up to 8 hours and in the refrigerator for up to 48 hours.

    a. Prepare up to 2 syringes if patient is aged 6 months to >3 years (total volume = 0.8ml)
    b. Prepare up to 4 syringes if patient is >=3 years of age (total volume = 1.6ml)

7. Dispose of all materials used to prepare administration syringes in the biohazard waste container. Clean all surfaces and treat all Vyjuvek spills. Any surface that may have come in contact with the Vjuvek biological suspension or gel should be cleaned. Treat all Vyjuvek spills with the virucidal agent provided. Blot using absorbent materials.

8. In the event of an accidental exposure to the Vyjuvek (i.e., through a splash to the eyes or mucous membranes), flush the area with clean water for at least 15 minutes.

PROCEDURE/ ADMINISTRATION

1. Apply Vyjuvek gel to the selected wound(s) in droplets spaced evenly within the wound, approximately 1 cm by 1 cm apart. The resulting droplet pattern should loosely resemble a grid. Avoid touching the administration syringe to the skin.

2. Use clean scissors to cut the non-adherent hydrophobic dressing to a size slightly larger than the wound and place the dressing on top of the Vyjuvek gel droplets.

3. Use scissors to cut the standard dressing used by the patient to a size slightly larger than the hydrophobic dressing and place the standard dressing on top of the hydrophobic dressing.

4. Dispose of all materials used to prepare administration syringes in the biohazard waste container. Clean all surfaces and treat all Vyjuvek spills. Any surface that may have come in

contact with the Vjuvek biological suspension or gel should be cleaned. Treat all Vyjuvek spills with the virucidal agent provided. Blot using absorbent materials.

DOCUMENTATION

- Document the procedure, patient's response to the procedure, appearance/progression of the treated wounds, and record lot numbers and expiration dates for all vials used.