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### Eculizumab (Soliris) and Ravulizumab (Ultomiris) Clinical Guideline for Home Intravenous Therapy

Section: Clinical Guideline Compliance: ACHC Infusion Pharmacy ACHC Standards: URAC Standards: Policy ID: CG001 Effective: 10/1/23 Reviewed: Revised: Approved by, Title and Date Approved: Kathleen Patrick, President, 10/1/23

## I. BACKGROUND

Eculizumab (Soliris) is a monoclonal antibody used for the treatment of patients with paroxysmal nocturnal hemoglobinuria (PNH), atypical hemolytic uremic syndrome (aHUS), myasthenia gravis (anti-acetylcholine receptor positive) and for neuromyelitis optica spectrum disorder (NMOSD) in adult patients who are anti-aquaporin-4 (AQP4) antibody positive. Eculizumab specifically binds to the complement protein C5 with high affinity, thereby inhibiting its cleavage to C5a and C5b and preventing the generation of the terminal complement complex C5b-9. Eculizumab inhibits terminal complement-mediated intravascular hemolysis in PNH patients and complement-mediated thrombotic microangiopathy (TMA) in patients with aHUS. The precise mechanism by which eculizumab exerts its therapeutic effect in MG and NMOSD patients are unknown, but it is presumed to involve the reduction of terminal complement complex C5b-9.

Ravulizumab-cwvz (Ultomiris) is a monoclonal antibody therapy used in the treatment of PNH, aHUS, and myasthenia gravis (anti-acetylcholine receptor positive). Ravulizumab specifically binds to the complement protein C5 with high affinity, thereby inhibiting its cleavage to C5a and C5b preventing the generation of the terminal complement complex C5b9. Ravulizumab inhibits terminal complement-mediated intravascular hemolysis in patients with PNH and TMA in patients with aHUS.

The following outlines the procedures for servicing patients in need of outpatient eculizumab and ravulizumab home infusions.

## II. PATIENT ACCEPTANCE CRITERIA

- A. All candidates for home care service must be evaluated by the clinician(s) and deemed appropriate to receive home care based upon the following criteria:
  - 1. Prescriber preference
  - 2. Allergy profile
  - 3. Ability to secure contracted nursing for subsequent infusions
  - 4. Other relevant social and/or medical history

- B. Physician orders for eculizumab and ravulizumab must include:
  - 1. Patient weight for ravulizumab dosing and for pediatric eculizumab dosing
  - 2. Drug and dose (including weight based- dosage)
  - 3. Route of administration
  - 4. Frequency of administration
  - 5. Emergency medications per protocol
  - 6. Orders for pre-medications
  - 7. Line care per protocol
  - 8. Routine lab monitoring, if applicable
- C. Baseline labs or tests prior to therapy
- D. Dispensing pharmacy treatment protocol for anaphylaxis will be instituted unless a more comprehensive patient-specific orders are provided by physician. See policy, Management of Allergic/Anaphylactic Reactions (Appendix A).
- E. Healthcare provider with enrollment in REMS program
  - 1. Prescribers must counsel the patient about the risk of meningococcal infection, provide the patient with REMS educational materials, and ensure the patient is vaccinated with a meningococcal vaccine.
  - 2. Enrollment in the eculizumab REMS and Ravulizumab-cwvz REMS program and additional information are available by telephone: 1-888-SOLIRIS (1-888-765-4747) and at <u>www.solirisrems.com</u> or <u>https://ultomirisrems.com/</u> respectively.
- F. Patients must receive meningococcal vaccine at least 2 weeks prior to treatment initiation.
  - 1. If urgent eculizumab or ravulizumab initiation is necessary and <2 weeks after vaccination, provide 2 weeks of antibacterial prophylaxis

#### III. PHARMACOLOGY OVERVIEW

- A. Indications and Dosing
  - \* Subcutaneous ravulizumab dosing and administration will not be discussed in the scope of this guideline

#### 1. Eculizumab

a. Adults

i. PNH

- 1). 600 mg weekly for the first 4 weeks, followed by
- 2.) 900 mg for the fifth dose 1 week later, then
- 3.) 900 mg every 2 weeks thereafter.
- ii. aHUS, generalized myasthenia gravis, and NMOSD
  - 1.) 900 mg weekly for the first 4 weeks, followed by
  - 2.) 1200 mg for the fifth dose 1 week later, then
  - 3.) 1200 mg every 2 weeks thereafter.

b. Pediatrics (2 months-17 years)

\*Dosing is based off actual body weight. Eculizumab has not been studied in extremes of body weights

i. Ahus

Weight based dosing as follows:

Patient Body Weight	Induction	Maintenance
5 kg to less than	300 mg weekly x	300 mg at week 2 then 300 mg
10 kg	1 dose	every 3 weeks
10 kg to less	600 mg weekly x	300 mg at week 2 then 300 mg
than 20 kg	1 dose	every 2 weeks
20 kg to less	600 mg weekly x	600 mg at week 3 then 600 mg
than 30 kg	2 doses	every 2 weeks
30 kg to less	600 mg weekly x	900 mg at week 3 then 900 mg
than 40 kg	2 doses	every 2 weeks
40 kg and over	900 mg weekly x	1200mg at week 5; then 1200 mg
	4 doses	every 2 weeks

#### 2. Ravulizumab

- \* Dosing is based off actual body weight. Ravulizumab has not been studied in extremes of body weights
  - a. Adults
    - i. PNH and Myasthenia Gravis

Weight based dosing as follows:

Patient Body Weight	Induction	Maintenance
40 kg to less	2400 mg IV	3000 mg IV infusion every 8 weeks
than 60 kg	infusion	beginning 2 weeks after loading dose
60 kg to less	2700 mg IV	3300 mg IV infusion every 8 weeks
than 100 kg	infusion	beginning 2 weeks after loading dose
100 kg or	3000 mg IV	3600 mg IV infusion every 8 weeks
greater	infusion	beginning 2 weeks after loading dose

ii. aHUS

Weight based dosing as follows:

Patient Body Weight	Induction	Maintenance
20 to less than 30 kg	900 mg IV infusion	2100 mg 2 weeks after loading dose then every 8 weeks

30 to less than	1200 mg IV	2700 mg 2 weeks after loading dose
40 kg	infusion	then every 8 weeks
40 to less than	2400 mg IV	3000 mg 2 weeks after loading dose
60 kg	infusion	then every 8 weeks
60 to less than	2700 mg IV	3300 mg 2 weeks after loading dose
100 kg	infusion	then every 8 weeks
100 kg or	3000 mg IV	3600 mg 2 weeks after loading dose
greater	infusion	then every 8 weeks

- b. Pediatrics ( $\geq 1$  month old)
  - i. aHUS and PNH

Weight based dosing as follows:

Patient Body Weight	Induction	Maintenance
5 kg to less	600 mg IV	300 mg 2 weeks after loading dose
than 10 kg	infusion	then every 4 weeks
10 kg to less	600 mg IV	600 mg 2 weeks after loading dose
than 20 kg	infusion	then every 4 weeks
20 kg to less	900 mg IV	2100 mg 2 weeks after loading dose
than 30 kg	infusion	then every 8 weeks
30 kg to less	1200 mg IV	2700 mg 2 weeks after loading dose
than 40 kg	infusion	then every 8 weeks
40 kg to less	2400 mg IV	3000 mg 2 weeks after loading dose
than 60 kg	infusion	then every 8 weeks
60 to less than	2700 mg IV	3300 mg 2 weeks after loading dose
100 kg	infusion	then every 8 weeks
100 kg or	3000 mg IV	3600 mg 2 weeks after loading dose
greater	infusion	then every 8 weeks

c. Switching from eculizumab, administer loading dose 2 weeks after last eculizumab infusion, then administer maintenance doses once every 8 weeks, starting 2 weeks after the loading dose

#### B. Dose Adjustments

- 1. No dosage adjustment is recommended in patient with renal or hepatic impairment.
- 2. In case of missed dose, administer eculizumab at the recommended dosage regimen time points, or within two days of these time points.
- 3. Concomitant use of intravenous immunoglobulin (IVIg) administration has been shown to ravulizumab levels. Use a supplemental dose of ravulizumab 600 mg IV within 4 hours following completion of IV immunoglobulin cycle. Drug interaction studies have not been conducted with eculizumab or patients treated with IV immunoglobulin.

### C. Duration

1. Duration of therapy should be dependent on patient response and adverse reactions.

#### D. Contraindications

- 1. Unresolved serious Neisseria meningitidis infection
- 2. Patients not currently vaccinated against Neisseria meningitidis (unless risks of treatment delay outweigh risk of developing a meningococcal infection)
- E. Warnings and Precautions
  - 1. Infections
    - a. Serious infections with Neisseria species (other than N. meningitides), including disseminated gonococcal infections, have been reported
    - b. In addition to meningitis, the risk of other infections, especially with encapsulated bacteria (ex. Streptococcus pneumoniae, H. influenzae) is increased ensure patient is up to date with vaccinations per CDC guidelines
    - c. Fungal infections can also occur in immunocompromised patients receiving these medications
  - 2. Hypersensitivity reactions
    - a. Infusion reactions: Infusion reactions, including anaphylaxis or hypersensitivity, may occur; interrupt infusion for severe reaction (ex. cardiovascular instability, respiratory compromise).
- F. Pharmacokinetics
  - 1. Distribution: eculizumab 5-8 L; ravulizumab 5.22-5.74 L
    - a. Half-life elimination: eculizumab ~ 270 to 414 hours (during plasma exchange the half-life is reduced to 1.26 hours); ravulizumab 49.6-56.6 days
- G. Adverse reactions (eculizumab)
  - 1. Common Adverse Reactions
    - a. Increased blood pressure (adults/adolescents 33%; pediatrics 18%)
    - b. Contusion (8-10%)
    - c. Diarrhea (adults 15-16%; adolescents 37%; pediatrics 32%)
    - d. Nausea (adults 10-16%; adolescents 23%)
    - e. Vomiting (adults/adolescents 30%; pediatrics 10-40%)
    - f. Anemia (adults/adolescents 26%)
    - g. Backache (10-19%)
    - h. Headache (adults 26-44%; adolescents 41%; pediatrics 18%)
    - i. Insomnia (adults/adolescents 14%)
    - j. Nasal congestion (21%)
    - k. Nasopharyngitis (21-27%)
    - 1. Respiratory tract infection (adults 7-29%; adolescents 19%; pediatrics 32%)
    - m. Fever (adults 7%; adolescents 21%; pediatrics 47%)
    - n. Influenza (11%)
  - 2. Serious Adverse Reactions
    - a. Leukopenia (adults/adolescents 15%)
    - b. Antibody development (1-3%)
    - c. Infectious disease
    - d. Meningococcal disease
    - e. Viral disease

- H. Adverse Reactions (ravulizumab)
  - 1. Common Adverse Reactions
    - a. Increased blood pressure (24-25%)
    - b. Abdominal pain (6-23%)
    - c. Constipation (14-25%)
    - d. Diarrhea (9-38%)
    - e. Nausea (9-26%)
    - f. Vomiting (25-26%)
    - g. Anemia (13-23%)
    - h. Headache (40%)
    - i. Upper respiratory infection (54%)
    - j. Fever (7-50%)
  - 2. Serious Adverse Reactions
    - a. Anaphylaxis, hypersensitivity reaction
    - b. Meningococcal disease
    - c. Infectious disease
- I. Drug interactions (for both eculizumab and ravulizumab):
  - Intravenous immunoglobulin (IVIg) treatment may interfere with the endosomal neonatal Fc receptor (FcRn) recycling mechanism of monoclonal antibodies such as eculizumab or ravulizumab and thereby decrease serum eculizumab and ravulizumab concentrations. Drug interaction studies have not been conducted with eculizumab or patients treated with IVIg. Ravulizumab patients who have received IVIg require a supplemental dose of ravulizumab following the completion of an IVIg cycle (within 4 hours).
    - a. Avoid concurrent use of potent immunosuppressants due to increased risk for infection

#### **IV. ADMINISTRATIVE GUIDELINES**

- A. Administration- IV infusions should be given immediately after reconstitution and dilution. Use both eculizumab and ravulizumab within 4 hours of preparation per current USP Immediate-Use Guidelines.
  - 1. For ravulizumab- Use an in-line 0.2-micron low protein-binding or add on 0.22 micron filter per Alexion Pharmaceuticals prescribing information
- B. Do not co-administer eculizumab or ravulizumab with other drug products in the same IV line

#### V. NURSING PROCEDURE

- A. Supplies may include but are not limited to:
  - 1. Supplies for administration of eculizumab via gravity:
    - a. Alcohol swabs

- b. Gloves
- c. Dressing change kit
- d. IV pole
- e. IV Start Kit
- f. Peripheral IV catheter (ex. 22 Gauge x 1" and 24 Gauge x <sup>3</sup>/<sub>4</sub>" for patients needing peripheral access)
- g. Port access needle (ex. 22 Gauge x <sup>3</sup>/<sub>4</sub>" to 1" safe step for patients with a port)
- h. Tape
- i. Extension set 8"
- j. IV injection cap
- k. IV administration set (flow regulator [ex: dial-a-flow] or gravity)
- 1. Syringes (35 mL) and needles (ex: 20 G x 1")
- m. Sharps container
- 2. Supplies for administration of eculizumab/ravulizumab via ambulatory infusion pump:
  - a. Alcohol swabs
  - b. Gloves
  - c. Dressing change kit
  - d. IV pole
  - e. IV start kit
  - f. Peripheral IV catheter (ex. 22 Gauge x 1" and 24 Gauge x <sup>3</sup>/<sub>4</sub>" for patients needing peripheral access)
  - g. Port access needle (ex. 22 Gauge x <sup>3</sup>/<sub>4</sub>" to 1" safe step for patients with a port)
  - h. Tape
  - i. Extension set 8"
  - j. IV injection cap
  - k. Syringes (5 mL-60 mL depending on volume of drug needed) and needles (ex: 20 G x1")
  - n. Ambulatory pump tubing with **0.22 micron filter** (ravulizumab requires filter)
  - o. Pole mounted ambulatory pump
  - p. Batteries for ambulatory pump (Ex: 9 Volt Duracell battery or 4 Double A batteries)
  - q. Battery change procedure teaching sheet
  - r. Continuous delivery mode teaching sheet
  - s. Pump return box
  - t. Sharps container
- 3. Supplies for administration of ravulizumab via Freedom 60 Syringe Pump
  - a. Alcohol swabs
  - b. Gloves
  - c. Dressing change kit
  - d. IV start kit
  - e. Peripheral IV catheter (ex. 22 Gauge x 1" and 24 Gauge x <sup>3</sup>/<sub>4</sub>" for patients needing peripheral access)
  - f. Port access needle (ex. 22 Gauge  $x \frac{3}{4}$ " to 1" safe step for patients with a port)
  - g. Tape
  - h. Extension set 8"
  - i. IV injection cap
  - j. Syringes (5mL-50mL depending on volume of drug needed) and needles (ex: 20 G x 1")
  - k. Syringe 50 mL for final container to attach to syringe pump

- 1. Syringe Transfer Device
- m. Freedom 60 tubing
- n. 0.22 micron filter (ravulizumab requires a filter)
- o. Freedom 60 Syringe pump
- p. Freedom 60 syringe pump delivery mode teaching sheet
- q. Pump return box
- r. Sharps container

#### B. Prescription Items

- 1. Vials of eculizumab or ravulizumab
- 2. Prefilled saline bag, prefilled saline syringe, or stock saline bag for diluent
- C. How Supplied
  - 1. Eculizumab: Supplied as 300 mg single-use vials containing 30 mL of 10 mg/mL sterile, preservative-free solution
  - 2. Ravulizumab: Supplied as 300 mg/30 mL (10 mg/mL), 300mg/ 3mL (100mg/mL), and 1,100mg/11 mL (100mg/mL) single-dose vials containing a clear to translucent, slight whitish color preservative-free, solution
- D. Storage and Handling
  - 1. Eculizumab: Vials must be stored in the original carton until time of use under refrigerated conditions at 2-8° C (36-46° F) and protected from light
  - 2. Ravulizumab: Vials must be stored in the original carton until time of use under refrigerated conditions at 2-8° C (36-46° F) and protected from light
    - a. Do not freeze
    - b. Do not shake
- E. Compatibility
  - 1. Eculizumab: Stable in 0.9% Sodium Chloride, D5W, and Lactated Ringers
  - 2. Ravulizumab: Stable in 0.9% Sodium Chloride only
- F. Procedures (eculizumab):
  - 1. Explain the reasoning for visit and use of eculizumab.
  - 2. Don gloves.
  - 3. Establish venous access prior to preparation of drug.
  - 4. Counsel patient on warnings, precautions, and potential side effects including but not limited to: increased blood pressure, contusion, diarrhea, nausea, vomiting, anemia, headache, infections, and infusion and hypersensitivity reactions
  - 5. Prepare product
    - a. Inspect drug vials visually for particulate matter and discoloration prior to administration. Do not administer if drug is discolored or contains particulate matter
    - b. Dilute required dose to a final concentration of 5 mg/mL by adding eculizumab to an appropriate amount of 0.9% Normal saline solution
    - c. Diluent and final infusion volumes are as follows:

Eculizumab Dose	Diluent Volume to Add	Final Infusion Volume
300 mg	30 mL	60 mL
600 mg	60 mL	120 mL
900 mg	90 mL	180 mL
1200 mg	120 mL	240 mL

- d. Dispensing pharmacy will provide prefilled bags or the nurse will need to remove saline from a stock bag, so the final concentration is 5mg/mL. Exact final infusion volumes are seen in the above chart. Recommended to provide prefilled saline bags to prevent errors.
- e. Draw up eculizumab dose from vials and inject into saline bag
- f. Gently invert bag to mix. Do not shake.
- g. Discard any portion of unused drug from vial
- h. Allow time for infusion to get to room temperature prior to administering the infusion
- i. Infusion rates
  - i. Adults: Administer via IV infusion over 35 minutes via gravity, a syringetype pump, or an infusion pump; infusion may be slowed or stopped due to adverse reactions. Total infusion time should not exceed 2 hours.
  - ii. Pediatrics: Administer via IV infusion over 1 to 4 hours via syringe-type pump, or an infusion pump
- j. Post infusion monitoring: Monitor patients for 60 minutes after infusion is complete

#### G. Procedures: (ravulizumab)

- 1. Explain the reasoning for visit and use of ravulizumab.
- 2. Don gloves.
- 3. Establish venous access prior to preparation of drug.
- 4. Counsel patient on warnings, precautions, and potential side effects including but not limited to: increased blood pressure, abdominal pain, constipation, diarrhea, nausea, vomiting, anemia, headache, infections, infusion related and hypersensitivity reactions
- 5. Prepare product
  - a. Inspect drug vials visually for particulate matter and discoloration prior to administration. Do not administer if drug is discolored or contains particulate matter
  - b. Do not mix 100 mg/mL and 10 mg/mL vials together
  - c. Dilute 10mg/mL vials to a final concentration of 5 mg/mL by adding to an appropriate amount of Normal saline and dilute 100mg/mL vials to a final concentration of 50mg/mL by adding to appropriate amount of Normal saline
  - d. Diluent and final infusion volumes are as follows:

#### Ravulizumab 10mg/mL vials or subsequent 5mg/mL infusions

Ravulizumab Dose	Diluent Volume to Add	Final Infusion Volume
300 mg	30 mL	60 mL
600 mg	60 mL	120 mL
900 mg	90 mL	180 mL
1200 mg	120 mL	240 mL
2100 mg	210 mL	420 mL
2400 mg	240 mL	480 mL

2700 mg	270 mL	540 mL
3000 mg	300 mL	600 mL
3300 mg	330 mL	660 mL
3600 mg	360 mL	720 mL

#### Ravulizumab 100mg/mL vials or subsequent 50mg/mL infusions

Ravulizumab Dose	Diluent Volume to Add	Final Infusion Volume
300 mg	3 mL	6 mL
600 mg	6 mL	12 mL
900 mg	9 mL	18 mL
1200 mg	12 mL	24 mL
2100 mg	21 mL	42 mL
2400 mg	24 mL	48 mL
2700 mg	27 mL	54 mL
3000 mg	30 mL	60 mL
3300 mg	33 mL	66 mL
3600 mg	36 mL	72 mL

- e. Dispensing pharmacy will provide prefilled saline bags or prefilled saline syringes. It is recommended to provide prefilled saline bags or syringes to prevent errors. Alternatively, the nurse will need to remove saline from a stock bag for a total volume. The final concentration is 5mg/mL or 50mg/mL. Exact final infusion volumes are seen in above charts.
- f. Draw up Ravulizumab dose from vials and inject into prefilled saline bag
- g. Gently invert bag to mix. Do not shake.
- h. Discard any portion of unused drug from vials. Allow time for infusion to get to room temperature prior to administering the infusion
- i. Administer ravulizumab via IV infusion with a 0.22 micron filter
- j. See charts below to determine administration rate via ambulatory pump for larger volumes and Freedom 60 Syringe pump for smaller volumes of 60mL or less:

#### Ravulizumab 5mg/mL infusion Loading Dose

Body Weight (kg)	Loading Dose (mg)	Total Volume (mL)	Maximum Infusion Rate (mL/hr)
5 to less than 10	600	120	31
10 to less than 20	600	120	63
20 to less than 30	900	180	120
30 to less than 40	1200	240	184
40 to less than 60	2400	480	252
60 to less than 100	2700	540	317
100 or greater	3000	600	333

## Ravulizumab 5mg/mL Maintenance Dose

Body Weight (kg)	Maintenance Dose (mg)	Total Volume (mL)	Maximum Infusion Rate (mL/hr)
5 to less than 10	300	60	31
10 to less than 20	600	120	63
20 to less than 30	2100	420	127
30 to less than 40	2700	540	192
40 to less than 60	3000	600	257
60 to less than 100	3300	660	330
100 or greater	3600	720	327

## Ravulizumab 50mg/mL Loading Dose

Body Weight (kg)	Loading Dose (mg)	Total Volume (mL)	Maximum Infusion Rate (mL/hr)
5 to less than 10	600	12	8
10 to less than 20	600	12	16
20 to less than 30	900	18	30
30 to less than 40	1200	24	46
40 to less than 60	2400	48	64
60 to less than 100	2700	54	92
100 or greater	3000	60	144

### Ravulizumab 50 mg/mL Maintenance Dose

Body Weight (kg)	Maintenance Dose (mg)	Total Volume (mL)	Maximum Infusion Rate (mL/hr)
5 to less than 10	300	6	8
10 to less than 20	600	12	16
20 to less than 30	2100	42	33
30 to less than 40	2700	54	49
40 to less than 60	3000	60	65
60 to less than 100	3300	66	99
100 or greater	3600	72	144

k. Post infusion monitoring: Monitor patients for 60 minutes after infusion is complete

### VI. CLINICAL MONITORING

- A. Prior to therapy:
  - 1. Assess if patient is up-to-date on vaccinations
    - a. Patients are required to have a meningococcal vaccine at least 2 weeks prior to starting eculizumab and ravulizumab if they have not already been vaccinated
  - 2. No current, active infections
  - 3. Ensure patient is enrolled in corresponding REMS program (see under Patient Acceptance Criteria section)
- B. During and after infusions:
  - 1. Monitor for signs or symptoms of hypersensitivity or infusion related reactions
    - a. Patients should be monitored by the infusion nurse for one hour after the completion of an eculizumab or ravulizumab infusion
  - 2. Monitor for signs or symptoms of infection
  - a. Meningitis related side effects including headache, fever, and stiff neck
  - 3. Monitor for signs or symptoms of anemia
    - a. Monitor CBC
    - b. Monitor symptoms including shortness of breath, coldness in extremities, fatigue, dizziness, lightheadedness, and/or abnormal bleeding
  - 4. Monitor for efficacy in the following disease states: PNH, aHUS, Myasthenia Gravis, and Neuromyelitis Optica Spectrum Disorder
    - a. PNH and aHUS: reduction in dyspnea, abdominal pain, chest pain, thrombosis, bruising, bleeding, blood in urine or stool, headaches, shortness of breath, jaundice, paleness, blood clots, blood transfusions, fatigue, nausea, vomiting, edema, and abnormally low urine output.
    - b. Myasthenia Gravis: reduction in eyelid drooping, blurred or double vision, difficulty speaking, difficulty chewing or swallowing, choking, difficulty supporting the neck, shortness of breath/difficulty breathing, weakness in arms and legs, and difficulty walking/standing.
    - c. Neuromyelitis Optica Spectrum Disorder: monitor for worsening vision loss, limb weakness, sensory loss, bladder dysfunction, nausea, vomiting, hiccups, excessive somnolence or daytime narcolepsy, and neuroendocrine disorders

### **REFERENCES:**

- 1. Soliris[package insert]Boston, MA. Alexion Pharmaceuticals, Inc.; 2020.
- 2. Ultomiris[package insert]Boston, MA. Alexion Pharmaceuticals, Inc; 2022.

# APPENDIX A: ANAPHYLAXIS KIT INTRUCTIONS

# **Emergency Medication After Your Infusion**

Please call your pharmacy if you have any questions or concerns. In the event of an emergency, always call 911.

## Your nurse will tell you when you need to use Emergency Medications. The epinephrine dose will be noted on the Anaphylaxis Protocol included with your kit.

Start with a clean work surface and clean hands.

## Open the supply bag labeled <u>Anaphylaxis Kit Contents</u>.

You will need:

- 1. Bag containing Pills (2 Acetaminophen and 2 Diphenhydramine)
- 2. Bag containing Alcohol Prep Pads
- 3. Bag labeled <u>IM Epinephrine</u>

All other contents will not be needed.

## **Open the IM Epinephrine Bag**

## 1. Remove 1 of each item

- a. 1-syringe
- b. 1 brown labeled filter needle (BD Filter Needle)- *\*for ampul use only\**
- c. 1 black labeled safety needle (Magellan Hypodermic Safety Needle 22G x 1")
- d. 1 ampul of epinephrine

## **Prepare IM (intramuscular) injection of Epinephrine:**

- **1.** Attach the brown filtered needle to syringe
  - a. Be careful to not touch the tip of the syringe or the needle.
- 2. Using an alcohol swab, wipe the neck of the epinephrine ampul.
- **3.** Holding the ampul upright, **swirl and flick the ampul until all fluid flows to the bottom chamber** (the top chamber should be empty).
- 4. Using a new alcohol wipe, grasp the neck of the ampul and with your other hand grasp the bottom chamber of the ampul. Quickly snap the top of the ampul off, directing the snap way from you.

- 5. Place the tip of the brown filter needle inside the ampul. Tilting the ampul, withdraw dose of medication into the syringe by gently pulling back on the plunger. Be careful to not pull the plunger out of the syringe.
- 6. Remove the needle from the ampul and hold the syringe upright with the needle pointing upward. Gently tap the side of the syringe to bring any air to the top of the syringe.
- 7. Push the air out of the syringe by gently pushing on the plunger.
- **8.** Replace the cap on the brown filter needle. Discard remainder in ampul.
- 9. Remove the brown filter needle and place the black safety needle onto the syringe.

Give your IM Epinephrine injection



- **1. Grasp your leg muscle at the outer mid-thigh** and **cleanse the area** with a new alcohol wipe.
- 2. Push the needle into your leg muscle straight in at a 90-degree angle.
- **3.** Inject the medication by depressing the plunger in a slow and steady motion.
- 4. Remove the needle and wipe the site with the alcohol wipe.
- 5. May repeat dose every 5 minutes (maximum 3 doses) if ordered per protocol.

# Take the pills by mouth.

- a. 2 Acetaminophen
- b. 2 Diphenhydramine

Place all trash in the bag the pills came in and take with you when you seek medical care. Give the bag to the nurse or EMT, so your doctor will know what medication you already took. They will properly dispose of the syringe and needles. Call 911 or have someone drive you to the emergency department.