These Clinical Guidelines have been created using resources that were current as of the "Reviewed" date noted at the beginning of the document. Clinicians should refer to the manufacturer's Prescribing Information (or equivalent) for the most up-to-date information. While CarepathRx has published these Clinical Guidelines after a close review of available literature and a clinical review process, given the evolving nature and complexity of modern pharmaceutical products, CarepathRx does not and cannot warrant or guarantee that these Clinical Guidelines reflect the objectively best or highest standard of care at any given time.

Nothing within these Clinical Guidelines is intended to supersede or interfere with any individual clinician's decision-making or professional judgment with respect to either (1) prescribing or dispensing the drug or product in question or (2) the overall treatment plan for an individual patient.

Guidelines for Outpatient Immune Globulin (IVIG) Therapy for Home Intravenous Therapy

Section: Clinical Guidelines
Compliance: ACHC Infusion Pharmacy
ACHC Standards: N/A
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I. BACKGROUND

Intravenous Immune Globulin (IVIG) is produced from pooled plasma containing polyclonal IgG from the serum of thousands of screened donors. The IgG molecule is the main component of IVIG. Numerous quality control procedures and manufacturing standards are in place to ensure highly purified and stable solutions, although slight differences exist among products. Multiple IVIG products are available, and choice of product depends on patient/disease factors and clinical judgment.

Mechanistically, IVIG exhibits a broad range of immunomodulatory, anti-inflammatory, and immunosuppressive effects. It has been shown to inactivate autoreactive T-cells by blocking their interaction with antigen-presenting cells and to restore immune balance by modulating cytokine production. Studies demonstrate that IVIG contains antibodies and natural antagonists against pro-inflammatory cytokines, contributing to this effect. Furthermore, IVIG may interfere with the migration of autoimmune T-cells across the blood–nerve barrier. It also impacts innate immunity by disrupting the complement cascade and blocking Fc receptor-mediated activity, thereby reducing macrophage activation and downstream inflammatory responses.

In summary, IVIG exerts its therapeutic benefits through a variety of mechanisms including modulation of IgG levels, regulation of lymphocyte and macrophage function, cytokine production, complement regulation, and the clearance of pathogenic IgG. As a result, IVIG provides adequate concentrations of antibodies against a broad range of pathogens for patients with hypogammaglobinemia, antibody deficiency disorders, other immunodeficiency states, as well as certain infections.

The following outlines the procedures and protocols for coordination of servicing patients in need of outpatient IVIG 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 dispensing pharmacy's admission criteria.

B. The decision to administer a first dose in the home by a field nurse will be determined on a case-by-case basis and reviewed by nursing and pharmacy management. The following criteria will be evaluated:

1. Prescriber preference
2. Allergy profile

3. Age
4. Other relevant social and/or medical history including IgA levels

C. Physician orders for IVIG must include:

1. Patient weight
2. Drug and Concentration
3. Dose (including weight-based dose)
4. Route of administration
5. Frequency of administration
6. Emergency medications per protocol
7. Orders for pre-medications, if applicable
8. Line care protocol
9. Routine lab monitoring, if applicable

D. Baseline labs or tests prior to starting therapy (including IG panel)

E. Dispensing pharmacy treatment protocol for anaphylaxis will be instituted unless a more comprehensive patient-specific orders are provided by physician. See Appendix A (Nursing CarepathRx policy on *Management of Allergic/Anaphylactic Reactions*)

III. PHARMACOLOGY OVERVIEW

A. Indications:

1. Prevention of infections in immune-deficient patients

a. Primary and secondary Immunodeficiency states (Chronic lymphocytic leukemia, multiple myeloma, hematopoietic stem cell transplantation, hypogammaglobulinemia)
b. Infections and infection-related disorders (chronic parvovirus infection complicated by anemia, toxic shock syndrome, and measles post exposure prophylaxis if the patient is immuno-compromised or nonimmune)

2. Suppression of an inflammatory or autoimmune process

a. Neuroimmunology disorders (chronic inflammatory demyelinating polyneuropathy, multifocal motor neuropathy, Guillain-Barré syndrome, myasthenia gravis)
b. Autoimmune/inflammatory conditions (Dermatomyositis/Polymyositis, immune thrombocytopenia, autoimmune hemolytic anemia, autoimmune neutropenia, acquired von Willebrand syndrome, Kawasaki disease)
c. Alloimmune processes (hemolytic disease of the fetus and newborn, post-transfusion purpura, antibody-mediated organ transplant rejection, hyper-hemolytic crisis in individuals with sickle cell disease who have received transfusions)

**Subcutaneous dosing and administration will not be discussed in the scope of this guideline.*

B. Dosage

1. Prevention of infections in immune-deficient patients

a. 400 to 800 mg/kg IV every three to four weeks
b. Dosing is adjusted depending on the patient's progress and trough or steady-state IgG levels.

2. Suppression of an inflammatory or autoimmune process

a. Usually requires higher doses
b. 1-2 grams/kg repeated as appropriate depending on disease state

C. Dose Adjustment:

1. Renal Impairment: No dosage adjustment is required in patients with any degree of kidney impairment, including those on dialysis (hemodialysis, peritoneal dialysis, CRRT, PIRRT) or with augmented renal clearance. Exercise caution with with eGFR <60 or other renal risk factors, ensure adequate hydration, use the minimum effective dose, and infuse slowly.

2. Liver impairment: No dosage adjustments recommended.

D. Duration:

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

E. Contraindications:

1. Anaphylaxis or severe systemic reaction to human immunoglobulins or to any component of the product
2. Hereditary intolerance to fructose, including infants and neonates for whom sucrose or fructose tolerance has not been established
3. Hyperprolinemia (type I or II); Privigen(R) contains the stabilizer L-proline
4. IgA deficiency with antibodies against IgA, and a history of hypersensitivity - IVIG products contain trace amounts of IgA
5. Severe thrombocytopenia or any coagulation disorder which would contraindicate IM injections

F. Warnings and Precautions:

1. Anaphylaxis and Hypersensitivity Reactions: Hypersensitivity and anaphylactic reactions may occur, some of which can be severe. Patients with known anti-IgA antibodies and IgA deficiency are at higher risk. A sudden and severe drop in blood pressure may occur in rare cases. Discontinue therapy immediately if an anaphylactic reaction is suspected. Emergency treatment, including epinephrine (1 mg/mL), should be readily available during administration.
2. Infusion Reactions: Monitor all patients during and after IVIG infusion for signs of adverse reactions such as fever, chills, nausea, vomiting, and, in rare cases, shock. The risk of infusion reactions may increase during the initial infusion, when switching products, or if the patient has had a treatment interruption exceeding 8 weeks.
3. Aseptic Meningitis Syndrome (AMS): AMS has been reported, typically with high-dose IVIG (≥1 g/kg) or rapid infusion rates. Symptoms usually occur within a few hours to 2 days

after treatment and typically resolve within several days of discontinuation. Female patients and those with a history of migraines may be at higher risk.

4. Hemolysis: IVIG has been associated with acute and delayed hemolysis. Severe complications such as hemolysis-induced renal impairment or disseminated intravascular coagulation (DIC) have been reported. Risk factors include high-dose therapy (≥2 g/kg), underlying inflammation, and non-O blood type. Monitor closely for signs of hemolytic anemia, especially in patients with pre-existing anemia or cardiopulmonary compromise.
5. Hereditary Fructose Intolerance (HFI): Some IVIG formulations contain sorbitol, which is contraindicated in patients with HFI. This rare condition (1 in 20,000 births) may present with recurrent vomiting, abdominal pain, and hypoglycemia. Sorbitol-containing products should not be administered to patients with HFI.
6. Hyperproteinemia and Hyponatremia: IVIG may lead to increased serum protein levels, serum viscosity, and pseudohyponatremia. It is essential to differentiate pseudohyponatremia from true hyponatremia to avoid inappropriate fluid restriction and increased thrombotic risk.
7. Hypertension: Elevations in blood pressure (e.g., systolic ≥180 mmHg or diastolic >120 mmHg) have been observed during or shortly after infusion with certain products (e.g., Panzyga, Privigen). These elevations typically resolve with monitoring or adjustments to antihypertensive therapy.
8. Pulmonary Edema / TRALI: Monitor for transfusion-related acute lung injury (TRALI), a rare but serious complication characterized by non-cardiogenic pulmonary edema, hypoxemia, fever, and respiratory distress. TRALI typically occurs within 1–6 hours of infusion.
9. Fluid Overload: High-dose regimens (e.g., 1 g/kg/day for 1–2 days) may not be appropriate in patients at risk of fluid overload. Use caution in individuals with heart failure, renal dysfunction, or other fluid-sensitive conditions.
10. IgA Deficiency: Patients with IgA deficiency and anti-IgA antibodies are at increased risk for hypersensitivity reactions. Use is contraindicated in patients with documented IgA deficiency and a history of severe reactions.
11. Renal Impairment: Use with caution in patients with renal impairment. Ensure adequate hydration and use the lowest effective dose and slowest infusion rate to minimize risk. Avoid sucrose-containing products, when possible, as these have been linked to higher rates of renal complications.
12. Product-Specific Considerations:

    a. Human Plasma Origin: As a plasma-derived product, IVIG carries a theoretical risk of transmitting infectious agents (e.g., viruses, vCJD, CJD). Despite rigorous donor screening and viral inactivation steps, the risk cannot be completely eliminated. Any suspected infections believed to be associated with product use should be reported to the manufacturer.
    b. L-Proline: Present in some formulations (e.g., Hizentra, Privigen); contraindicated in patients with hyperprolinemia.
    c. Maltose: Present in some products and may interfere with certain glucose monitoring systems, leading to falsely elevated readings. Use caution in patients with corn allergy.
    d. Polysorbate 80: Present in some IVIG formulations. Hypersensitivity and delayed reactions have been reported. Use caution, especially in neonates and patients with known sensitivity. Polysorbate 80 has been associated with severe adverse effects in preterm infants. Refer to specific product labeling for details.

G. Pharmacokinetics:

1. Absorption: IV administration provides immediate antibody levels.
2. Distribution: Volume of distribution (Vd): 0.05–0.13 L/kg.
3. Metabolism: Metabolized by concentration-dependent catabolism; Half-life (highly variable) ~30 days
4. Excretion: Not renally excreted; high molecular weight precludes clearance via dialysis.
**Refer to the product's prescribing information for further details.*

H. Adverse Reactions:

1. Cardiovascular: Heart murmur (6.6%), Hypertension (3.4%–14.3%), Hypotension (5%–22%), Increased BP (6%–8%), Increased HR/Tachycardia (5%–22%), Increased systolic pressure (6.4%), Peripheral edema (8.2%), Chest discomfort (5%–9%), Chest pain (5%–11%), Myocardial infarction (NR)
2. Dermatologic: Flushing (5.6%–5.9%), Injection site reactions (5%–100%), Pruritus (6%–8%), Rash (4.1%–8.3%), Urticaria (5%–8.2%)
3. Endocrine/Metabolic: Increased body temperature (7.3%–36.8%), Hyponatremia (NR)
4. Gastrointestinal: Aphthous ulcers (6.4%), Diarrhea (6%–28%), Nausea (5%–26%), Upper abdominal pain (3.9%–10.6%), Vomiting (5%–23%)
5. Hematologic: Anemia (5%–10.5%), Leukopenia (5%–7.1%), Neutropenia (5%), Hemolysis (7.1%), Hemolytic anemia (NR), Thrombosis (2%–22%)
6. Hepatic: Hepatitis C (NR)
7. Immunologic: Infusion reactions (7%), Anaphylaxis (NR)
8. Musculoskeletal: Arthralgia (1.7%–13%), Muscle weakness (6.82%), Myalgia (5%–20%), Pain in limb (1.8%–11.5%), Muscle spasm (6%–6.8%), Backache (1.7%–28%)
9. Neurologic: Asthenia (5%–14.3%), Dizziness (5%–13.1%), Headache (6.9%–75%), Lethargy (6%), Migraine (5%–6.6%), Somnolence (NR), Tremor (5%), Aseptic meningitis (1.6%)
10. Otic: Otalgia (6.4%–18%)
11. Renal: Elevated serum creatinine (5%), Acute renal failure (NR), Hypokalemic nephropathy (NR), Acute tubular necrosis (NR)
12. Respiratory: Asthma (8.5%–29%), Cough (6%–26%), Nasal congestion (13%–15%), Nasal dryness (5%), Nasopharyngitis (5%), Throat pain (6.4%–9.1%), Pharyngitis (5%–16.1%), Pharyngolaryngitis (5%–15%), Rhinitis (24.1%), Sinusitis (2%–16%), Wheezing (9%–9.1%), TRALI (NR), Pulmonary embolism (0.9%), Respiratory failure (NR)
13. Other: Dehydration (5.7%), Fatigue (5.9%–24%), Fever (3%–37%), Illness (5%), Pain (5%–13%), Rigor (13.1%–37%), Shivering (5%–19.4%), Anaphylaxis/hypersensitivity reactions

I. Drug/Lab Interactions:

1. Ravulizumab/Eculizumab
    a. May result in decreased Ravulizumab/Eculizumab serum levels.
2. Loop diuretics
    a. May result in an increased blood viscosity and subsequently increased risk of thromboembolic events.
3. Live vaccines
    a. Interference with the immune response to the live vaccine when given concurrently with IVIG

b. Withhold live virus vaccination for recommended number of months after IVIG administration according to formulation being used

4. 1,3-beta-D-glucan detection

    a. Immune globulin can lead to false positive readings in assays that depend on detection of beta-D-glucans for diagnosis of fungal infections and may persist for weeks following infusion of immune globulin

5. Coombs test - anti-human globulin

    a. After infusion of IVIG, the transitory rise of the various passively transferred antibodies in the patient's blood may yield false positive serological testing results (positive Coombs test), with the potential for misleading interpretation

6. Glucose measurement, blood

    a. IVIG may cause an interference in blood/plasma glucose measurement using the glucose dehydrogenase pyrroloquinoline quinone (GDH-PQQ) based test, producing falsely elevated blood glucose levels

IV. ADMINISTRATIVE GUIDELINES

A. Administration: IV infusions should be administered promptly after preparation. Initiate the infusion within 4 hours in accordance with current USP Immediate-Use guidelines. For stability information beyond this timeframe, refer to the specific product's package insert.

B. Some products require filtration. Refer to individual product labeling.

C. Administer in separate infusion line from other medications.

D. Of clinical note, each intact IVIG product with a distinct lot/batch number as specified on the container, is comprised of a different donor plasma pool. Changes in clinical response/tolerance due to product variation cannot be ruled out

V. NURSING PROCEDURE

A. Supplies may include but are not limited to:

1. Alcohol Swabs
2. Gloves
3. Tape
4. IV access supplies as applicable

    a. Peripheral IV access supplies for patients requiring peripheral IV access
        1) IV start Kit
        2) Peripheral IV catheter (ex. 22 Gauge x1" and 24 Gauge x ¾")
        3) Extension set 8" with needless connector

b. Port access supplies for patients with a port
    1) Port needle (ex. 22 Gauge x ¾ to 1" safe step)
    2) Needless connector
    3) Central line dressing change kit
5. IV Pole
6. Appropriately sized syringes and needles (20 G x 1")
7. Sharps container
8. Supplies if utilizing a pole mounted ambulatory infusion pump:

    a. Ambulatory pump tubing
        1) 1.2-micron filter (if filter is needed)
        2) Dry spike adapter (if using non vented tubing)
    b. Pole mounted ambulatory pump
    c. Batteries for ambulatory pump (Ex: 9 Volt Duracell battery or 4 Double A batteries)
    d. Battery change procedure teaching sheet
    e. Continuous delivery mode teaching sheet
    f. Pump return box

B. Prescription items: (examples below)

    1. IVIG vials as prescribed
    2. Diluent bag of 0.9% sodium chloride if needed for hydration
    3. Standard flushes per protocol

C. How Supplied: IVIG products are typically supplied in single-use vials or pre-mixed containers. Formulation and concentration vary by manufacturer and may be lyophilized (requiring reconstitution) or in liquid form ready for dilution or direct infusion. Refer to product-specific labeling for exact presentation.

D. Storage and Handling: Store IVIG products according to manufacturer recommendations, typically under refrigeration (2–8°C). Do not freeze. Allow product to reach room temperature before administration. Inspect for particulate matter or discoloration before use. Once reconstituted (if applicable), use within manufacturer-stated stability window. Refer to product-specific labeling for exact storage conditions.

E. Compatibility: Do not mix with other medications or infuse concurrently through the same line without verified compatibility. Always consult product-specific prescribing information for confirmed diluent and line compatibility.

F. Procedures: Preparation of product, Infusion rates, post infusion monitoring time.

    1. Explain the reasoning for visit and use of IVIG.
    2. Don gloves.
    3. Assess for signs and symptoms of infection prior to establishing venous access and preparing medication. Notify ordering physician and pharmacist if signs or symptoms are present.
    4. Establish venous access prior to preparation of drug.
    5. Counsel patient on warnings, precautions, and potential side effects including but not limited to headache, fever, chills, flushing, nausea, hypotension, thrombosis risk, renal dysfunction, or aseptic meningitis.
    6. Prepare Product:

a. Follow manufacturer-specific guidelines for reconstitution (if lyophilized) or inspection (if liquid).
b. Allow refrigerated products to come to room temperature before use to minimize infusion-related adverse events. Do not place it back in the refrigerator once it has reached room temperature.
c. Avoid vigorous shaking or mixing to prevent foaming.
d. Inspect reconstituted solutions to confirm complete dissolution and uniformity.
e. Check all products for particulates, discoloration, or evidence of tampering before pooling or administration. Do not use compromised products.
f. Obtain vital signs:
    1) Prior to infusion initiation
    2) 30 minutes after infusion has started
    3) Every 30–60 minutes thereafter, based on RN evaluation and patient response
    4) 15 minutes after completion of the infusion
    5) Caregiver may be trained to perform and document vital sign monitoring, if applicable

7. Infusion Rates: Begin infusion at a slow rate (e.g., 0.5–1 mg/kg/min) and titrate upward based on tolerance and product-specific guidance. Monitor patient closely during titration periods. Refer to product-specific labeling for specific infusion rates.

8. Adjust the infusion rate as needed in response to adverse reactions:

    a. Mild reaction:
        1) Pause infusion until symptoms resolve
        2) Resume at a slower rate
    b. Moderate/severe or persistent mild reaction:
        1) Stop infusion
        2) Administer emergency medications as needed
        3) Notify physician and transfer patient to emergency services if warranted

9. Post infusion monitoring: Monitor patient and vital signs periodically during the infusion and 30 minutes after the infusion is complete per CarepathRx Nursing Best Practice Administration Guidelines.

    a. Document the procedure and patient response, including:
        1) Vital signs
        2) Tolerability
        3) Any adverse events and corresponding interventions
        4) Education provided
        5) Completion of post-infusion observation

VI. CLINICAL MONITORING

A. Pre-Infusion Monitoring and Assessment

1. Baseline Laboratory and Clinical Assessments:

a. Evaluate hematologic parameters (CBC), renal function (BUN/SCr), metabolic panel (including glucose), and hepatic function (e.g., transaminases).
b. Screen for infectious diseases (e.g., hepatitis) as appropriate.
c. Assess volume status and urine output.
d. Evaluate immune globulin levels (IgA)

2. Initial Risk Assessments:

    a. Evaluate for risk of renal impairment, thrombosis, or hemolysis prior to initiating IVIG.

    b. Perform a baseline Coombs test if initiating high-dose IVIG for autoimmune conditions.
    c. Record patient's baseline weight to assist in accurate dose calculation.

3. Vital Signs Monitoring:

    a. Obtain and document temperature, pulse, respiratory rate, and blood pressure prior to starting the infusion.

4. Medication Review:

    a. Review patient's concomitant medications for potential interactions or risk of nephrotoxicity.

B. During Infusion Monitoring

1. Vital Signs Monitoring:

    a. 15 minutes after infusion initiation
    b. Every 30 minutes during the infusion based on patient status and RN judgment

2. Adverse Reaction Surveillance:

    a. Monitor continuously for infusion-related reactions such as chills, flushing, headache, hypotension, or rash.
    b. In the event of a mild reaction:
        1) Pause infusion until symptoms resolve, then resume at a slower rate.

    c. In the event of a moderate/severe or persistent reaction:
        1) Stop infusion
        2) Administer emergency medications as appropriate
        3) Notify the provider and transfer to a higher level of care if needed

3. Coombs Test Monitoring (if applicable):

    a. If administering high-dose IVIG over multiple days, consider checking hemoglobin and Coombs test before subsequent doses to detect possible hemolysis.
    b. If a previously negative Coombs test turns positive:
        1) Consider switching IVIG product to one with reduced isohemagglutinins
        2) Delay or split the remaining dose

3) Refer to hematology for further evaluation if autoimmune hemolytic anemia is suspected

J. Post-Infusion Monitoring and Follow-Up

1. Vital Signs Monitoring:
    a. 30 minutes after infusion completion

2. Immediate Observation:
    a. Monitor the patient for at least 30 minutes post-infusion for any delayed infusion-related reactions.
    b. Document any adverse events, symptoms, and interventions.

3. Ongoing Laboratory Monitoring:
    a. Repeat baseline labs (hematology, renal, hepatic panels) every 6 to 12 months or as clinically indicated.
    b. CBC and renal function should be monitored periodically during long-term therapy.
    c. Serum IgG trough levels should be measured prior to subsequent infusions (target ≥500 mg/dL).
4. Weight Monitoring:
    a. Assess patient monthly weight and adjust IVIG dose accordingly if there is significant change.

5. Physician Follow-Up:
    a. Ensure the patient has a follow-up appointment within 4 weeks of the first dose to review clinical response and lab results.

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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 Anaphylaxis Kit Contents.

You will need:

1. **Bag containing Pills** (2 Acetaminophen and 2 Diphenhydramine)
2. **Bag containing Alcohol Prep Pads**
3. **Bag labeled IM Epinephrine**

All other contents will not be needed.

Open the IM Epinephrine Bag

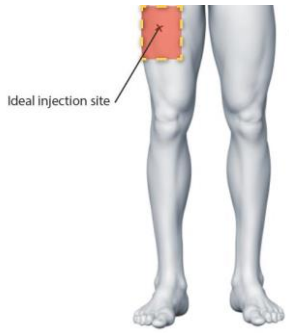
1. **Remove 1 of each item**
    a. 1 -syringe
    b. 1 – brown labeled filter needle (BD Filter Needle)- **for ampule use only**
    c. 1 – black labeled safety needle (Magellan Hypodermic Safety Needle 22G x 1”)
    d. 1 ampule of epinephrine

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 ampule.**
3. Holding the ampule upright, **swirl and flick the ampule 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 ampule and with your other hand grasp the bottom chamber of the ampule. **Quickly snap the top of the ampule off, directing the snap way from you.**
5. **Place the tip of the brown filter needle inside the ampule**. Tilting the ampule, **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 ampule and h**old 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 ampule.
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.