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.

**Intravenous Albumin (Human) Clinical Guideline for Home Intravenous Therapy**

**Section:** Clinical Guidelines
**Compliance:** ACHC Infusion Pharmacy
**ACHC Standards:** N/A
**URAC Standards:** N/A
**Policy ID:** CG025
**Effective:** 1/1/2021
**Reviewed:** 5/1/21, 5/1/22, 5/1/25
**Revised:** 5/1/25
**Approved by, Title and Date Approved:** Kathleen Patrick, President, 1/1/21, 5/1/21, 5/1/22, 5/1/25

## I. BACKGROUND

Albumin is a naturally occurring plasma protein derived from pooled human blood, available in two concentrations: 5% (isotonic) and 25% (hypertonic). Each formulation contains approximately 130–160 mEq of sodium per liter. Albumin plays a vital role in maintaining oncotic pressure, promoting the movement of fluid from the interstitial space into the intravascular compartment, thereby expanding plasma volume and supporting circulatory stability.

Therapeutically, albumin is indicated for the treatment of conditions associated with hypovolemia and hypoalbuminemia. Common clinical uses include volume resuscitation in cases of shock, hemorrhage, burns, and other fluid loss states. It is also used as a temporary replacement therapy in patients with low serum albumin levels due to chronic conditions such as nephrotic syndrome or end-stage liver disease. The following outlines the procedures for servicing patients in need of outpatient Intravenous Albumin (Human) 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

C. Albumin is not considered for first dose in the home. The first dose must be administered in the clinic setting with subsequent doses in the home, if requested.

D. Physician orders for Albumin must include:

1. Drug

2. Dose
3. Route of administration
4. Rate and frequency of administration
5. Emergency medications per protocol (i.e. pharmacy provided medications or EpiPen per retail pharmacy)
6. Orders for pre-medications
7. Line care protocol
8. Routine lab monitoring, if applicable

E. The decision to permit a patient or caregiver to administer Albumin without a nurse present in the home will be made on an individual basis under the following circumstances:

1. A second person must be present during administration
2. The home must have an available telephone.
3. The caregiver will be taught emergency measures in the event of an allergic response

F. Baseline labs or tests prior to starting therapy including BUN/Cr and BMP/electrolytes.

G. 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

**Refer to manufacturer's full Prescribing Information for most up to date information**

A. Indications:

1. Plasma volume expansion/maintenance of cardiac output (i.e. shock, hemorrhage, burns, etc.)
2. Albumin replacement in diseases associated with low levels of plasma proteins (i.e. nephrotic syndrome, end-stage liver disease, hypoalbuminemia, etc.)

B. Dosing:

1. Albumin dosing should be individualized based on patient weight, clinical condition, and fluid or protein losses, with the goal of restoring adequate circulating blood volume rather than targeting albumin levels alone.
2. Typical daily doses are 50–75 grams for adults and 25 grams for children, adjusted based on response.

C. Dose Adjustment:

a. May be required in cases of renal dysfunction. Administration of large volumes in patients with renal impairment has been associated with metabolic alkalosis due to resulting electrolyte imbalances.

D. Duration

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

E. Contraindications:

1. History of hypersensitivity reaction to albumin preparations or to any component of the product (eg, N-acetyltryptophan, sodium caprylate)
2. Patients with severe anemia or cardiac failure with normal or increased intravascular volume
3. Patients at risk for circulatory overload (eg, history of congestive cardiac failure, renal insufficiency, or stabilized chronic anemia)

F. Warnings and Precautions:

1. **Hypersensitivity:** Severe allergic or anaphylactic reactions may occur. If an allergic or anaphylactic reaction is suspected, discontinue the infusion immediately and manage appropriately.
2. **Coagulation Abnormality:** Large volumes of replacement may cause coagulation abnormalities. Monitor coagulation parameters and replete with blood constituents if necessary.
3. **Electrolyte Imbalance:** Large volumes of replacement may lead to electrolyte imbalances. Monitor electrolytes regularly and replace or maintain as needed.
4. **Hemodynamic Effects:** Cardiac or respiratory failure, kidney failure, and increased intracranial pressure can occur. Monitor hemodynamic parameters closely in all patients.
5. **Hypervolemia/Hemodilution:** Use cautiously in patients at risk for hypervolemia or hemodilution (e.g., heart failure, pulmonary edema, hypertension, hemorrhagic diathesis, cirrhosis, and esophageal varices). Adjust the rate of infusion based on hemodynamic status and solution concentration, particularly with rapid infusions. Avoid rapid infusions in patients with a history of cardiovascular disease, as this can cause volume overload and pulmonary edema. Discontinue infusion at the first signs of cardiovascular overload (e.g., headache, dyspnea, jugular venous distention, rales, or abnormal elevations in systemic or central venous blood pressure). All patients should be monitored for signs of hypervolemia, such as pulmonary edema. Blood pressure should be regularly monitored.
6. **Kidney Impairment:** Use with caution in patients with kidney impairment, as the protein load may precipitate azotemia. Patients with chronic kidney insufficiency receiving albumin may be at risk for aluminum accumulation and potential toxicities, including hypercalcemia, vitamin D-resistant osteodystrophy, anemia, and severe progressive encephalopathy.
7. **Sodium-Restricted Patients:** Use with caution in patients requiring sodium restriction. Albumin 5% and 25% solutions contain 130–160 mEq/L of sodium and are isotonic with plasma.
8. **Dosage Form Specific Issues:**

    a. **Aluminum:** The parenteral product may contain aluminum. High doses, prolonged use, or kidney dysfunction may lead to toxic aluminum concentrations. Premature neonates are particularly at risk due to immature kidney function and additional parenteral aluminum sources. Parenteral aluminum exposure greater than 4–5 mcg/kg/day is linked to CNS and bone toxicity. Tissue accumulation may occur at lower doses. Refer to the manufacturer's labeling for further details.
    b. **Dilution:** Do not dilute 5% albumin with sterile water for injection, as it may result in hemolysis or kidney failure.
    c. **Human Plasma:** This product is derived from human plasma and may potentially contain infectious agents that could transmit disease. Donor screening, testing, and viral inactivation or removal reduce the risk. Any infections suspected to be transmitted by this product should be reported to the manufacturer.
    d. **Latex:** Packaging may contain natural latex rubber.

9. **Pregnancy and lactation:** Albumin, being an endogenous substance derived from pooled human plasma, may be used during pregnancy if nonprotein colloids are contraindicated. In breastfeeding, endogenous albumin is present in breast milk. The decision to breastfeed during albumin therapy should weigh the risks of infant exposure against the benefits to both the mother and the infant.

G. Pharmacokinetics:

1. Distribution: Human albumin is mainly distributed in the extravascular space (~60-70%), with only 30–40% in plasma, where it supports oncotic pressure and plasma volume. It is synthesized exclusively in the liver and enters circulation directly or via lymphatics. Albumin shifts quickly from plasma, with a distribution half-life of ~16 hours, which increases when plasma levels drop.
2. Metabolism: Albumin degradation is not well understood, but less than 4% of the total albumin pool is broken down daily. While the liver plays little role in albumin catabolism under normal conditions, it, along with the kidneys and intestines, may become significant sites of degradation in disease states.
3. Excretion: Albumin has a half-life of 15 to 20 days and is primarily eliminated through degradation rather than excretion. In healthy individuals, renal excretion is minimal, and the kidneys play a negligible role. During conditions like nephrotic syndrome, increased urinary loss can trigger compensatory increases in synthesis. The intestinal mucosa also contributes slightly to degradation, accounting for about 10% of daily albumin breakdown.

H. Adverse Reactions:

1. Frequency Not Defined:

    a. Cardiovascular: Flushing, heart failure, hypotension, tachycardia
    b. Dermatologic: Pruritus, skin rash, urticaria
    c. Gastrointestinal: Nausea, vomiting
    d. Nervous System: Chills, rigors
    e. Respiratory: Bronchospasm, dyspnea, pulmonary edema
    f. Miscellaneous: Fever

2. Post-marketing:

    a. Cardiovascular: Acute myocardial infarction, atrial fibrillation
    b. Endocrine & Metabolic: Hyperchloremic metabolic acidosis (Ritzenthaler 2016)
    c. Gastrointestinal: Dysgeusia, sialorrhea
    d. Hypersensitivity: Anaphylactic shock, anaphylaxis (Lozano 2019), hypersensitivity reaction (including severe hypersensitivity reaction), nonimmune anaphylaxis (Fujita 2007), type 1 hypersensitivity reaction (Wang 2019)
    e. Nervous System: Headache
    f. Miscellaneous: Febrile reaction

I. Drug Interactions: There are no known significant interactions. Consult interaction database for patient specific assessment.

## IV. ADMINISTRATIVE GUIDELINES

A. Administration: IV infusions should be given immediately after spiking the vial. Begin infusion within 4 hours of preparation per current USP Immediate-Use Guidelines.

B. Some products may require a filter; refer to product labeling.

C. Record product name and batch number with each administration

D. Avoid co-administration with protein hydrolysates or solutions containing alcohol. May administer through the same administration set as 0.9% sodium chloride solutions or carbohydrates.

## 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
        i. IV start Kit
        ii. Peripheral IV catheter (ex. 22 Gauge x1" and 24 Gauge x ¾")
        iii. Extension set 8" with needless connector
    b. Port access supplies for patients with a port
        i. Port needle (ex. 22 Gauge x ¾ to 1" safe step)
        ii. Needless connector
        iii. Central line dressing change kit
5. IV Pole
6. IV administration set (flow regulator or gravity tubing) with in-line or add-on correct filter size, if required (see product labeling for details).
7. Sharps container
8. Supplies if utilizing a pole mounted ambulatory infusion pump:
    a. Ambulatory pump tubing with the correct filter size, if required (see product labeling for details).
    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. Albumin vials
2. Standard flushes per protocol

C. How Supplied:

1. Albumin is available as sterile intravenous solutions in 5% and 25% concentrations. The 5% solution is used for volume expansion and hypovolemia, while the 25% solution is used for severe hypoalbuminemia or fluid overload. These solutions come in various sizes, typically ranging from 50 mL to 500 mL or more.

D. Storage and Handling:

1. Store at a room temperature not exceeding 30 degrees C (86 degrees F). Protect from freezing. Discard unused portion

E. Compatibility: This medication can be diluted with Normal Saline (NS) or Dextrose 5% in Water (D5W) only, however undiluted solution is preferred within this guideline.

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

1. Explain the reasoning for visit and use of Albumin.

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 flushing, urticaria, nausea, chills, headache, fever, hypersensitivity reactions, electrolyte imbalances.

5. Prepare per product labeling. Do not agitate solution. Ensure correct strength and dose.

   **NOTE:** Solution should appear a clear amber color. Do not use cloudy, sediment-filled solutions. Use solution promptly.

6. Infusion Rates: Administer albumin at the recommended infusion rate. Adjust the rate as necessary based on the patient's clinical status and response. Typically, it is not recommended to exceed 1 to 2 mL/minute in patients without shock.

7. 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

## VI. CLINICAL MONITORING

A. Prior to therapy:

1. Assess baseline labs including renal function and electrolytes.

B. During therapy:

1. Monitor electrolytes, urine output, hemodynamic parameters, and volume status.
2. Labs recommended for monitoring

a. Electrolytes (including sodium, potassium, and calcium)
b. Coagulation profile (PT, aPTT, INR)
c. Hemoglobin and hematocrit (for signs of hemodilution)
d. Renal function tests (creatinine, BUN) to monitor renal status
e. Liver function tests (if applicable)

**Please refer to the package insert for the most up to date guidance on this medication.**

**REFERENCES:**

UpToDate. Albumin in parenteral nutrition. UpToDate. Accessed April 1, 2025.

Micromedex. Albumin (Human). Micromedex Solutions. Accessed April 1, 2025.

United States Pharmacopeia (USP). General Chapter, <797> Pharmaceutical Compounding—Sterile Preparations. (2023) USP-NF. Rockville, MD: United States Pharmacopeia. Accessed April 1, 2025.

## 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

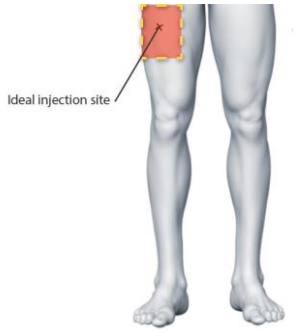
b. 1 – brown labeled filter needle (BD Filter Needle)- **for ampule use only**
c. 1 – black labeled safety needle (Magellan Hypodermic Safety Needle 22G x 1”)
d. 1 ampule of epinephrine

**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.

## APPENDIX B: EPINEPRINE KIT INSTRUCTIONS FOR IM INJECTION

**Emergency Medication After Your Infusion**

**Please call 1-800-755-4704 if you have any questions or concerns. We are available 24 hours a day, 7 days a week. In the event of an emergency, always call 911.**
**Your nurse will tell you when you need to use Emergency Medications.**
Start with a clean work surface and clean hands.
**Open the supply bag labeled Epinephrine Kit Contents.**

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

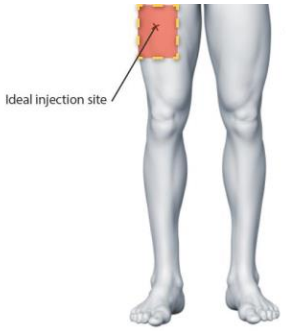
**Prepare IM (intramuscular) injection of Epinephrine:**

2. **Attach the brown filtered needle to syringe**

a. Be careful to not touch the tip of the syringe or the needle.

3. Using an **alcohol swab, wipe the neck of the epinephrine ampule**
4. Holding the ampule upright, **swirl and flick the ampule until all fluid flows to the bottom chamber** (the top chamber should be empty).
5. 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.**
6. **Place the tip of the brown filter needle inside the ampule**. Tilting the ampule, **withdrawal all the medication into the syringe** by gently pulling back on the plunger. Be careful not to pull the plunger out of the syringe.
7. 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.**
8. **Push the air out of the syringe by gently pushing on the plunger**.
9. Replace the cap on the brown filter needle.
10. **Remove the brown filter needle and place the black safety needle onto the syringe.**

Give your IM Epinephrine injection




2. **Grasp your leg muscle at the outer mid-thigh** and **cleanse the area** with a new alcohol wipe.
3. **Push the needle into your leg muscle straight** in at a 90-degree angle.
4. **Inject the medication** by depressing the plunger in a slow and steady motion.
5. **Remove the needle** and wipe the site with the alcohol wipe.

**Place all trash in the bag** and take it 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.